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Abstract N°: 9

Bimekizumab safe and effective self-administration using 2 mL devices by patients with moderate to severe plaque psoriasis: Results from two multicentre, randomised, open-label studies

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Introduction & Objectives:

Safe and effective self-injection of subcutaneous (SC) bimekizumab (BKZ) in patients with moderate to severe plaque psoriasis using a 1 mL safety syringe (sy) or auto-injector (AI) has previously been associated with an overall positive patient experience.1 The 2 mL sy or AI devices provide an alternative injection regimen to 1 mL devices (one instead of two injections). Here, the ability of patients to safely and effectively self-administer SC BKZ using a 2 mL sy or AI is reported.

Materials & Methods:

DV0002 (North America) and DV0006 (Germany, Hungary and Poland) were sub-studies of the phase 3 open-label extension (OLE) study, BE BRIGHT.1,2 Included patients received BKZ 320 mg every 4 weeks (Q4W) or Q8W based on treatment regimen and Psoriasis Area Severity Index (PASI) response at BE BRIGHT entry.

Patients were randomised 1:1 to BKZ-sy-2 mL or BKZ-AI-2 mL, and performed self-injection (after training in the self-injection technique) at baseline and Week 8. Safe and effective self-injection was defined as complete dose delivery of BKZ and absence of adverse events related to the device which led to study withdrawal.

Primary and secondary objectives were to assess patients' ability to safely and effectively self-administer BKZ at Week 8 and baseline, respectively. Other objectives were to evaluate patient experience of self-injection, using the injection site pain visual analogue scale (VAS; 0 [no pain]–100 [worst possible pain]) and the Self-Injection Assessment Questionnaire (SIAQ; 0–10 [higher scores better]), and the post-use structural and mechanical integrity of each device. Data were analysed using two full analysis sets (BKZ-sy-2 mL and BKZ-AI-2 mL) and are reported for the combined BKZ dose groups (BKZ Total) using observed cases.

Results:

In DV0002, 19 patients each were randomised to use BKZ-sy-2 mL and BKZ-AI-2 mL. All patients using BKZ-sy-2 mL (n=19) self-injected BKZ safely and effectively at baseline and Week 8. All (n=19) and 94.7% (n=18/19) of patients using BKZ-AI-2 mL self-injected BKZ safely and effectively at baseline and Week 8, respectively. In DV0006, 44 and 45 patients were randomised to use BKZ-sy-2 mL and BKZ-AI-2 mL, respectively. All patients using BKZ-sy-2 mL (n=44) and BKZ-AI-2 mL (n=45) safely and effectively self-injected BKZ at baseline and Week 8.

In DV0002/6, median pre-injection and post-injection SIAQ scores were high (≥7.5) across both devices, and were very high (>9.0) for feelings about injections, self-image, and injection-site reactions subscales (**Figure 1 and 2**).

In DV0002, median VAS scores were 6.0 and 11.5 using BKZ-sy-2 mL and BKZ-AI-2 mL, respectively, at baseline,

and 2.0 and 10.5 at Week 8. In DV0006, median VAS scores were 5.5 and 12.0 using BKZ-sy-2 mL and BKZ-AI-2 mL, respectively, at baseline, and 7.0 and 10.0 at Week 8, indicating low pain.

All devices maintained their structural and functional integrity post-use. One device deficiency complaint was received.

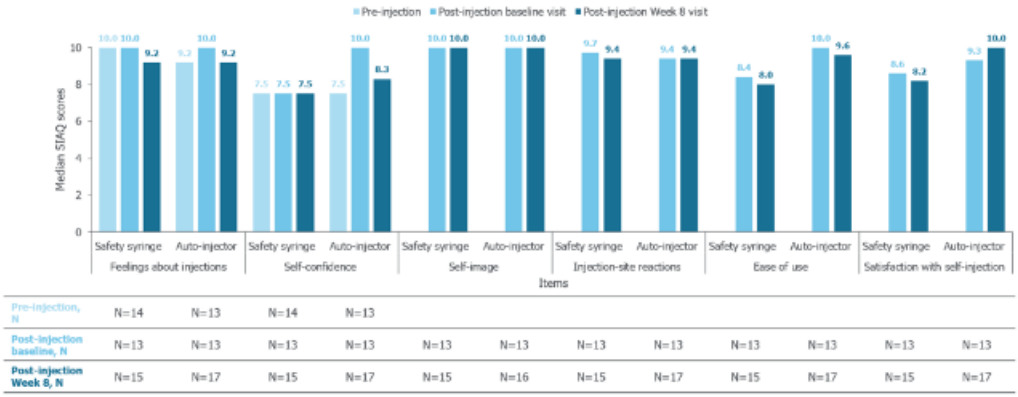
Conclusion:

A positive self-injection experience was associated with the 2 mL devices, as reported with 1 mL devices,1 providing patients with an option to self-administer a single injection of BKZ, which may benefit those who experience needle phobia or prefer fewer needlesticks for a single dose.3,4

References:

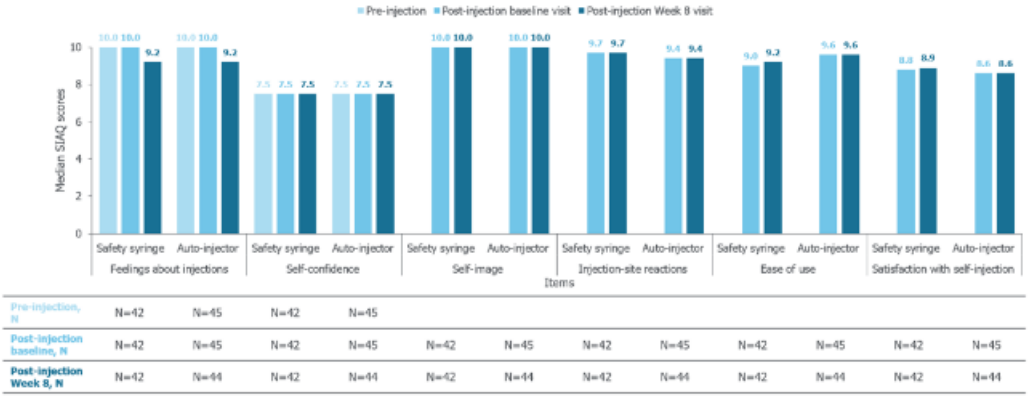
1. Bagel J. J Drugs Dermatol. 2022;21:162–71, NCT03766685; **2.** Strober B. Br J Dermatol 2023;188:749–59, NCT03598790; **3.** McLenon J & Rogers MAM. J Adv Nurs 2019;75:30–42;**4.** Overton P. Patient Prefer Adherence 2021:15:811–34.

Figure 1. SIAQ responses pre-injection at baseline and post-injection at baseline and Week 8 in DV0002 (OC [BKZ-sy-2 mL and BKZ-AI-2 mL])



SIAQ responses pre-injection at baseline and post-injection at baseline and Week 8 in DV0002 (OC) are provided for BKZ-sy-2 mL and BKZ-AI-2 mL. N numbers indicate the number of patients with an observed SIAQ subscale score at a given visit. Pre-injection scores were not applicable for the self-image, injection site-reactions, ease of use, and satisfaction with self-injection subscales. Subscale scores ranged from 0 to 10; higher scores indicated higher confidence and less concern with self-injections, and higher satisfaction with self-injection. Assessments where the self-injection was not performed by the patient, or the assessment was not done on the day of the injection were not included. AI: auto-injector; BKZ: bimekizumab; BKZ-AI-2 mL: 2 mL bimekizumab auto-injector; BKZ-sy-2 mL: 2 mL bimekizumab safety syringe; OC: observed case; SIAQ: Self-injection Assessment Questionnaire; sy: safety syringe.

Figure 2. SIAQ responses pre-injection at baseline and post-injection at baseline and Week 8 in DV0006 (OC [BKZ-sy-2 mL and BKZ-AI-2 mL])



Pre-injection, N	N=42	N=45	N=42	N=45								
Post-injection baseline, N	N=42	N=45	N=42	N=45	N=42	N=45	N=42	N=45	N=42	N=45	N=42	N=45
Post-injection Week 8, N	N=42	N=44	N=42	N=44	N=42	N=44	N=42	N=44	N=42	N=44	N=42	N=44

SIAQ responses pre-injection at baseline and post-injection at baseline and Week 8 in DV0006 (OC) are provided for BKZ-sy-2 mL and BKZ-AI-2 mL. N numbers indicate the number of patients with an observed SIAQ subscale score at a given visit. Pre-injection scores were not applicable for the self-image, injection site-reactions, ease of use, and satisfaction with self-injection subscales. Subscale scores ranged from 0 to 10; higher scores indicated higher confidence and less concern with self-injections, and higher satisfaction with self-injection. Assessments where the self-injection was not performed by the patient, or the assessment was not done on the day of the injection were not included. AI: auto-injector; BKZ: bimekizumab; BKZ-AI-2 mL: 2 mL bimekizumab auto-injector; BKZ-sy-2 mL: 2 mL bimekizumab safety syringe; OC: observed case; SIAQ: Self-injection Assessment Questionnaire; sy: safety syringe.

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Abstract N°: 21

A Multicenter, Randomized, Double-Blind, Parallel-Arm, Phase 3 Study to Compare Efficacy and Safety of BAT2206 with Ustekinumab in Patients with Moderate to Severe Plaque Psoriasis

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Introduction & Objectives: BAT2206 is being developed as a biosimilar to Ustekinumab, the human IgG1 monoclonal antibody targeting IL-12/23 p40. This is a multicenter, randomized, double-blind, parallel-arm, Phase 3 study with the primary objective of demonstrating equivalent efficacy of BAT2206 and Ustekinumab in subjects with moderate to severe psoriasis. The safety, pharmacokinetics (PK), and immunogenicity of BAT2206 and Ustekinumab were compared as well.

Materials & Methods: This study composed of a 28-week initial treatment period (TP1) and a 24-week secondary treatment period (TP2). Subjects with moderate to severe psoriasis were enrolled in the study and randomly assigned to BAT2206 or Ustekinumab group in a 1:1 ratio at baseline. BAT2206 or Ustekinumab were administered at Week 0, 4, and then every 12 weeks until Week 40, followed by a 12-week efficacy and safety follow up period up to Week 52. Subjects who achieved a ≥PASI-75 response at Week 28 entered into TP2, in which those in the BAT2206 group in TP1 continued treatment with BAT2206, whereas those in Ustekinumab group in TP1 were re-randomized 1:1 to either continue on Ustekinumab or switch to BAT2206 in TP2. The primary endpoint was percent change from baseline (CfB) in PASI score to Week 8 or Week 12, and the equivalence was to be concluded if the 2-sided 90% or 95% confidence interval (CI) fell entirely within the predefined equivalence margins, depending on the regulatory agencies for submission.

Results: A total of 556 European and Chinese subjects were enrolled in the study, with 544 subjects (97.8%) and 515 (92.6%) subjects completed TP1 and TP2, respectively. At week 8, the least square mean (standard error, SE) of CfB in PASI score were -76.507 (2.6526) and -75.543 (2.6847) for Ustekinumab or BAT2206, respectively, with the least square (LS) mean difference 95% CI (-2.751, 4.679) completely falling within the predefined equivalence margin. At week 12, the LS mean (SE) of CfB in PASI score were -86.813 (2.0105) and -85.039 (2.0731) for Ustekinumab or BAT2206, respectively, with the LS mean difference 90% CI (-0.679, 4.227) and 95% CI (-1.149, 4.697) completely falling within the predefined equivalence margins. The primary estimand was comparable for the subgroups between BAT2206 and Stelara with no major effects seen. Overall 344 subjects (62.0%) experienced 924 treatment-emergent adverse events (TEAEs), in which 234 were treatment related. The proportion of subjects who had at least 1 TEAE or treatment-related TEAE was similar across the treatment groups in both TP1 and TP2, with most TEAEs or treatment-related TEAE being mild. Fifteen subjects (2.7%) experienced 19 serious TEAEs and 4 subjects (0.7%) experienced 4 treatment-related serious TEAEs. No TEAE led to death during the study. Immunogenicity was comparable across treatment arms throughout the entire study, and the transition from Ustekinumab to BAT2206 in TP2 did not lead to an increased immunogenicity. No major differences were observed between the overall geometric means of serum concentrations of Ustekinumab and BAT2206 in TP1, nor for the Ustekinumab-Ustekinumab or Ustekinumab-BAT2206 groups compared with BAT2206 alone in TP2.**

Conclusion: The current study showed that BAT2206 and Ustekinumab are similar in terms of efficacy, safety, PK, and immunogenicity. Additionally, the transition from Ustekinumab to BAT2206 in TP2 had no impact on efficacy, safety, PK, or immunogenicity.

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Abstract N°: 23

Interleukin-23 inhibitors decrease Fibrosis-4 index in psoriasis patients with elevated Fibrosis-4 index but not inteleukin-17 inhibitors

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Introduction & Objectives: Recent studies indicate that hepatic diseases are associated with psoriasis. Non-invasive tests, including the Fibrosis-4 (FIB-4) index, which can confidently rule out the presence of advanced fibrosis, draw attention nowadays. However, data on the FIB-4 index in psoriasis patients and the effects of biologics on the FIB-4 index are limited. We investigated the relationships between the FIB-4 index and demographic or clinical characteristics, and the effects of biologics on the FIB-4 index in psoriasis patients.

Materials & Methods: Psoriasis patients aged 36–64 years who initiated interleukin (IL)-17 inhibitors or IL-23 inhibitors for psoriasis from May 2015 to December 2022 were consecutively included. Data were collected retrospectively from the patients' charts.

Results: A total of 171 psoriasis patients were included in this study. Thirty-four, 43, 21, 32, and 41 psoriasis patients were treated with secukinumab, ixekizumab, brodalumab, guselkumab, or risankizumab, respectively. In biologics-naïve patients, a significant but weak positive correlation was observed between FIB-4 index and the age ($r=0.3246$, $p=0.0018$). There was no significant correlation between FIB-4 index and other demographic or clinical characteristics. Regarding the effects of biologics on the FIB-4 index, no significant change was observed in psoriasis patients treated with any biologics. However, in psoriasis patients with a baseline FIB-4 index >1.3, patients treated with guselkumab and those treated with either IL-23 inhibitor showed significantly decreased FIB-4 index scores 6 months after initiating the biologics ($p=0.0323$, $p=0.0212$). In contrast, no change was observed in the FIB-4 index scores in patients treated with IL-17 inhibitors.

Conclusion: Our study revealed that the FIB-4 index was correlated with age in psoriasis patients. Furthermore, IL-23 inhibitors (but not IL-17 inhibitors) decreased the FIB-4 index at 6 months in psoriasis patients with elevated FIB-4 index at baseline. Further studies are needed to clarify whether IL-23 inhibitors improve liver fibrosis physiologically and functionally.

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Abstract N°: 37

A case of erythrodermic psoriasis successfully treated with ixekizumab combined with low-dose methotrexate to ensure sustained clearance: A case report

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Introduction & Objectives:

Erythrodermic psoriasis (EP) is a severe type of psoriasis that requires immediate and effective treatment to prevent serious complications. Although recommended as first-line treatment for EP, conventional systemic disease-modifying anti-rheumatic drugs (csDMARDs) such as methotrexate and/or cyclosporine can sometimes be ineffective or undesirable, hence the use of biologics. However, in cases of refractory disease, biologics may be combined with methotrexate to boost efficacy and optimize outcomes without compromising safety and tolerability. We report a case of EP in a pediatric patient who achieved complete skin clearance with ixekizumab in an off-label dosing and indication for his age group in the Philippines alongside low-dose methotrexate.

Materials & Methods:

A 16-year-old Filipino male with Fitzpatrick skin type IV sought consult at the dermatology clinic of a tertiary hospital for generalized erythema with scaling affecting >90% of his body surface area. He was a known case of chronic plaque psoriasis since age 11 with no other comorbidities. His paternal aunt had psoriasis. On further history taking, the patient was previously treated with methotrexate 10 mg weekly and folic acid supplementation, along with alternate courses of topical clobetasol and topical calcipotriol every 2 weeks until near remission was achieved. He was then eventually lost to follow-up and never went through phototherapy. At the time of consult, the patient was afebrile, had stable vital signs, and weighs 34 kilograms with a normal body mass index (BMI). The patient was diagnosed with EP and was treated simultaneously with methotrexate at a maximum of 17.5 mg per week and cyclosporine at 2.75 mg/kg/day. After 6 months of continuous treatment with no reported adverse effects, the patient still exhibited minimal improvement. Due to the refractory nature of his disease, the patient was started with ixekizumab 80 mg subcutaneous injections every 4 weeks in an off-label indication and dose for his age group in the Philippines. The biologic was given alongside low-dose methotrexate at 7.5 mg per week; cyclosporine was discontinued.

Results:

After 12 weeks of ixekizumab in combination with low-dose methotrexate, the patient achieved psoriasis area and severity index (PASI) 75. The patient received his last dose of ixekizumab at week 20 in combination with methotrexate of the same dose with good response at PASI 100, achieving complete skin clearance. Since discontinuation of ixekizumab, the patient remains lesion-free with low-dose methotrexate at week 32, with no reported adverse effects.

Conclusion:

This case illustrates the effective and safe use of a biologic drug combined with a csDMARD in the treatment of EP. Escalating treatment with ixekizumab was done to overcome resistance with combined methotrexate and cyclosporine, while the decision to utilize concomitant low-dose methotrexate alongside ixekizumab was because of economic reasons rather than problems with efficacy or immunogenicity. To the authors' knowledge, this is the

first documented case utilizing the combination technique for economic purposes, successfully without any negative sequelae. Furthermore, this case illustrates the strategies employed to overcome limitations in management secondary to finances in a resource-constrained setting such as the Philippines.

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Abstract N°: 41

Social media intervention as a reminder and educational tool to increase treatment adherence in patients with psoriasis: A randomized controlled trial

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Introduction & Objectives:

Despite years of symptomatic disease control and treatment, patients with psoriasis often lack a real understanding of their disease, its treatment and how to best manage its relapsing and remitting nature. Considering its high burden of disease, practical solutions to promote self-management and patient education are important public health strategies to address this phenomenon. The objective of this study was to determine whether educational messages and treatment reminders sent through Facebook were able to improve disease knowledge and treatment adherence in patients with psoriasis.

Materials & Methods:

This was a randomized, controlled, observer-blinded, three-arm, parallel clinical trial conducted from February to April 2023. Patients with psoriasis assigned to intervention received similar messages privately containing treatment reminders and educational messages for twelve weeks in alternating order of reminder-education-reminder, depending on the assigned frequency of intervention (once-a-week or thrice-a-week). Patients in the control group did not receive any message and were given the usual care on their assigned days of follow-up. The participants were assessed in two study visits (one at the beginning and one at the end of the twelfth week) using validated measures of disease severity, quality of life, treatment adherence and disease knowledge. The usability and satisfaction with the social media interventions were also obtained from those belonging to intervention at the end of the study.

Results:

A total of 159 psoriasis patients were included in the analysis. Treatment adherence among those who received the intervention significantly improved as compared to control, with better results in those who received more frequent interventions ($p=0.037$). Similar results were also seen in terms of physician-evaluated clinical outcomes and patient-reported quality of life, as those who received more frequent interventions reported better outcomes ($p<.001$). Knowledge scores likewise improved across all groups at the end of study, with everyone in the intervention group reporting complete satisfaction regardless of frequency of intervention.

Conclusion:

This study determined that educational messages and treatment reminders sent through Facebook were able to improve disease knowledge and treatment adherence among patients with psoriasis. This study illustrates the potential of social media interventions as a low-cost scalable public health strategy to empower patients in a resource-constrained setting such as the Philippines.

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Abstract N°: 43

Bimekizumab maintenance of response from the end of pivotal trials through 4 years: Results in patients with moderate to severe plaque psoriasis from BE BRIGHT

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Introduction & Objectives

Given the chronic nature of psoriasis, long-term efficacy of new treatments should be investigated. Maintenance of high response rates with bimekizumab (BKZ) have been reported previously through 4 years in patients with moderate to severe plaque psoriasis who achieved clinical responses at Week 16.1

Here, maintenance of response is reported in bimekizumab patients who achieved complete or near-complete skin clearance after 1 year (end of pivotal trials) through 4 years (196 weeks).

Materials & Methods

Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY pivotal phase 3 trials, and their OLE, BE BRIGHT.2–5 Included patients were randomised to BKZ 320 mg every 4 weeks (Q4W) to Week 16, then received BKZ Q4W or every 8 weeks (Q8W) until OLE entry (Week 52/56; Year 1). All included patients entered the OLE and received BKZ Q4W or Q8W based on Psoriasis Area and Severity Index (PASI) response and prior maintenance dose; all patients were re-assigned to BKZ Q8W in the third year of treatment via protocol amendment.

Data are reported for the combined BKZ dose groups (BKZ Total) and for the subset receiving BKZ Q4W to Week 16 then Q8W continuously into the OLE (BKZ Q4W/Q8W), the approved dosing regimen for most patients with psoriasis.6

Maintenance of ≥90% and 100% improvement from baseline in PASI (PASI 90 and PASI 100) through Year 4 (OLE Week 144) are reported in Year 1 PASI 90 and PASI 100 responders, respectively.

PASI responses at Year 1 are reported using non-responder imputation (NRI). Longer-term responses are reported using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. Observed case (OC) results are also reported in the **Figure** only.

Results

Overall, 771 patients were randomised to BKZ at baseline and received BKZ in the maintenance period and on OLE entry. Of the 771 patients forming the BKZ Total group, 699 (90.7%) and 583 (75.6%) patients were PASI 90 and PASI 100 responders at 1 year, respectively. Of the 197 patients in the BKZ Q4W/Q8W group, 192 (97.5%) and 167 (84.8%) patients were PASI 90 and PASI 100 responders at 1 year, respectively (**Figure**).

PASI 90 responses were maintained by 96.5% of Year 1 PASI 90 responders at Year 2 (OLE Week 48), 93.7% at Year 3 (OLE Week 96), and 87.9% at Year 4 (OLE Week 144; **Figure**). Among Year 1 PASI 100 responders, 87.3%, 80.9%, and 74.3% maintained PASI 100 at Year 2, 3, and 4, respectively.

Similarly high maintenance of PASI 90 and PASI 100 responses were observed in Year 1 responders who received BKZ Q4W/Q8W (**Figure**); 88.5% of PASI 90 and 77.8% of PASI 100 Year 1 responders maintained their respective responses at Year 4.

Conclusion

Of the high proportion of patients who achieved complete or near-complete skin clearance after 1 year of BKZ treatment in the pivotal phase 3 trials, the majority maintained these clinical responses through 4 years. Similar maintenance of response was seen in patients receiving BKZ Q4W/Q8W.

References

1. Blauvelt A. Presented at AAD 2024, P52661; **2.** Reich K. Lancet 2021;397:487–98, NCT03370133; **3.** Warren RB. N Engl J Med 2021;385:130–41, NCT03412747; **4.** Gordon KB. Lancet 2021;397: 475–86, NCT03410992; **5.** Strober B. Br J Dermatol 2023;188:749–59, NCT03598790; **6.** Bimekizumab Summary of Product Characteristics. 2023. www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed Apr24].

Figure. Maintenance of PASI 90 and PASI 100 in Year 1 responders who entered the BE BRIGHT OLE through Year 4 (mNRI, OC)

Response rates for both outcomes are reported among patients who achieved the PASI efficacy response of interest at Year 1 and entered the OLE. BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure the period after Week 52 corresponds to the BE BRIGHT OLE. Patients who entered the BE READY escape arm were considered as non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE. BKZ: bimekizumab; mNRI: modified non-responder imputation; N_{obs}: observed N; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI 90/100: ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks.

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Abstract N°: 50

Bimekizumab clinical efficacy in important body regions and health-related quality of life in patients with plaque psoriasis: Data from four phase 3/3b comparator-controlled trial periods

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Introduction & Objectives:

The impact of psoriasis on patients' health-related quality of life (HRQoL) can vary based on the body region affected.1–3 Psoriasis affecting certain areas, such as the scalp, can have a disproportionate impact on the physical and emotional wellbeing of patients; these are termed 'high-impact areas'.2,3

Here, we examine how achievement of complete clearance of skin in various body regions and in the scalp high-impact area translates into patient-perceived HRQoL benefits at Week 4 in patients treated with bimekizumab (BKZ) vs comparators.

Materials & Methods:

Data were analysed from patients with moderate to severe plaque psoriasis receiving BKZ 320 mg every 4 weeks (Q4W) vs comparators during the first 4 weeks of the comparator-controlled periods of four phase 3/3b trials. Included trials are: pooled BE VIVID/BE READY (BKZ vs placebo [PBO]),4,5 BE SURE (BKZ vs adalimumab [ADA]),6 BE RADIANT (BKZ vs secukinumab [SEC]),7 and BE VIVID (BKZ vs ustekinumab [UST]).4

Proportions of patients who achieved the following outcomes simultaneously with Dermatology Life Quality Index (DLQI) 0/1 (no effect of skin disease on patient's life) are reported at Week 4: PASI 100 (100% improvement from baseline in PASI; complete skin clearance) in each PASI body region (head/neck, trunk, arms, and legs), or a scalp Investigator's Global Assessment (IGA) score of 0 (complete scalp clearance).

Included patients had PASI >0 (for the relevant PASI body region) or scalp IGA ≥3 at baseline. Data are reported using non-responder imputation (NRI).

Results:

Across BE VIVID/BE READY, 670 patients were randomised to BKZ, and 169 to PBO. In BE SURE, 319 patients were randomised to BKZ, and 159 to ADA. In BE RADIANT, 373 patients were randomised to BKZ, and 370 to SEC. In BE VIVID, 321 patients were randomised to BKZ, and 163 to UST.

In each study, a greater proportion of BKZ-randomised patients achieved PASI 100 across each body region vs all comparators at Week 4 (**Figure 1**). Across studies, simultaneous PASI 100 and DLQI 0/1 achievement was greater

in BKZ-randomised patients at Week 4 (23.5–37.2% in the head/neck, 18.7–27.2% in the trunk, 16.3–19.9% in the arms, and 10.6–16.1% in the legs) vs comparators for each body region (**Figure 1**).

A greater proportion of BKZ-randomised patients achieved scalp IGA 0 vs all comparators at Week 4 (**Figure 2**). Across studies, 22.7–34.8% of BKZ-randomised patients achieved simultaneous scalp IGA 0 and DLQI 0/1 at Week 4, with lower responses observed for comparators (0.0–23.1%) (**Figure 2**).

Conclusion:

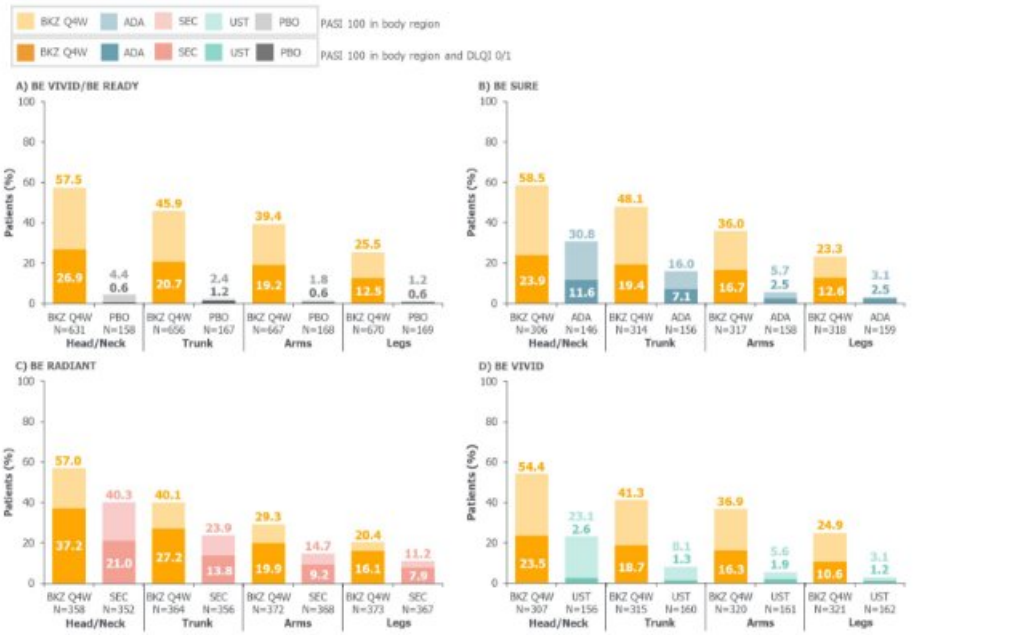
As early as Week 4, BKZ-treated patients experienced higher clinical responses in the scalp and each PASI body region compared to PBO, ADA, SEC, and UST. Higher clinical efficacy with BKZ translated simultaneously into numerically greater patient-perceived HRQoL benefits versus comparators. Simultaneous achievement of clinical responses and HRQoL benefits were more easily achieved in the head/neck and trunk versus the arms and legs, as reported elsewhere previously.8

References:

1. Augustin M & Radtke MA. Expert Rev Pharmacoecon Outcomes Res 2014;14:559–68;

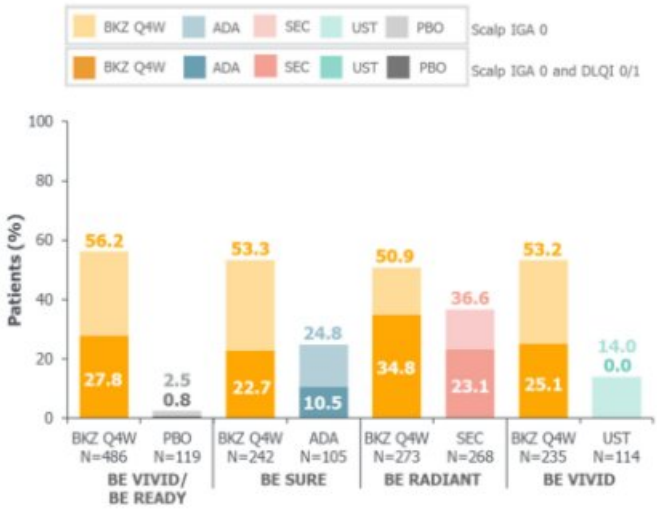
2. Timotijević ZS et al. Acta Dermatovenerol Croat 2017;25:215–22; **3.** Strober B et al. J Dermatolog Treat 2024;35:2287401; **4.** Reich K et al. Lancet 2021;397:487–98, NCT03370133; **5.** Gordon KB et al. Lancet 2021;397:475–86, NCT03410992; **6.** Warren RB et al. N Engl J Med 2021;385:130–41, NCT03412747; **7.** Reich K et al. N Engl J Med 2021;385:142–52, NCT03536884; **8.** Hjuler KF et al. Br J Dermatol 2019;181:332–7.

Figure 1. Simultaneous achievement of complete skin clearance (PASI 100) in PASI body regions and DLQI 0/1 at Week 4 (NRI)



Only patients with a PASI >0 for each given body region at baseline are included (N). ADA: adalimumab; BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PASI 100: 100% improvement from baseline in PASI; PBO: placebo; Q4W: every 4 weeks; SEC: secukinumab; UST: ustekinumab.

Figure 2. Simultaneous achievement of complete scalp clearance (scalp IGA 0) and DLQI 0/1 at Week 4 (NRI)



Only patients with a scalp IGA ≥3 at baseline are included (N). Scalp IGA response is defined as clear (0) with at least a two-category improvement from baseline, representing complete scalp clearance. ADA: adalimumab; BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; NRI: non-responder imputation; PBO: placebo; Q4W: every 4 weeks; SEC: secukinumab; UST: ustekinumab.

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Abstract N°: 56

An International Delphi Consensus to Define a Clinically Appropriate Definition of Disease Modification for Plaque Psoriasis

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Introduction & Objectives:

In moderate to severe psoriasis, biologic therapies have achieved high levels of complete skin clearance and maintenance of this response over several years for many patients. However, questions remain as to how the disease can be controlled, brought into remission, or modified. Current definitions and measurement of disease modification are of limited utility in a clinical setting.

This work acknowledges that the rapidly developing therapeutic landscape for plaque psoriasis brings the question of potential for disease modification into focus.

Objective: To achieve consensus on a definition of disease modification that can be applied within a clinical setting.

Materials & Methods:

In May 2021, a literature review on the topic of disease modification in psoriasis was conducted using the PubMed database. Search terms included but were not limited to: ‘disease modification’, ‘disease progression, ‘disease interception’, ‘treatment target’, ‘drug therapy’, ‘biomarker’, and ‘drug-free remission’.

Following the review, a panel of experts in psoriasis care from across Europe and North America convened in October 2021. Employing Delphi methodology guided by an independent facilitator, the panellists identified 6 main topics of focus.

These topics were discussed, and 35 statements were developed and used to inform an online Delphi survey. This was distributed through a convenience sampling method to 97 healthcare professionals specialising in psoriasis care across Europe and North America.

Respondents were offered a 4-point Likert scale to indicate their responses. Completed surveys were anonymously collated and analysed by the independent facilitator. Results were then shared with the expert panel to determine conclusions.

Stopping criteria for consensus rounds were defined as a three-month period to collect responses, a minimum of 50 responses within this timeframe, and 90% of statements passing the threshold for consensus. The a priori threshold for consensus agreement was set at 75% and was further defined to be ‘very high’ at ≥90%.

Results:

A total of 63 responses (65% response rate) were received. Consensus was achieved for 32 statements and was not achieved for 3 statements. Given the high level of agreement with the statements, and that the stopping criteria were met, a second round of testing was not performed.

Conclusion:

The authors offer a definition of disease modification for plaque psoriasis that could be utilised in a clinical setting:

'A sustained improvement in the disease course of plaque psoriasis resulting from a change in pathophysiology that minimises the need for treatment.'

To determine the strength of this definition, the next step will be to test it within a real-world clinical setting.

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Abstract N°: 87

Real World Effectiveness of Initiating Topical Therapy Compared with Initiating Apremilast Early or Late

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Introduction & Objectives: The International Psoriasis Council recommends considering systemic therapy based on special area involvement, topical treatment failure, or body surface area (BSA).1 This approach enables patients with significant disease impact to be identified earlier and advance to appropriate therapy. The objective of the study was to assess real world effectiveness of topical initiators (TI) compared with early or late apremilast initiators (EAI or LAI), measured by change in BSA and achievement of treatment targets, from pre-initiation to 6- and 12-months post-initiation.

Materials & Methods: A retrospective observational study was conducted in the OM1 database, including electronic medical records and claims data. Patients were systemic-naive adults with a psoriasis diagnosis, a first observed BSA value between 1% and ≤10% (index date), no prior evidence of psoriatic arthritis, ≥365 days of baseline data, and initiation of either apremilast or a topical prescription of a second type between 2014 and 2022 after index date. EAI and LAI were defined as patients with initiation ≤6 and >6 months after index date, respectively. Outcomes included mean BSA, achievement of BSA ≤1% (in patients with a baseline BSA >1%), and ≥75% improvement in BSA (BSA-75) after 6- and 12-months of apremilast or index topical initiation. Relative risks (RR) for achieved outcomes were estimated using a Poisson model for a three-way comparison between EAI, LAI, and TI. Adjustments were made based on the index BSA value; potential confounding and differential censoring were addressed using inverse probability of treatment and missingness weights (to account for missing BSA outcomes) for the study population.

Results: The study included 9,777 TI, 2,073 EAI, and 1,516 LAI. Baseline characteristics are shown in Table 1; mean age and sex were balanced across groups. Mean index BSAs were 4.6%, 6.0%, and 4.9% for TI, EAI, and LAI, respectively. The median number of days between index BSA and treatment initiation were 0, 16, and 485, for TI, EAI, and LAI, respectively. At treatment initiation, BSA was 4.8%, 6.1%, and 7.3% for TI, EAI, and LAI, respectively (Table 2). For TI, mean BSA at 6- and 12-months post-initiation was 5.5% and 5.3 %. At 6 months, the proportion of patients achieving BSA ≤1% (RR [95% CI]) was significantly higher for EAI (1.54 [1.27, 1.87]) and LAI (1.56 [1.25, 1.95]) versus TI; additionally, the proportion of patients achieving a BSA-75 was significantly higher for EAI (1.52 [1.21, 1.89]) and LAI (1.59 [1.24, 2.03]) versus TI. At 12 months, the proportion of patients achieving BSA ≤1% was significantly higher for EAI versus TI, and BSA-75 was significantly higher for EAI and LAI versus TI.

Conclusion: Topical cycling is a recognized treatment pattern in clinical care.2 We investigated the effectiveness of this approach versus early and delayed systemic therapy. We found early apremilast initiators were 54% and 52% more likely to achieve BSA ≤1% and BSA-75 goals, respectively, at 6 months compared to those who received topical therapy alone. BSA among topical initiators remained similar from baseline to 12 months. Earlier initiation of apremilast could attenuate patient life course impairment related to topical cycling in mild-to-moderate psoriasis.2,3

Table 1. Baseline characteristics for topical initiators, early apremilast initiators, and late apremilast initiators				
Characteristics	**Topical Initiators (TI) n=9777**	**Early Apremilast Initiators (EAI) n=2073**	**Late Apremilast Initiators (LAI) n=1516**	**Overall Apremilast Initiators n=3589**
Age, mean (SD)	53.2 (16.0)	51.6 (15.4)	52.4 (15.0)	51.9 (15.2)
Female, n (%)	5583 (57.1)	1238 (59.7)	884 (58.3)	2122 (59.1)
Days from first PsO diagnosis to index date				
Mean (SD)	622.6 (725.8)	341.5 (593.7)	398.8 (570.7)	365.7 (584.7)
Median (IQR)	329.0 (34.0, 1030.0)	29.0 (0, 390.0)	91.5 (0, 641.5)	45.0 (0, 500.0)
Days from index date to treatment initiation				
Mean	49.7	41.0	649.9	298.2
Median	0	16	485	108
BSA%				
Mean (SD)	4.6 (3.1)	6.0 (3.2)	4.9 (3.2)	5.5 (3.2)
Median (IQR)	4.0 (2.0, 7.0)	5.0 (3.0, 10.0)	5.0 (2.0, 7.0)	5.0 (3.0, 10.0)
1–3%, n (%)	3250 (33.2)	338 (16.3)	440 (29.0)	778 (21.7)
3–10%, n (%)	6527 (66.8)	1735 (83.7)	1076 (71.0)	2811 (78.3)
Comorbidities, n (%)				
Anxiety	676 (6.9)	141 (6.8)	89 (5.9)	230 (6.4)
Malignancies*	406 (4.2)	31 (1.5)	23 (1.5)	54 (1.5)
Depression	589 (6.0)	142 (6.8)	82 (5.4)	224 (6.2)
Dyslipidemia	1538 (15.7)	307 (14.8)	243 (16.0)	550 (15.3)
Hypertension	1836 (18.8)	387 (18.7)	272 (17.9)	659 (18.4)
Renal dysfunction/CKD	1108 (11.3)	247 (11.9)	175 (11.5)	422 (11.8)
Obesity	1013 (10.4)	221 (10.7)	148 (9.8)	369 (10.3)
Type 2 diabetes mellitus	721 (7.4)	171 (8.2)	118 (7.8)	289 (8.1)
Prior treatments, n (%)				
Topicals, any	9777 (100.0)	1728 (83.4)	1274 (84.0)	3002 (83.6)
1 topical	1008 (10.3)	522 (25.2)	335 (22.1)	857 (23.9)
2 topicals	2918 (29.8)	508 (24.5)	383 (25.3)	891 (24.8)
≥3 topicals	5843 (59.8)	698 (33.7)	556 (36.7)	1254 (34.9)

*Excluding nonmetastatic skin cancer.
BSA=body surface area; CKD=chronic kidney disease; IQR=interquartile range; PsO=psoriasis; SD=standard deviation

Table 2. Mean BSA and achieved treatment targets of topical initiators, early apremilast initiators, and late apremilast initiators at treatment initiation, and 6 and 12 months post-initiation				
		Topical Initiators (TI) N=9777	**Early Apremilast Initiators (EAI) N=2073**	**Late Apremilast Initiators (LAI) N=1516**
Initiation				
BSA	N	8065	1908	759
	Mean (SD)	4.8 (2.2)	6.1 (3.9)	7.3 (8.0)
6 months				
BSA	N	2954	802	450
	Mean (SD)	5.5 (7.1)	4.9 (5.1)	5.2 (6.6)
BSA ≤1%*	N	380	166	98
	RR (95% CI)	Ref	1.54 (1.27, 1.87)†	1.56 (1.25, 1.95)†
BSA-75‡	N	289	151	85
	RR (95% CI)	Ref	1.52 (1.21, 1.89)†	1.59 (1.24, 2.03)†
12 months				
BSA	N	2419	541	354
	Mean (SD)	5.3 (7.5)	4.6 (6.4)	5.1 (7.0)
BSA ≤1%*	N	393	161	84
	RR (95% CI)	Ref	1.49 (1.23, 1.80)†	1.22 (0.96, 1.54)
BSA-75‡	N	313	152	78
	RR (95% CI)	Ref	1.50 (1.22, 1.85)†	1.33 (1.03, 1.71)†

The comparative analysis was adjusted for the index BSA value.
*Excluded patients with index BSA=1%.
†Statistically significant difference from topical initiators.
‡BSA-75= ≥75% improvement in BSA.
BSA=body surface area; CI=confidence interval; Ref=referent category; RR=relative risk; SD=standard deviation

References

\1. Strober B et al. *J Am Acad Dermatol.* 2020;82(1):117-122.

\2. Kimball AB et al. *J Eur Acad Dermatol Venereol.* 2010;24(9):989-1004.

\3. Shah M et al. *SKIN: J. Cutan. Med.* 2024;8 (1):1217-1231.

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Abstract N°: 133

Treatments used among patients with psoriasis: a first look at a new patient-centered psoriasis registry

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Introduction & Objectives: Psoriasis management in the US has changed substantially, with increasing treatment options including new topical, oral, and biologic medications. The objective of this study was to examine the demographics, disease characteristics, and treatment usage in the first patients enrolled in the new patient-centered psoriasis registry, the FORWARD Psoriasis Registry.

Materials & Methods: Adult patients with psoriasis were recruited from dermatology offices as part of a national practice group, through a patient support program for deucravacitinib, and online from the FORWARD registry website between August and December 2023. Patients were not required to be on therapy for psoriasis. We descriptively report demographics, disease characteristics, current treatments at enrollment.

Results: A total of 702 patients met inclusion criteria and completed the full enrollment questionnaire. Mean age was 53 years and 66% were female; mean BMI was 30 (SD 7); 88% self-reported as White and 6% as Hispanic. A diagnosis of PsA was reported by 28%. Most (75%) had private insurance. Median psoriasis duration was 10 (IQR 3-23) years. 85% had plaque psoriasis, 19% guttate, 14% inverse, 6% generalized pustular and 3% erythrodermic. Body surface area as assessed by the PREPI questionnaire was minimal (<1% BSA) in 21%, mild (1%-2%) in 39%, moderate (3%-10%) in 34%, and severe (>10%) in 6%. The most commonly used therapies included IL23 inhibitors (11%), IL17 inhibitors (8%), apremilast (7%), and TNF inhibitors (5%). Additionally, 14% of the cohort were using deucravacitinib; 62% reported using topicals, and 48% reported use of any systemic agent.

Conclusion: The FORWARD psoriasis registry represents a new patient-centered approach and proof of concept for studies seeking to understand the natural history of the disease, treatment outcomes, and treatment needs relevant for individuals with psoriasis, and long-term outcomes related to comorbidities.

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Abstract N°: 161

Long-term consequences of the use of mustard compounds in a patient suffering from psoriasis

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Introduction & Objectives:

In the 1960s-1980s, both sulfur and nitrogen mustard derivatives (mechlorethamine) were used in psoriasis topically. The ointment form of sulfide was used as the drug "Psoriazin", produced in the Soviet Union. Indeed, it was never registered in Poland, but patients bought it abroad.

Derivates of mustards are alkylating factors with confirmed mutagenicity. They create cyclic ammonium ions that react with nitrogen in nucleic acids (guanine, adenine), alkylation DNA and RNA, and thiol groups in proteins, causing oxidative stress and impaired detoxification processes.

The mechanism of action of sulfur mustard in psoriasis is to inhibit the proliferation of epidermal cells in the basal layer, causing their damage in the form of apoptosis, pyknosis, necrosis, and acantholysis.

Materials & Methods:

We present the case of a patient with long-term complications after using sulfur mustard for psoriasis.

A 76-year-old man was admitted to the Dermatology Clinic due to numerous erythematous and exfoliative lesions on the face, trunk, and upper limbs. The patient underwent twice removal of a nodular lesion from the right auricle, and a histopathological examination revealed squamous cell carcinoma. In the past (the 1980s) for plaque psoriasis, he used sulfur mustard ointment, bought at the market from Russians.

On admission, a physical examination revealed numerous erythematous, nodular, and exfoliative lesions on the face, scalp, chest, upper back, and forearms. Histopathological examination of the lesions after excisions revealed basal cell carcinomas in two lesions and actinic keratosis. Imiquimod cream was used to treat the foci of actinic keratosis on the forearms and trunk, and two photodynamic therapy treatments were performed on the foci on the face and scalp, resulting in improvement of the local condition. Regular check-ups were recommended, as well as appropriate skin care combined with maximum limitation of exposure to ultraviolet radiation.

Results:

Early side effects after their use include allergic contact dermatitis, urticarial reactions, and leukopenia, while late complications include the occurrence of skin cancers, especially basal cell carcinomas, Bowen's disease, and squamous cell carcinomas. Of note, mutations in the tumor suppressor gene p53, known as the "guardian of the genome," have been detected in Japanese mustard gas workers.

Conclusion:

Patients who have suffered from psoriasis for many years and have used mustard derivatives in the past should be regularly screened for skin cancer.

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Abstract N°: 199

Sustained Improvements in Psoriasis Area and Severity Index and in Percent Body Surface Area of Psoriasis with JNJ-77242113 in Patients with Moderate-to-Severe Plaque Psoriasis: Treat-to-Target Analyses in the FRONTIER 1 & 2 Studies

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Introduction & Objectives: FRONTIER 1 (Phase 2 dose-ranging) showed superior clinical efficacy of JNJ-77242113 (JNJ-2113), a targeted oral peptide that inhibits IL-23 signaling by binding the IL-23 receptor, vs placebo (PBO) at Week(W) 16 in patients (pts) with moderate-to-severe plaque psoriasis (PsO) [1], including achievement of stringent measures of disease control [2]. Clinical response to JNJ-2113 through W52 was examined in FRONTIER 2 (long-term extension). This post-hoc analysis assessed the durability of JNJ-2113 effect on relative improvements in Psoriasis Area and Severity Index (PASI) scores and achievement of absolute PASI and PsO body surface area (BSA) treat-to-target thresholds through W52.

Materials & Methods: FRONTIER 1 pts (randomized 1:1:1:1:1:1; 41-43 pts/arm) received JNJ-2113 25mg once daily (QD), 25mg twice daily (BID), 50mg QD, 100mg QD, 100mg BID, or PBO through W16. FRONTIER 1 pts entering FRONTIER 2 received the same JNJ-2113 regimen (25mg QD [n=35]; 25mg BID [n=40]; 50mg QD [n=39]; 100mg QD [n=40]; 100mg BID [n=38]); PBO pts crossed over to JNJ-2113 100mg QD (PBOà100mg QD [n=35]). Least squares mean (LSM) percent changes from baseline (BL) in PASI through W52 were estimated with mixed models for repeated measures (MMRM). Proportions of pts achieving absolute treat-to-target PASI thresholds of ≤5, ≤3, ≤2, ≤1, and 0 and PsO BSA thresholds of ≤3% and ≤1% through W52 were determined using non-responder imputation.

Results: As early as W8, and through W16, LSM percent improvements from BL in PASI were greater with JNJ-2113 vs PBO (all nominal $p<0.001$ at W16) and maintained through W52 (Fig 1). Rates of achieving PASI and BSA thresholds were also higher with JNJ-2113 vs PBO (all nominal $p<0.05$ at W16) and maintained through W52 (Fig 2). As was seen at W16, the greatest improvements and highest response rates at W52 were among pts receiving the 100mg BID regimen, including LSM percent improvement from BL in PASI of 90.2% (Fig 1); PASI ≤5, ≤3, ≤2, ≤1, and =0 rates of 76.2%, 71.4%, 66.7%, 57.1%, and 40.5%, respectively; and BSA ≤3% and ≤1% rates of 71.4% and 59.5%, respectively (Fig 2). Among 100mg BID-treated pts achieving BSA treat-to-target goals of ≤3% and ≤1% at W16, 85.7% and 81.8%, respectively, maintained response at W52.

Conclusion: Treatment with JNJ-2113 provided robust and sustained skin improvements in pts with moderate-to-severe PsO** based on percent PASI improvements and stringent treat-to-target PASI/BSA thresholds. The highest levels of improvement and response rates were observed with 100mg BID, with two-thirds of pts achieving PASI ≤2 or BSA ≤3% and approximately half achieving PASI ≤1 or BSA ≤1% at W16. Patient- and group-level data

indicated maintenance of stringent response through W52.

References:

\1. Bissonnette R., et al. *N Engl J Med.* 2024;390(6):510-21.

\2. Papp K.A., et al. Improvements in Psoriasis Area and Severity Index and in Percent Body Surface Area of Psoriasis With JNJ-77242113: Treat-to-Target Analyses in the FRONTIER 1 Study.* Poster presented at: AAD Annual Meeting; March, 2024; San Diego, CA, USA.

\3. Mahil S.K., et al. *Br J Dermatol.* 2020;182(5):1158-66.

\4. Armstrong A.W., et al. *J Am Acad Dermatol.* 2017;76(2):290-8.

Figure 1. Percent change from BL in PASI over time through W52

LSM percent change from BL is shown; error bars correspond to ± 95% confidence interval (CI). LSM percent changes were estimated with MMRM, adjusting for treatment group, visit, treatment group by visit interaction, baseline weight category (≤90 vs >90kg), baseline weight category-by-visit interaction, baseline PASI total score, and baseline PASI total score-by-visit interaction. Zero change was assigned after pts discontinued study agent due to lack of efficacy/worsening of PsO or initiated a prohibited PsO treatment. Missing data were handled by MMRM under missing at random assumption.
All nominal p<0.001 vs PBO at W16.

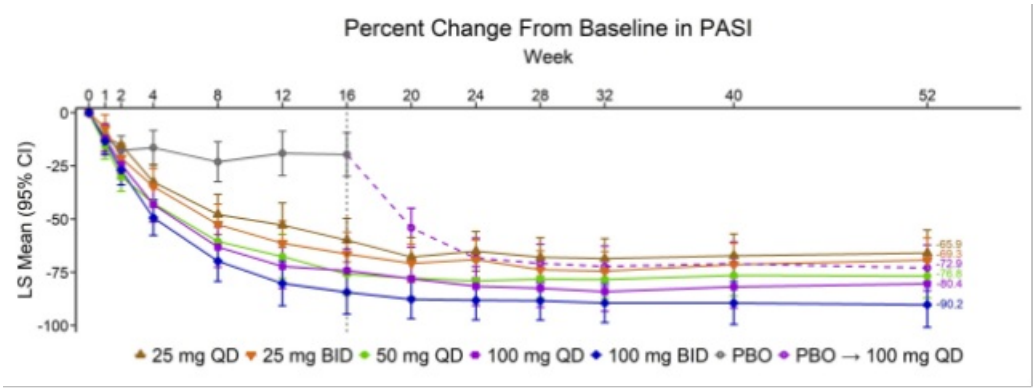
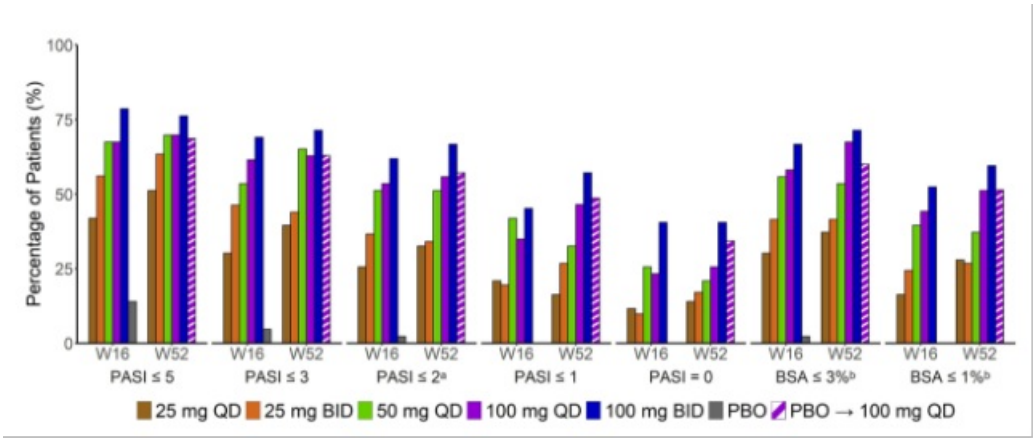


Figure 2. Achievement of PASI and BSA thresholds at W16 and W52 (NRI)

Non-responder imputation (NRI): Pts who discontinued study agent due to lack of efficacy/worsening of PsO, or who initiated a prohibited PsO treatment were considered non-responders after the occurrence. Pts with missing data were considered non-responders.
All nominal p<0.05 vs PBO at W16.
[a] Per the British Association of Dermatologists Biologics and Immunomodulators Register, a relevant treat-to-target approach for a clinical setting is absolute PASI ≤2 [3].
[b] Per the National Psoriasis Foundation, at 12 weeks (3 months) after treatment initiation, an acceptable response is BSA ≤3% and a target response is ≤1% [4].



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Abstract N°: 234

Impact of Bariatric Surgery on Clinical Psoriasis Activity in Obese Patients: A Retrospective Cohort Study

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Introduction & Objectives: Psoriasis is a chronic inflammatory skin disease with systemic involvement. The association with obesity, an independent risk factor for psoriasis, affects its treatment due to lower response to systemic therapies and increased risk of adverse effects. Additionally, treatment cost is potentially affected by obesity. Currently, the effect of bariatric surgery on psoriasis is not yet clearly defined.

Materials & Methods: We carried out a** single-center retrospective cohort study with the following inclusion criteria: (i) patients with obesity undergoing bariatric surgery between January 1, 2012 and December 31, 2021 (ii) psoriasis documented in a Dermatology consultation. No exclusion criteria were defined. The data were analyzed until a period of 24 months after surgery, migration, loss of follow-up, or death from any cause. The main endpoint was the percentage of patients with improvement in the Psoriasis Area Severity Index (PASI) score 12 and 24 months after surgery, in relation to the PASI 12 months before surgery. Secondary analyzes focused on changes in therapeutic class or dosage in the treatment instituted for psoriasis.

Results: 17 patients who met the eligibility criteria were included, with a mean age of 52.2 ± 10.9 (29-66) years and a mean disease duration of 7.8 ± 4.8 (1-15) years. The average PASI 12 months prior to surgery was 9.5 ± 8.6 (1-29) and nine patients were diagnosed with arthropathic psoriasis. The mean pre-surgical body mass index (BMI) was 40.6 ± 4.6 (34-52) kg/m2. The majority of patients (82.4%) underwent Roux-en-Y gastric bypass and 12 months postoperatively the mean BMI was 27.2 ± 3.3 (22-34) kg/m2 with an average weight reduction of 35.4 ± 16.9 (20-94) kg. The variation in PASI scores showed a positive correlation with the variation in BMI both 12 months (ρ=0.425, p=0.089) and 24 months after surgery (ρ=0.411, p=0.111). 64.70% of patients showed a reduction in PASI 12 months after surgery, in relation to the PASI they had 12 months before the surgical intervention. Thirteen patients were treated with systemic drugs at the time of surgery, of which 47.1% corresponded to biotechnological therapy. Twelve months after surgery, there was a reduction in the dosage or therapeutic class of psoriasis in 41.2% of patients.

Conclusion: Bariatric surgery has shown a potential benefit in the clinical evolution of psoriasis in obese patients, although additional investigations are needed.

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Abstract N°: 265

Effectiveness of Brodalumab in Patients with Plaque Psoriasis in the Canadian Real-World Setting: 6-Month Follow-up Interim Results from the CARE Study

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin condition affecting 2-3% of the Canadian population, and plaque psoriasis (PsO) is the most common sub-type.1-3 Brodalumab is an interleukin 17 receptor A antagonist (IL-17RA) indicated in Canada for the treatment of moderate-to-severe PsO in adult patients who are candidates for systemic therapy or phototherapy.4

The CARE study aims to describe the real-world outcomes of brodalumab in adult patients with moderate-to-severe PsO in Canada. The objective of this interim analysis was to describe the effectiveness of brodalumab in patients with PsO up to 6 months post-initiation.

Materials & Methods:

CARE is an ongoing Canadian multi-center, 12-month prospective, observational study in adult patients with PsO who initiated brodalumab as part of routine clinical care between October 2021 and February 2024. Study visits are conducted at baseline, and then 3, 6, and 12 months post-brodalumab initiation.

This interim analysis includes a subset of patients who completed the baseline and 6-month follow-up (M6) visits. The effectiveness of brodalumab was assessed by examining the physician-assessed Psoriasis Area and Severity Index (PASI) responses, Static Physician's Global Assessment (sPGA) scores, and patient-reported Psoriasis Symptom Inventory (PSI) scores at baseline, 3 months post-initiation (M3), and M6. Complete case analysis was used to descriptively assess and summarize all study data.

Results:

278 patients (male: 57.2%; Caucasian: 75.9%; mean age: 51.0 years, SD: 13.8) with verified baseline and M6 data were included in the interim analysis.

At baseline, 84.9% (236/278) of patients had not previously been treated with biologics, and 55.0% (148/269) had a disease duration of 10 years or more. Most patients had one or more comorbidities of interest (68.3%, 190/278), with hypertension being the most common (25.5%, 71/278). The mean PASI and PSI scores were 14.1 (SD: 9.3) and 18.5 (SD: 7.3), respectively. Most patients had an sPGA score of 3 (62.2%; 173/278) or 4 (32.4%; 90/278).

Table 1 shows the PASI, sPGA, and PSI scores at baseline and changes in scores at M3 and M6. At M3, PASI

75/90/100 were observed in 79.0% (211/267), 64.8% (173/267) and 45.3% (121/267) of patients, respectively. Greater proportions of patients achieved PASI 75 (81.2%; 220/271), PASI 90 (70.8%; 192/271), and PASI 100 (50.6%; 137/271) at M6.

Most patients (67.9%; 182/268) achieved an sPGA of clear (0) or almost clear (1) at M3, and the proportion was higher at M6 (76.2%; 208/273). The proportion of patients that achieved a 2-grade or more improvement of the sPGA score compared to baseline was 73.5% (197/268) at M3 and 77.7% (212/273) at M6.

The mean change in PSI was -13.5 (SD: 8.3) at M3 and -13.8 (SD: 8.3) at M6. The mean percentage change in PSI at M3 and M6 were -70.4 % (SD: 35.6%) and -71.5 % (SD: 34.1%), respectively.

Conclusion:

Adult patients with moderate to severe PsO observed rapid improvements in psoriasis signs and symptoms after 3 months of brodalumab therapy that were sustained or increased after 6 months.

Table 1. PASI, sPGA, and PSI up to the 6-Month Follow-up Visit

Physician and Patient Reported Outcomes	Baseline	Month 3	Month 6
Number of Patients	278	277	278
PASI Score			
N	278	268	273
Mean (SD)	14.1 (9.3)	1.6 (2.6)	1.4 (2.8)
PASI Response[a]			
N	-	267	271
PASI 75, n (%)	-	211 (79.0)	220 (81.2)
PASI 90, n (%)	-	173 (64.8)	192 (70.8)
PASI 100, n (%)	-	121 (45.3)	137 (50.6)
sPGA			
N	278	268	273
0 - Clear, n (%)	2 (0.7)	123 (45.9)	139 (50.9)
1 - Almost clear, n (%)	0 (0.0)	59 (22.0)	69 (25.3)
2 - Mild, n (%)	13 (4.7)	60 (22.4)	34 (12.5)
3 - Moderate, n (%)	173 (62.2)	23 (8.6)	28 (10.3)
4 - Severe, n (%)	90 (32.4)	3 (1.1)	3 (1.1)
Missing, n	0	9	5
sPGA (0,1)[b], n (%)			
N	278	268	273
n (%)	2 (0.7)	182 (67.9)	208 (76.2)
sPGA improvement of grade 2 or more [c]			
N	-	268	273
n (%)	-	197 (73.5)	212 (77.7)
PSI Score			
N	270	246	240
Mean (SD)	18.5 (7.3)	4.9 (5.6)	4.9 (5.9)
Change in PSI score from baseline			
N	-	242	234
Mean (SD)	-	-13.5 (8.3)	-13.8 (8.3)
Change in PSI score from baseline - Percentage (%)			
N	-	241	233
Mean (SD)	-	-70.4 (35.6)	-71.5 (34.1)

SD: Standard Deviation, PASI: Psoriasis Area and Severity Index, PSI: Psoriasis Symptom Inventory, sPGA: Static Physician's Global Assessment

[a]Percentages calculated based on the number of patients for whom the change from baseline can be evaluated at the respective timepoint.

[b]Percentages calculated based on the number of patients with a recorded sPGA score.

[c]Percentages calculated based on the number of patients for whom the change in sPGA can be evaluated at the respective timepoint.

References:

1. Armstrong AW, Read C. Pathophysiology, Clinical Presentation, and Treatment of Psoriasis: A Review. JAMA 2020;323(19):1945-1960. DOI: 10.1001/jama.2020.4006.
2. Eder L, Widdifield J, Rosen CF, et al. Trends in the Prevalence and Incidence of Psoriasis and Psoriatic Arthritis in Ontario, Canada: A Population-Based Study. Arthritis Care Res (Hoboken) 2019;71(8):1084-1091. DOI: 10.1002/acr.23743.
3. Papp KA, Gniadecki R, Beecker J, et al. Psoriasis Prevalence and Severity by Expert Elicitation. Dermatol Ther (Heidelb) 2021;11(3):1053-1064. DOI: 10.1007/s13555-021-00518-8.
4. Monograph SP. SILIQ™ Product Monograph. 2019.

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Abstract N°: 289

Association of Vitamin D Deficiency with Psoriasis and Metabolic Syndrome: A Case-control Study in Indian Patients

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Introduction & Objectives: Substantial evidence suggests a higher risk of metabolic syndrome as a result of persistent inflammation in patients with psoriasis. Psoriasis may also be associated with vitamin D deficiency. Objective is to correlate vitamin D deficiency with psoriasis and metabolic syndrome.

Materials & Methods: Serum vitamin D levels were quantified and metabolic syndrome was assessed in 42 cases —whose psoriasis severity had been measured by PASI—and an equal number of age/gender matched controls. The resultant data were analysed statistically. Odds ratio was calculated wherever applicable and a two-tailed $P<0.05$ was considered statistically significant.

Results: Vitamin D deficiency (<20ng/ml) occurred in 43 subjects [(51.19%); 26 (62%), patients and 17 (40.4%), controls] and was statistically significant in patients (OR 2.39, P 0.044) though lacking correlation with disease severity. Metabolic syndrome seen in 25 (30%) subjects—15 (36%) patients and 10 (24%) controls—emerged to be significant (OR 3.71, P 0.047) in cases with vitamin D deficiency. Hypertension—observed in 31 (37%) subjects;18 (43%) cases, 9 each (21.4%) with/without metabolic syndrome and 13 (31%) controls, 7 (16.6%) with and 6 (14.3%) without metabolic syndrome (P 0.25) —correlated independently with vitamin D deficiency in patients (P 0.009).

Conclusion: Despite *limitations* of small sample size and observational nature, our study—probably the first such hereto from India—showed statistically significant associations between vitamin D deficiency, metabolic syndrome and hypertension in patientswith psoriasis. Future larger studies are needed for strengthening this evidence prior to recommendation of its clinical application in optimum management of patients.

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Abstract N°: 309

Efficacy of Apremilast in Adults with Mild-to-Moderate Plaque Psoriasis with Scalp Involvement: Pooled Data from PROMINENT, ADVANCE, and EMBRACE Trials

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Introduction & Objectives: Plaque psoriasis (PsO) with scalp involvement occurs in 65–80% of PsO,1,2 yet most patients are dissatisfied with scalp topical therapies.3,4 Apremilast, an oral immunomodulating phosphodiesterase-4 inhibitor approved for PsO, has demonstrated efficacy in a placebo-controlled randomized controlled trial involving moderate-to-severe PsO with scalp involvement.5 In patients with limited skin involvement, scalp involvement exacerbates PsO burden. In this pooled analysis of three studies, we evaluate the effect of apremilast on scalp and skin responses as well as on patient-reported outcomes (PROs) in patients with mild-to-moderate plaque psoriasis with scalp involvement.

Materials & Methods: Data from PROMINENT,6 ADVANCE,7 and EMBRACE8 trials conducted in patients with baseline body surface area (BSA) <10, baseline Scalp Physician Global Assessment (ScPGA) ≥2, and ≥1 post-baseline ScPGA value were pooled. Outcomes included achievement of ScPGA response (clear/almost clear [0/1]), static Physician Global Assessment (sPGA) score clear/almost clear (0/1) with ≥2-grade improvement (sPGA response), ≥75% BSA improvement (BSA-75), Psoriasis Area and Severity Index (PASI) score <3, and ≥4-point reduction in the PRO of Dermatology Life Quality Index (DLQI) score at 16 weeks.

Results: Pooled data from 548 patients (apremilast: 336; placebo: 212) showed mean baseline ScPGA 2.7 and sPGA 2.6 in both treatment groups. A significantly higher proportion of patients achieved ScPGA response with apremilast vs placebo (46.7% vs 19.8%; P<0.0001) at 16 weeks.Additional skin responses significantly improved with apremilast vs placebo: sPGA 23.8% vs 6.9%, BSA-75 26.8% vs 7.1%, and PASI<3 53.9% vs 18.9%, P<0.0001). DLQI score significantly improved with apremilast vs placebo (61.1% vs 31.2%; P<0.0001).

Conclusion: Apremilast consistently demonstrated significant efficacy and PRO improvement compared with placebo at 16 weeks in patients with PsO with scalp and limited skin involvement.

References

\1. Ghafoor R, et al. J Drugs Dermatol. 2022;21(8):833-837.

\2. Augustin M, et al. Br J Dermatol. 2019;181(2):358-365.

\3. Chan CS, et al. J Am Acad Dermatol. 2009;60(6):962-971.

\4. Zeichner JA, et al. Cutis. 2010;86(3 Suppl):5-31; quiz 32.

\5. Van Voorhees AS, et al. J Am Acad Dermatol. 2020;83(1):96-103.

\6. Okubo Y, et al. Dermatol Ther (Heidelb). 2022;12(6):1469-1480.

\7. Stein Gold L, et al. J Am Acad Dermatol. 2022;86(1):77-85.

\8. Mrowietz U, et al. J Eur Acad Dermatol Venereol. 2023;37(2):348-355.

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Abstract N°: 329

Early and Durable Improvements in Patient-Reported Symptoms and Signs of Moderate-to-Severe Psoriasis with JNJ-77242113: 1-Year Results from FRONTIER 1 & 2

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Introduction & Objectives: The Phase 2 FRONTIER 1 trial showed superior clinical efficacy of JNJ-77242113 (JNJ-2113), a targeted oral peptide that inhibits IL-23 signaling by binding the IL-23 receptor, vs placebo (PBO) at Week(W)16 in patients (pts) with moderate-to-severe plaque psoriasis (PsO) [1]. Durability of response to JNJ-2113 was examined through W52 in FRONTIER 2, the long-term extension of FRONTIER 1. JNJ-2113 effect on pt-reported PsO signs/symptoms was also assessed through W52 in FRONTIER 1&2.

Materials & Methods: FRONTIER 1 pts, randomized (1:1:1:1:1:1; 41-43pts/arm) to 25mg once daily (QD), 25mg twice daily (BID), 50mg QD, 100mg QD, 100mg BID, or PBO through W16, who continued to FRONTIER 2 received the same JNJ-2113 regimen (25mg QD [n=35]; 25mg BID [n=40]; 50mg QD [n=39]; 100mg QD [n=40]; 100mg BID [n=38]) or crossed over from PBO to JNJ-2113 100mg QD (PBO→100mg QD [n=35]). Proportions of pts with clinically meaningful improvement (CMI) in symptoms (itch, skin tightness, burning, stinging, pain) and signs (dryness, cracking, scaling, shedding or flaking, redness, bleeding) assessed in the PsO Symptom and Sign Diary (PSSD), and who achieved PSSD symptom/sign score=0, were determined through W52 and compared between JNJ-2113 vs PBO at W16 (Cochran-Mantel-Haenszel [CMH] chi-square test).

Results: Among 255 pts, mean (SD) baseline PsO duration (18.2y [12.8]), PsO Area and Severity Index (PASI) score (19.1 [5.8]), and PSSD symptom (51.8 [23.8])/sign (64.6 [18.3]) scores (range:0-100) indicated established, moderate-to-severe disease, as assessed by investigators and pts; 78% previously received systemic treatments.

Most PSSD symptoms/signs rapidly improved with JNJ-2113, including improvements in itch severity as early as W1 (Fig 1A). At W16, rates of CMI in symptoms/signs were significantly higher with JNJ-2113 vs PBO (nominal $p<0.05$, except 50mg QD bleeding). Highest W16 rates were generally seen with 100mg BID across symptoms (itch 83%, skin tightness 78%, burning 79%, stinging 81%, pain 79%) and signs (dryness 83%, cracking 78%, scaling 75%, shedding or flaking 75%, redness 72%, bleeding 71%) vs 5-35% for PBO (Fig 2). Through W52, rates of CMI in PsO symptoms/signs were mostly maintained across JNJ-2113 groups and comparable following PBO→100mg QD (Fig 2).

Greater proportions of JNJ-2113 vs PBO pts achieved PSSD symptom/sign score=0 at W16 (nominal $p<0.05$, except 25mg QD sign score). Symptom/sign-free status was generally maintained at W52 with JNJ-2113.

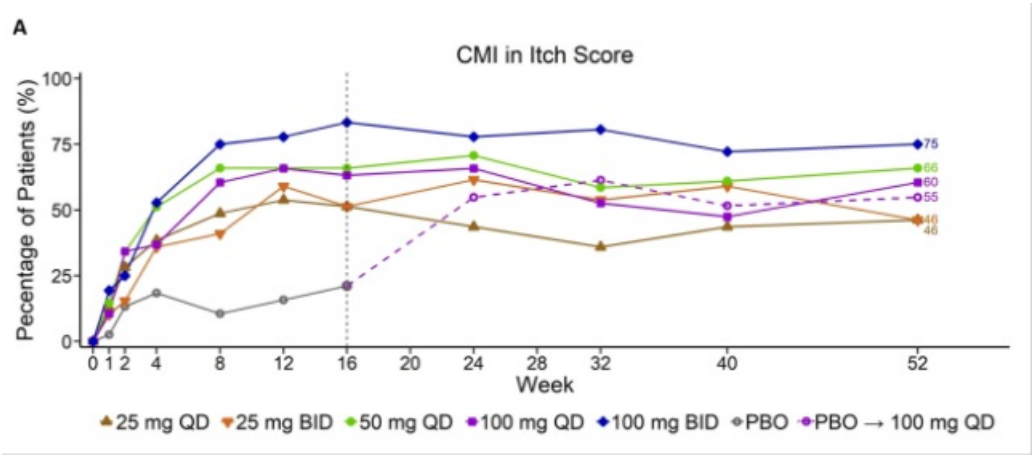
Conclusion: Early clinically meaningful improvement (CMI) in pt-reported PsO symptoms/signs, including itch at W1, were observed with JNJ-2113 vs PBO; W16 CMI rates were maintained through W52. Highest rates of CMI

were generally seen with JNJ-2113 100mg BID. Greater proportions of JNJ-2113 pts achieved symptom/sign-free status at W16, with durable response rates at W52.

Reference:

\1. Bissonnette R., et al. *N Engl J Med.* 2024;390(6):510-21.

Figure 1: Proportions of pts achieving CMI in psoriatic (A) itch and (B) pain over time through W52.
CMI was considered an improvement of ≥4 points for both itch and pain (among pts with respective baseline scores ≥4). Pts who discontinued due to lack of efficacy, worsening PsO or initiation of a protocol-prohibited medication or therapy were considered to be non-responders. Observed data were used for pts who discontinued for other reasons. Pts with missing data were considered non-responders.
All nominal p<0.05 vs PBO at W16; p-values are based on CMH chi-square test stratified by baseline weight category (≤90 kg vs >90 kg).



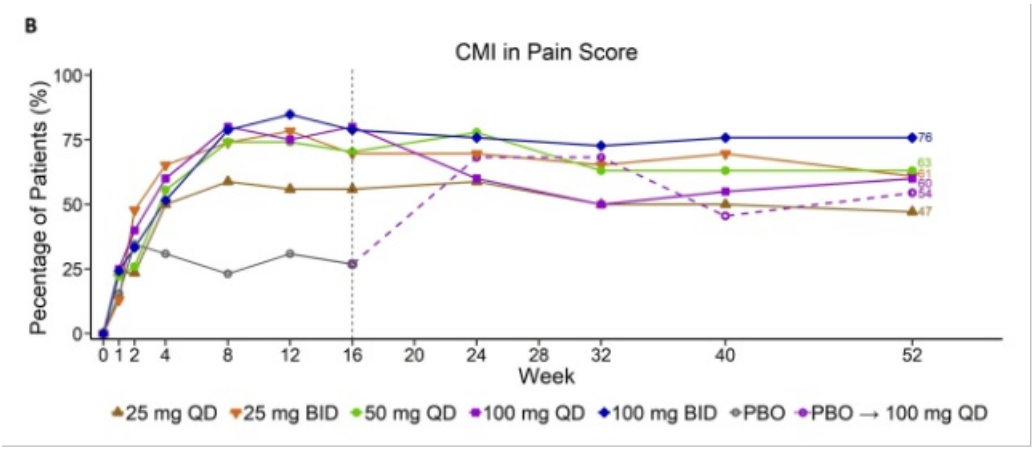
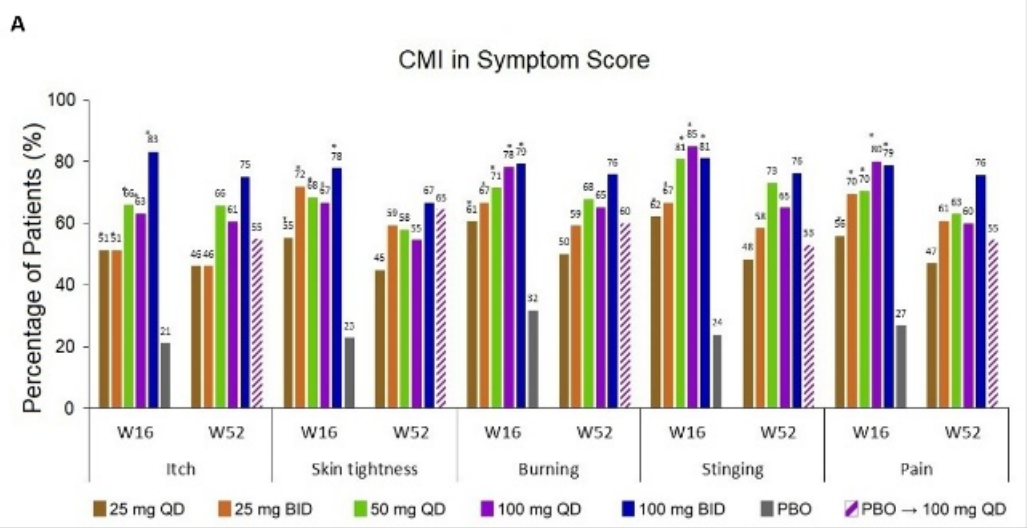
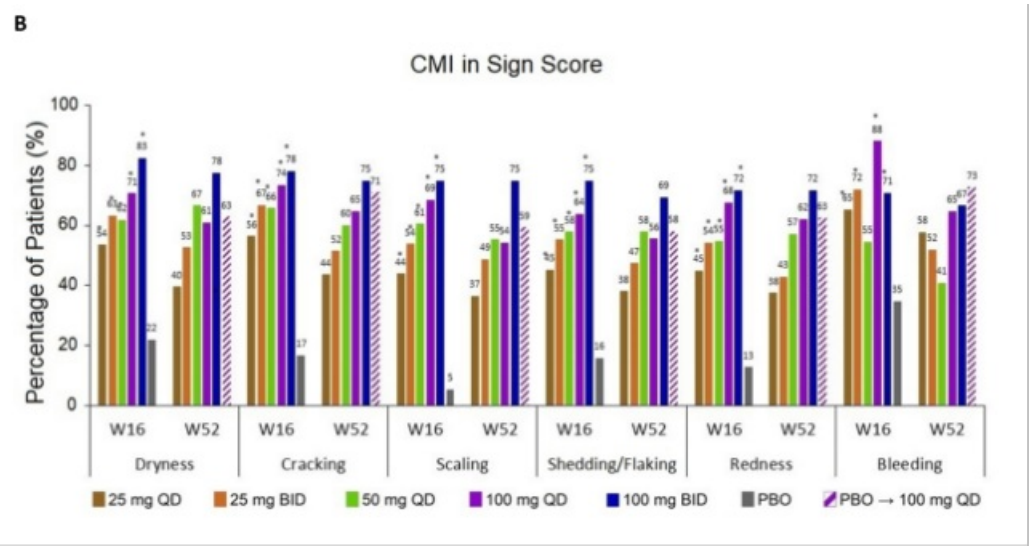


Figure 2: Proportions of pts achieving CMI in PSSD (A) symptoms and (B) signs at W16 and W52.
CMI was considered an improvement of ≥3 points for bleeding and stinging (among pts with baseline scores ≥3); ≥4 points for itch, dryness, cracking, tightness, burning, and pain (among pts with baseline scores ≥4); and ≥5 points for scaling, shedding or flaking, and redness (among pts with baseline scores ≥5). Pts who discontinued due to lack of efficacy, worsening PsO or initiation of a protocol-prohibited medication or therapy were considered to be non-responders. Observed data were used for pts who discontinued for other reasons. Pts with missing data were considered non-responders.
***Nominal p<0.05 vs PBO at W16**; p-values are based on CMH chi-square test stratified by baseline weight category (≤90 kg vs >90 kg).

A


CMI in Symptom Score
Percentage of Patients (%)
W16
W52
Itch
Skin tightness
Burning
Stinging
Pain
25 mg QD
25 mg BID
50 mg QD
100 mg QD
100 mg BID
PBO
PBO → 100 mg QD

B


CMI in Sign Score
Percentage of Patients (%)
W16
W52
Dryness
Cracking
Scaling
Shedding/Flaking
Redness
Bleeding
25 mg QD
25 mg BID
50 mg QD
100 mg QD
100 mg BID
PBO
PBO → 100 mg QD

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Abstract N°: 360

Efficacy and Safety of AK111 in Patients with Moderate to Severe Plaque Psoriasis: Results from a Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase II Clinical Study

Jinhua Xu*[1], Caihong Huang[2], Guoqin Wang[3], Yu Xia[2], Max Wang[3], Baiyong Li[2]

[1]Huashan hospital, Fudan University , Shanghai , China,[2]Akeso Biopharma, Inc. , Zhongshan, China, [3]Akeso Biopharma, Inc. , Zhongshan , China

Introduction & Objectives:

Interleukin 17 (IL-17) not only participates in the anti-infection immune response, but also plays a key role in some chronic inflammatory diseases, including psoriasis. Inhibition of IL-17A can reduce the disease activity of psoriasis and improve quality of life(QoL) of the patients. AK111 is a novel humanized immunoglobulin (Ig) G1 monoclonal antibody that selectively binds and neutralizes IL17A. This study aimed to evaluate the efficacy and safety of AK111 in patients with moderate to severe plaque psoriasis.

Materials & Methods:

A total of 251 patients (male and female) with age ranging from 18 to 75 years were actually enrolled. There were 5 groups in this study, all patients were randomized in a 1:1:1:1:1 ratio to receive either AK111 or matching placebo. Patients from group 1 and group 3 received AK111 150mg and 300mg respectively, drug administered at week 0/1/2/3/4, and then every 4 weeks until week 60. Group 2 and group 4 received AK111 150mg and 300mg respectively, drug administered at week 0/2/4/6/8, and then every 4 weeks until week 60. Group 5(placebo) was converted to AK111 treatment at week 12 with randomized ratio at 1:1. Patients were assigned to receive AK111 300mg at week 12/13/14/15/16(group 5a) and AK111 300mg at week 12/14/16/18/20(group 5b), and then every 4 weeks until week 60. See figure 1 for study design.

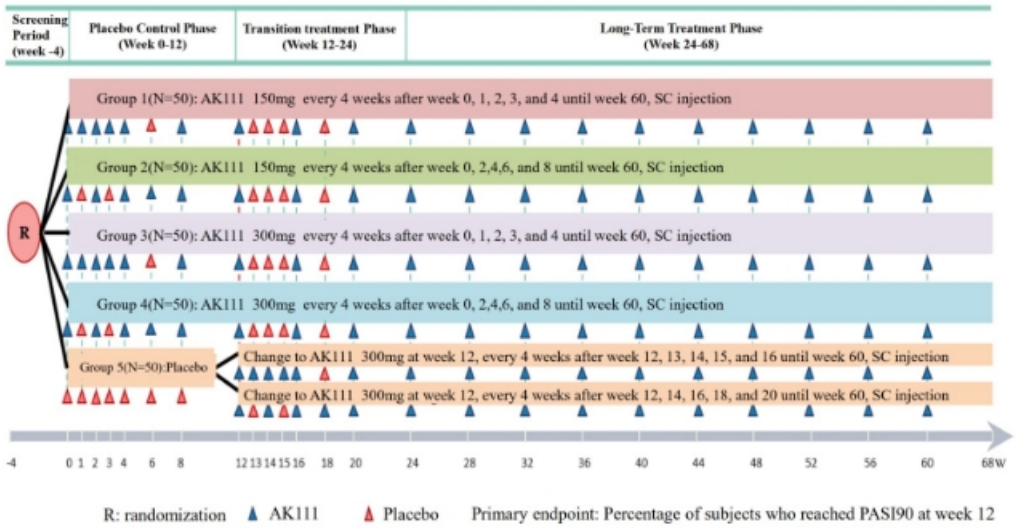

Figure 1 Study design

Results:

Efficacy: The ≥90% improvement in Psoriasis Area and Severity Index (PASI 90) response rates of AK111 group1-4 at week 12 were 70.0% (35/50), 77.6% (38/49),62.0%(31/50) and 66.7% (34/51) respectively, which were

significantly higher than the placebo group (0/51)□p□0.0001. The≥75% improvement in Psoriasis Area and Severity Index (PASI 75) response rates of AK111 group1-4 at week 12 were 90.0%(45/50), 91.8%(45/49), 84.0%(42/50) and 88.2%(45/51) respectively. PASI 75 from AK111 treatment groups were also higher than the placebo group 3.9%(2/51)□p□0.0001. Same trend also found in Static Physicians Global Assessment (sPGA) 0/1 response rate between AK111 treatment groups and placebo group. Furthermore, the efficacy can maintain until week 52 and 68.

Safety: At week 12, a total of 123(61.5%) patients experienced at least one treatment-emergent adverse event (TEAE) in AK111 treatment groups, and 31(60.8%) patients in placebo group. A total of 168 (84%) patients experienced at least one TEAE in AK111 treatment groups, and 39(88.6%) patients in placebo group (converted to AK111 treatment at week 12) between week 0-68. The majority of TEAE were grade 1 or grade 2. 10(4.0%) patients experienced serious adverse event (SAE). No death was reported in this study.

Conclusion:

AK111 was generally safe and well tolerated, also able to improve PASI90, PASI 75 and sPGA0/1 response rate in patients with moderate to severe plaque psoriasis.

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Abstract N°: 423

Effectiveness of interleukin-23 inhibitors (anti-IL23) in patients with plaque psoriasis: A tertiary hospital experience

An Wang[1], Lorena Calderón Lozano[1], Borja González[1], Luisa María Guzmán-Pérez[1], Christian Gutiérrez-Collar[1], Carmen Garcia-Donoso[1], Sofía Sánchez Fernández[2], Raquel Rivera[2]

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Introduction & Objectives:

Biological treatments targeting anti-IL 23 have demonstrated efficacy in psoriasis across various clinical trials. However, there is a lack of comparative trials among these treatments, and meta-analyses only analyze data from trials, which may differ from real-world patient experiences. Hence, we aimed to investigate the status of patients with psoriasis undergoing treatment with anti-IL 23 agents, analyzing patient profiles, treatment effectiveness, and dosage regimens employed.

Materials & Methods:

We present an observational, cross-sectional study that included psoriasis patients treated with anti-IL23 agents for at least 3 months, at a tertiary care hospital from January 2019 to November 2023. Demographic characteristics of the patients were analyzed. Psoriasis severity and treatment response were assessed using the Psoriasis Area and Severity Index (PASI), calculating the median PASI score with each drug and the median treatment duration.

Results:

A total of 158 patients were included: 81 (51.3%) on Guselkumab, 19 (12.0%) on Tildrakizumab, and 58 (36.7%) on Risankizumab. No significant differences were found in terms of gender (33.5% female), age (52.0 years), weight (83.7 kg), or mean duration of psoriasis (23.0 years). Forty-four (27.9%) were biologic-naive. There were no significant differences in baseline PASI (7.45; 5.00-10.00; p=0.086) and current PASI (0.50; 0-1.50; p=0.19). 46.8% of patients received a spaced dosing regimen compared to the standard regimen.

Conclusion:

In our experience, patients treated with anti-IL23 agents maintain good disease control in real-world settings. Additionally, a considerable percentage remain under spaced dosing, implying greater efficiency. No significant differences in effectiveness were found among the three treatments, possibly due to limitations in our study.

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Abstract N°: 438

Treatment discontinuation patterns in patients with psoriasis receiving apremilast in North America: a registry-based analysis

Bruce Strober[1], Yichen Zhong[2], Stefan Varga[2], Andrew Napoli[2], Adam P. Sima[3], Alicia Beeghly[3], Joe Zhuo[2]

[1]Yale University School of Medicine, [2]Bristol Myers Squibb, [3]CorEvitas, LLC.

Introduction & Objectives: The CorEvitas Psoriasis Registry provides real-world information on treatment patterns of patients with psoriasis. The objective of this analysis was to describe characteristics and treatment patterns of patients in the Registry who received treatment with apremilast.

Materials & Methods: All patients had plaque psoriasis and initiated apremilast between April 1, 2015, and September 8, 2022; patients with concurrent biologic use were excluded. Estimates of time until apremilast discontinuation and percentages of patients with persistent apremilast use were obtained from a Kaplan-Meier survival curve. Reasons for discontinuation were recorded.

Results: A total of 325 patients (mean age, 52.7 years [SD, 15.3]; 55.1% female; 79.3% White) were included in this analysis. Most patients were systemic treatment naive (57.5%) and biologic treatment naive (67.7%). Mean Psoriasis Area and Severity Index score was 5.9 (SD, 5.6); mean affected body surface area was 10.6% (SD, 13.4%). Persistence on apremilast was 44% (95% confidence interval [CI], 38–49) at 12 months and 27% (95% CI, 21–33) at 24 months. The median time to discontinuation was 8.6 months (95% CI, 7.0–11.5). The most common reasons for discontinuation were active disease (33.9%) and minor side effects (28.9%).

Conclusion: Drug survival is considered an indicator of real-world tolerability and treatment effectiveness. Patients in the CorEvitas Psoriasis Registry who were treated with apremilast frequently discontinued treatment because of lack of efficacy and/or minor side effects, suggesting that better systemic options are necessary to meet the needs of patients with psoriasis.

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Abstract N°: 458

Malignancy rates in patients with a history of malignancy in the Psoriasis Longitudinal Assessment and Registry (PSOLAR)

Richard Langley*[1], David Fiorentino[2], Jerry Bagel[3], Kimberly Parnell Lafferty[4], Elizabeth Skobelev[4], Wayne Langholff[5], Mark Lebwohl[6], Vincent Ho[7], Bruce Strober[8, 9]

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Introduction & Objectives:

Psoriasis patients with a history of malignancy are at increased risk for new and recurrent cancers; as such, they are typically excluded from clinical trials.1 Hence, data are limited on the safety of biologics in patients with a history of malignancy. We report malignancy rates in PSOLAR stratified by prior or no history of malignancy before registry entry.

Materials & Methods:

PSOLAR is an international, prospective, observational study evaluating long-term safety and clinical outcomes for patients eligible to receive systemic therapy for psoriasis. Patients were stratified by prior history of malignancy (excluding non-melanoma skin cancer [NMSC]) at enrollment. Unadjusted incidence rates of new or recurrent malignancies (excluding NMSC) overall and by exposure to any biologic or non-biologic through December 28, 2021 are reported.

Results:

The PSOLAR study included 12,091 patients with a median duration of follow-up of 7.88 years (75,831 patient-years). Overall, new or recurrent malignancies were reported for 12.9% (72/556) of patients with history of malignancy (11.6% [46/397] exposed to biologics; 16.4% [26/159] exposed to non-biologics), and for 3.5% (408/11,535) of patients without history of malignancy (3.7% [362/9744] exposed to biologics; 2.6% [46/1791] exposed to non-biologics). Among patients with history of malignancy, cumulative malignancy rates (95% confidence interval) per 100 patient-years were 2.57 (1.97-3.30) for patients exposed to biologics and 3.60 (2.46-5.08) for patients exposed to non-biologics; corresponding rates among patients without history of malignancy were 0.61 (0.55-0.68) for patients exposed to biologics and 0.54 (0.40-0.70) for patients exposed to non-biologics.

Conclusion:

In PSOLAR, patients with history of malignancy (excluding NMSC) who received biologics had numerically lower rates of malignancy than those who received non-biologics. Overall, results suggest no increased risk of malignancy in patients treated with biologics compared with other psoriasis therapies. More data are needed to better assess the relationship between biologics and malignancy risk.

Reference

1. Papp KA, et al. *Dermatol Ther.* 2023;13(4):867-89.

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Abstract N°: 486

Long-term management outcome assessment of adult patients with moderate-to-severe plaque psoriasis treated with brodalumab in Greece: The ReSOLVE study.

Pantelis Panagakis*[1], Vasiliki Chasapi[2], Kanella Kalapothakou[3], Despina Exadaktylou[3], Ioanna Lefaki-Mantekou[4], Electra Nikolaidou[5], Marina Papoutsaki[5], Natalia Rompoti[5], Dimitrios Xekardakis[6], Konstantinos Sfaelos[7], Alexandros Stratigos[5]

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Introduction & Objectives:

Brodalumab is a fully human anti–interleukin-17 receptor A (IL-17RA) monoclonal antibody, approved by the European Medicines Agency (EMA) in July 2017 for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy.

ReSOLVE was a non-interventional (NIS), single cohort prospective, real-world study of patients who initiated brodalumab as part of routine clinical management of their psoriasis. The primary objective was to assess the short- and long-term outcomes of patients with moderate-to-severe psoriasis starting with brodalumab in clinical practice. This analysis focuses on long-term (52 weeks) outcomes.

Materials & Methods:

The secondary objective was to describe patient profiles managed with brodalumab in the real-world setting.

All analyses were conducted using the as-observed data.

Results:

A total of one hundred forty five patients with moderate-to-severe plaque psoriasis were included in the study: the mean age was 49.9 years, the mean duration of psoriasis was 12.6 years, and most patients were male (65.5%), and of Greek origin (93.1%). At baseline, the majority of the patients had very severe, severe or moderate psoriasis (93.1%) as assessed with the static Physician's Global Assessment Score (sPGA). The mean [standard deviation, (SD)] total Psoriasis Area and Severity Index (PASI) score was 15.9 (10.3) and the mean (SD) Dermatology Life Quality Index (DLQI) score was 13.0 (6.4). At baseline, all patients completed the Patients Global Assessment questionnaire (PaGA), with the majority of them (77.3%) reporting severe and moderate psoriasis. In total, one hundred thirty patients (89.7%) had received previous treatment for psoriasis that were discontinued prior to brodalumab administration and one hundred nine (75.2%) were biologic naïve.

For patients who continued brodalumab after 12 weeks of treatment, the proportion of patients who achieved PASI ≤ 3 was 97.6% at Week 52. The mean (SD) total PASI score decreased from 15.9 (10.3) at baseline to 0.3 (1.0) at Week 52. Regarding sPGA, 0-1 (clear-almost clear) was achieved by 96.9% of patients at Week 52. Regarding PASI 75/90/100 achievement, the respective proportions of patients were 97.6%, 93.7% and 78.7%, at

Week 52.

Regarding Patient Reported Outcomes (PROs), at Week 52, 81.9% of patients in the FAS population reported being free of symptoms as assessed by PaGA. At week 52, 85.8% of patients reported being extremely satisfied with their treatment as assessed by Treatment Satisfaction Questionnaire for Medication (TSQM). The mean (SD) DLQI score was decreased from 13.0 (6.4) at baseline to 0.6 (1.5) at Week 52.

Conclusion:

This analysis revealed that 52 weeks following treatment with brodalumab provided clinically relevant long-term improvements in disease severity and psoriasis related symptoms as reflected by PASI reduction and improvement in the self-reported DLQI, PaGA and TSQM.

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Abstract N°: 494

Pharmacogenetics in psoriasis management. A review

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Pharmacogenetics in psoriasis management. A review

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Introduction & Objectives:

Psoriasis is a chronic immunological skin disease. Genetics play important role in psoriasis pathogenesis. Nowadays, several biological and small molecule drugs are being developed for management of psoriasis. These therapies vary in efficacy from one person to another. Response rates to systemic treatments for moderate-to-severe psoriasis range from 35 to 80%.

Pharmacogenetics is the study of variations in DNA sequence related to drug response. There is rising demands to identify biomarkers that could help predict treatment outcomes and individualize treatment for patients with psoriasis.

Materials & Methods:

We searched the data bases for studies that corrlates genetic polymorphism in psoriaisi patients to treatment response

Results:

Numerous genetic variants (such as ABC transporter, DNMT3b, MTHFR, ANKLE1, IL-12B, IL-23R, MALT1, CDKAL1, IL17RA, IL1B, LY96, TLR2, etc.) were found to be associated with treatment response for methotrexate, cyclosporin, acitretin, anti-TNF, anti-IL-12/23, anti-IL-17, anti-PDE4 agent

Conclusion:

Pharmacogenetics are being used to search for biomarkers that can predict response to systemic treatments. These biomarkers could improve patient quality of life and reduce health costs and potential side effects.

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Abstract N°: 517

Assessment of 11 β-hydroxysteroid dehydrogenase type I activity in patients with psoriasis vulgaris: A novel insight into the pathogenesis of the disease.

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Introduction & Objectives:

Psoriasis is a relapsing dermatologic disease with a complex multifactorial etiology involving both genetic and environmental factors. The interaction between these factors can disrupt the epidermal homeostasis, triggering a viscous inflammatory circle that leads to epidermal hyperplasia. In psoriasis, many studies suggested a defect in Hypothalamic-Pituitary-Adrenal axis and glucocorticoids (GCs) secretion, which can aggravate inflammatory cascade, making the skin unable to restore its own homeostasis. Accumulating evidence established the presence of cutaneous steroidogenesis with 11 β-hydroxysteroid dehydrogenase enzyme (11βHSD) being the most important final step of this pathway. It acts by its 2 isozymes; 11βHSD1 (which activates cortisol), but not 11βHSD2 (which inactivates cortisol), was expressed in human skin in both epidermal keratinocytes and dermal fibroblasts with a crucial role in maintaining healthy skin.

Materials & Methods:

This case-control study was conducted on 31 adult patients with a dermatologist-confirmed diagnosis of psoriasis vulgaris and 30 age matched healthy controls, with negative family history of psoriasis. Psoriasis vulgaris patients were divided into 3 equal groups based on the degree of severity of psoriasis as measured by Psoriasis Area and Severity index (PASI) score. The aim of the study was to evaluate 11βHSD type I enzyme level in psoriasis patients, in both lesional and non-lesional skin, compare it to controls, and correlate its activity with PASI and the Perceived Stress Scale (PSS). Further punch biopsies were taken from the same lesion in psoriasis patients to correlate between the enzyme level and different histopathological features in psoriasis.

Results:

A significant decrease of 11βHSD1 level in psoriasis patients, either in lesional or non-lesional skin, compared to healthy controls was observed. In addition, decreased 11βHSD1 level was observed in lesional compared to non-lesional skin in psoriasis patients. There was no significant correlation between the enzyme levels and PASI score or PSS score in patients with psoriasis. However, PSS score was negatively correlated with 11βHSD1 level in healthy controls. Further histopathological assessment revealed that lower enzyme levels were associated with higher degrees of epidermal acanthosis and inflammation.

Both Figures (1) & (2) show lesional skin of a psoriasis patient, stained with H&E. The images magnifications are x10 (left side) and x40 (right side). The Average Epidermal thickness was measured from the bottom of the rete ridge to the bottom of the stratum corneum (black arrow).

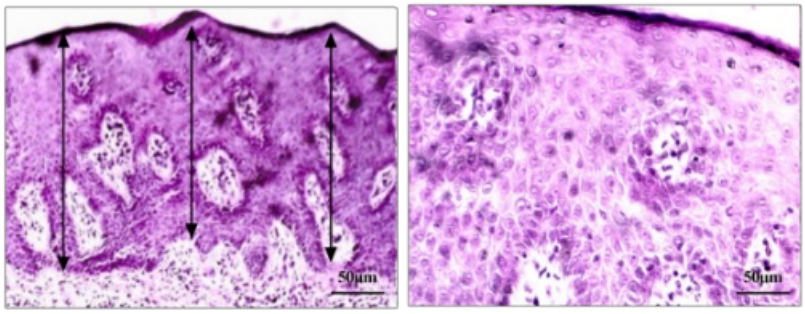

Figure (1): Images show significant increase in epidermal thickness (acanthosis) and inflammatory cell density. The Average Epidermal thickness equals **560 µm.**

The lesional enzyme level from the same lesion was very low**(184.6 ng/g tissue).**

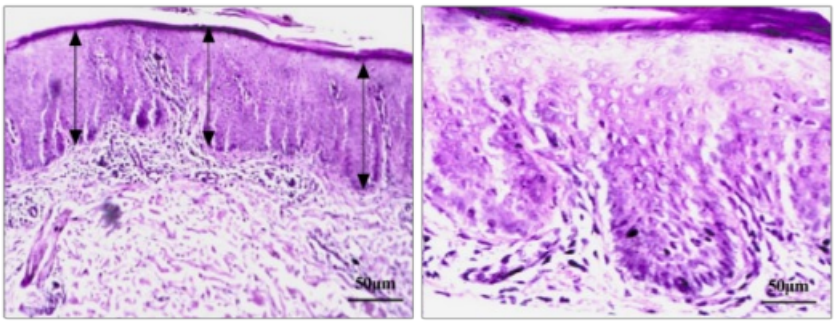

Figure (2): Images show less increase in epidermal thickness (acanthosis) and inflammatory cell density. The Average Epidermal thickness equals **284 µm.**

The lesional enzyme level from the same lesion was relatively higher**(386.6 ng/g tissue).**

Conclusion:

Our study showed that 11βHSD1 enzyme level, being a vital part of skin homeostatic mechanism, is dysfunctional in case of psoriasis. This can explain the role of 11βHSD1 in controlling psoriatic inflammation, including the degree of epidermal proliferation, which might reveal a new part of the complex symphony of psoriasis pathogenesis.

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Abstract N°: 557

Phase 2b, long-term extension, dose-ranging study of oral JNJ-77242113 for the treatment of moderate-to-severe plaque psoriasis: FRONTIER-2

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Introduction & Objectives:

JNJ-77242113, a targeted oral peptide, inhibits interleukin (IL)-23 signaling by binding to IL-23 receptor. At all doses, JNJ-77242113 showed superior efficacy at Week 16 versus placebo (PBO) in patients with moderate-to-severe psoriasis in FRONTIER-1.** FRONTIER-2 was a multicenter, long-term extension, double-blind, dose-ranging, phase 2b study evaluating efficacy and safety of JNJ-77242113 in adults with moderate-to-severe plaque psoriasis who were candidates for systemic treatment or phototherapy.

Materials & Methods:

FRONTIER-1 randomized patients 1:1:1:1:1:1 to JNJ-77242113 25 mg daily (QD), 25 mg twice daily (BID), 50 mg QD, 100 mg QD, 100 mg BID, or PBO through Week 16. In FRONTIER-2, patients completing FRONTIER-1 (at Week 16) continued their assigned dose through Week 52; those randomized to PBO crossed over to 100 mg QD (PBO→100 mg QD). The primary endpoint was the proportion of patients achieving ≥75% improvement in Psoriasis Area and Severity Index (PASI 75) at Week 52. Response rates were estimated using non-responder imputation and FRONTIER-1 baseline data.

Results:

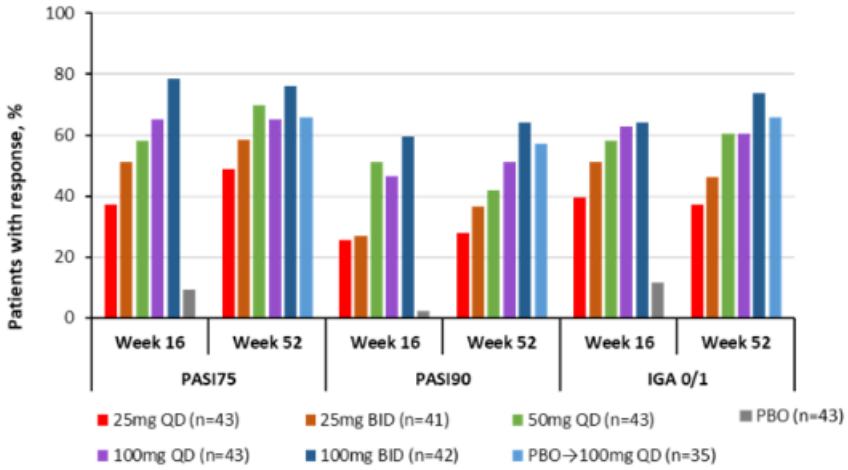
Response rates among JNJ-77242113–treated patients from FRONTIER-1 were maintained, across dose groups, through Week 52 (**Figure 1**). Patients who crossed over to JNJ-77242113 from PBO at Week 16 (PBO→100 mg QD) had substantially higher response rates at Week 52 (**Figure 1**). At Week 52, proportions of patients achieving PASI 75 with JNJ-77242113 were: 25 mg QD 48.8%; 25 mg BID 58.5%; 50 mg QD 69.8%; 100 mg QD 65.1%; 100 mg BID 76.2%, and PBO→100 mg QD 65.7%; respective rates for PASI 90/PASI 100 were 27.9%/14.0%, 36.6%/17.1%, 41.9%/20.9%, 51.2%/25.6%, 64.3%/40.5%, and 57.1%/34.3%. Proportions of patients achieving an Investigator's Global Assessment (IGA) score of 0/1 or 0 with JNJ-77242113 at Week 52 were: 25 mg QD 37.2%/14.0%, 25 mg BID 46.3%/19.5%, 50 mg QD 60.5%/23.3%, 100 mg QD 60.5%/30.2%, 100 mg BID 73.8%/42.9%, and PBO→100 mg QD 65.7%/31.4%. Approximately 90% of patients receiving JNJ-77242113 100 mg BID who had achieved a PASI 75, PASI 90, or IGA 0/1 response at Week 16 maintained the response at Week 52 (**Figure 2**). Across dose groups, 58.6% of patients experienced adverse events (AEs), with no evidence of a dose-dependent increase in AEs, including gastrointestinal disorders. The proportion of patients with serious AEs

through Week 52 was 4% and all serious AEs were considered unrelated to study treatment.

Conclusion:

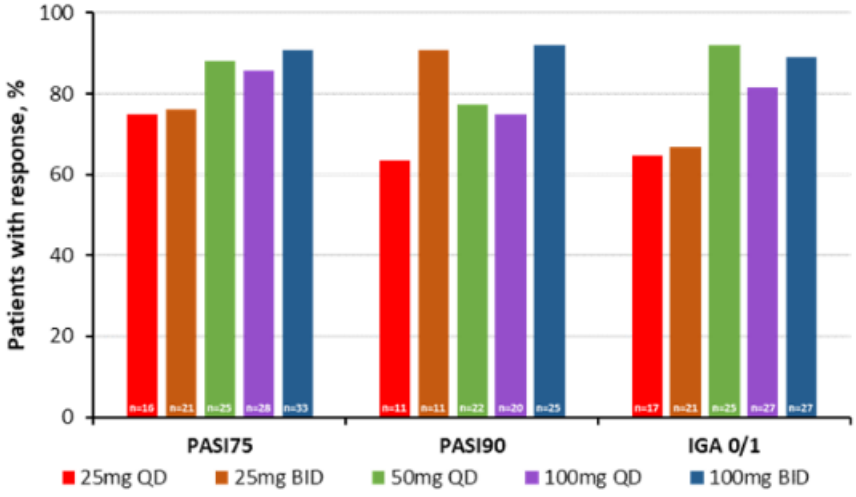
In patients with moderate-to-severe psoriasis receiving JNJ-77242113, the first targeted oral peptide to selectively block IL-23 pathway signaling, rates of near-complete/complete skin clearance from FRONTIER-1 were maintained through Week 52; the highest response rates were seen in patients randomized to JNJ-77242113 100 mg BID. Among patients who had achieved a PASI or IGA response at Week 16, responses were maintained in substantial proportions of patients at Week 52. Consistent with prior studies, no safety signals were identified.

Figure 1. Response rates achieved at Week 16 and Week 52 across treatment groups



BID, twice daily; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; PBO, placebo; QD, daily.
Gray bars show data on patients who were randomized to PBO and, at Week 16, had not yet received JNJ-77242113 100 mg QD.

Figure 2. Maintenance of response at Week 52 among patients with a response at Week 16



BID, twice daily; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; QD, daily.

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Abstract N°: 565

Diminished IL-38 Coincides with Enhanced Epidermal Neutrophil Infiltration in Generalized Pustular Psoriasis Lesions

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease with a significant disease burden. The most common type, psoriasis vulgaris (PV), is characterized by well-defined erythematous plaques with silvery scales, while the potentially fatal generalized pustular psoriasis (GPP) displays highly inflammatory erythemas and pustules. Both types of psoriasis exhibit neutrophil accumulation in the epidermis, but GPP has markedly greater neutrophil infiltration, which can drive and sustain severe inflammation.

Interleukin (IL)-38, a novel IL-1 family cytokine, may act as a competitive inhibitor to IL-36 agonists. With 43% homology to IL-36Ra, IL-38 may possess a similar capacity to inhibit neutrophil accumulation in psoriasis. Previous studies have shown reduced epidermal IL-38 expression in PV lesions, which subsequently increased after anti-IL-17 therapy. However, whether the higher neutrophil accumulation in GPP lesions is related to lower IL-38 expression remains unclear. This study aimed to compare epidermal IL-38 expression in GPP with PV lesions and explore its correlation with neutrophil accumulation.

Materials & Methods:

Formalin-fixed paraffin-embedded skin samples from 19 GPP and 19 PV patients diagnosed between 2015 and 2021 were included. Healthy skin samples were taken from breast tumor excess skin.

Immunohistochemistry was used to evaluate IL-38 expression in the skin samples. Slides were examined at 100x magnification, and 3 representative epidermal fields were captured. Interleukin-38 expression was semi-quantitatively scored from 0 (negative) to 3+ (strong) by two experienced observers, with inter-observer agreement calculated using Kappa.

Epidermal neutrophil numbers were quantified in hematoxylin-eosin (H&E) stained sections at 400x magnification. Representative fields, including 1 abscess (Munro's microabscess or pustule of Kogoj) and 3 non-abscess areas, were captured. Neutrophil counts relative to pixel area were calculated using ImageJ software. The correlation between epidermal IL-38 expression and neutrophil accumulation was evaluated using Spearman's test.

Results:

Based on immunohistochemical evaluation, the majority of epidermis in all samples expressed IL-38 at a 1+ (weak; 43.73%) or 2+ (moderate; 39.47%) intensity. Semiquantitative analysis revealed a lower mean IL-38 expression score in GPP than in PV lesions (1.211 ± 0.63 vs. 1.789 ± 0.71, $p<0.05$). The inter-observer agreement on IL-38 scoring was excellent, with a Kappa value of 0.806.

The average number of neutrophils in the epidermis was 4.5´10-5 ± 2.39´10-5 per pixel area, with abscess areas containing up to 7 times more neutrophils than non-abscess areas. Notably, the epidermal neutrophil counts in GPP were more than twice those observed in PV lesions (6.16´10-5 ± 0.46´10-5 vs. 2.85´10-5 ± 0.32´10-5, $p<0.0001$]. Further analysis revealed a weak inverse correlation between epidermal IL-38 expression and

neutrophil accumulation in psoriatic lesions (r=−0.2780, $p<0.05$), suggesting that diminished IL-38 levels coincided with enhanced neutrophil infiltration.

Conclusion:

Generalized pustular psoriasis lesions exhibited reduced IL-38 expression and increased epidermal neutrophil accumulation compared to psoriasis vulgaris lesions, suggesting that diminished IL-38 may contribute to the enhanced neutrophil infiltration in the epidermis of generalized pustular psoriasis.

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Abstract N°: 585

Long-term efficacy and safety of bimekizumab in real-world setting: a 52-week prospective study

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Introduction & Objectives:

Bimekizumab, is the most recent monoclonal antibody licensed for the management of moderate-to-severe plaque psoriasis. It acts through the dual inhibition of interleukin (IL)-17A and IL17F, setting it apart from other anti-IL17 biologics. To date, real-life data on the use of bimekizumab are limited to few case reports and short-term experiences. The aim of our study was to evaluate the effectiveness and safety of bimekizumab in long-term.

Materials & Methods:

A monocentric prospective study enrolling patients with moderate-to-severe plaque psoriasis undergoing treatment with bimekizumab was performed. At baseline, demographic and clinical data [psoriasis duration, Psoriasis Activity Severity Index (PASI), Dermatology Life Quality Index (DLQI), comorbidities, previous psoriasis treatments, presence of psoriatic arthritis] were collected. Psoriasis severity and adverse events (AEs) were evaluated at each follow-up visit [week (W)4-16-36-52]. The present study was conducted respecting the Declaration of Helsinki, and all patients signed an informed consent. GraphPad Prism software (v.8.0: GraphPad-Software-Inc. La Jolla, CA, USA) was used for all statistical analyses, considering significant a p-value<0.05.

Results:

Among the patients attending our Psoriasis Center and treated with bimekizumab, 46 reached 1-year of follow-up. A statistically significant improvement of PASI was reported since W4, continuing to improve up to W52. Similarly, DLQI significantly improved since W4 up to W52. An excellent profile in terms of safety was reported, with few AEs collected.

Conclusion:

Bimekizumab showed to be an effective and safe treatment in real life, also in long-term.

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Abstract N°: 603

Efficacy and safety of sonelokimab, a novel IL-17A- and IL-17F-inhibiting Nanobody, in patients with active psoriatic arthritis (PsA): Week 12 skin, nail, and multidomain outcomes from the global, randomized, double-blind, placebo-controlled Phase 2 ARGO trial

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Introduction & Objectives: Sonelokimab is a novel humanized Nanobody designed to inhibit central drivers of psoriatic disease, IL-17A and IL-17F, and penetrate difficult-to-reach sites of inflammation. Here, we describe the Week (W) 12 skin- and nail-based outcomes in the ARGO trial of sonelokimab in patients with active PsA.

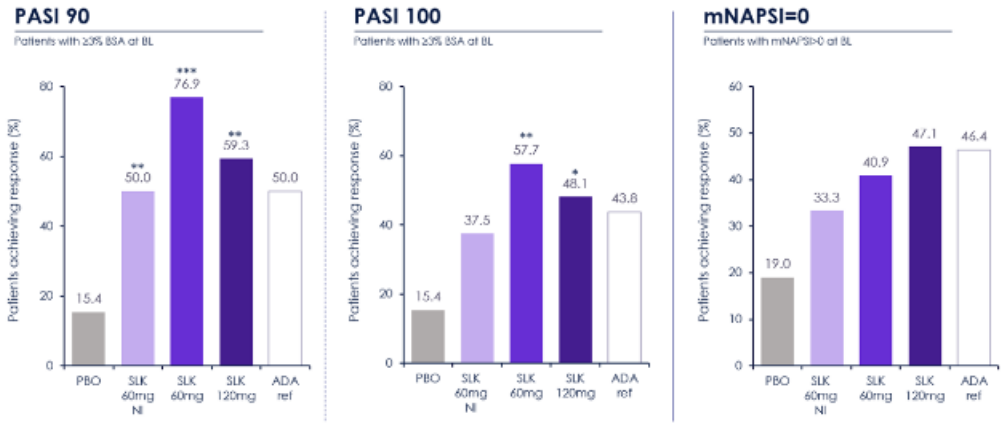
Materials & Methods: ARGO is a global, 24-week, randomized, prospective, parallel-group, double-blind, placebocontrolled Phase 2 trial (NCT05640245). Eligible patients were ≥18 years old with active PsA (68-tender joint count ≥3, 66-swollen joint count ≥3), active psoriasis or a dermatologistconfirmed psoriasis diagnosis. Patients were randomized (1:1:1:1:1; stratified by sex and prior biologic use) to sonelokimab 60mg Q4W no induction (NI), sonelokimab 60mg Q4W (with induction), sonelokimab 120mg Q4W (with induction), placebo, or adalimumab 40mg Q2W (reference arm, not powered for statistical comparison); induction dosing for sonelokimab was Q2W until W8 (except in the NI arm). The primary endpoint was American College of Rheumatology (ACR) 50 response at W12, with Psoriasis Area and Severity Index (PASI) 90 at W12 as the key skin endpoint. Other endpoints included PASI 100, multidomain composites, and modified Nail Psoriasis Severity Index (mNAPSI) outcomes. PASI/mNAPSI outcomes were examined in patients with ≥3% BSA/mNAPSI>0 at baseline (69%/55%). Primary analysis was non-responder imputation, intention-to-treat. *P*-values other than for ACR50 and PASI 90 at W12 are nominal

Results: 207 patients were randomized (sonelokimab 60mg NI, 41; sonelokimab 60mg, 41; sonelokimab 120mg, 43; placebo, 40; adalimumab, 42); <4% discontinued by W12. Sonelokimab 60mg and 120mg (with induction) met the primary endpoint of ACR50 vs. placebo at W12 (60mg, 46.3%, *P*=0.012; 120mg, 46.5%, *P*=0.009); sonelokimab

60mg NI was not significant, therefore only results with induction are reported hereafter. A significantly greater proportion of patients treated with sonelokimab achieved the key endpoint of PASI 90 at W12 vs. placebo (60mg, 76.9%, *P*<0.001; 120mg, 59.3%, *P*=0.003; placebo, 15.4%), as well as the higher threshold endpoint of PASI 100 (**Figure 1**). Composite scores encompassing skin and other PsA domains were also improved: >40% of patients in the sonelokimab 60mg arm achieved MDA (43.9%, *P*=0.02; placebo, 20.0%) and >40% achieved a composite of both ACR50 and PASI 90 (60mg, 42.3%, *P*=0.007; 120mg, 44.4%, *P*=0.009; placebo, 7.7%). Stringent composite endpoints such as ACR50 and PASI 100, or even ACR70 and PASI 100, also showed high levels of response (**Figure 2**). Significant improvement in mNAPSI was observed with sonelokimab vs. placebo at W12 in patients with mNAPSI>0 at baseline (mean baseline mNAPSI: 13.4), with >40% of patients receiving sonelokimab achieving complete resolution of fingernail disease (mNAPSI=0: 60mg, 40.9%; 120mg, 47.1%; placebo, 19.0%). Reference arm responses were as expected from previous studies, supporting the trial validity. There were no unexpected safety findings, with two (1.6%) mild or moderate cases of oral candidiasis and no new cases of IBD or MACE on sonelokimab treatment.

Conclusion: In the ARGO Phase 2 trial in patients with active PsA, sonelokimab 60mg and 120mg (with induction) achieved high levels of response in skin, nail, and multidomain endpoints by W12, demonstrating the potential of both doses to improve outcomes across PsA domains. These findings warrant further investigation in Phase 3 trials.

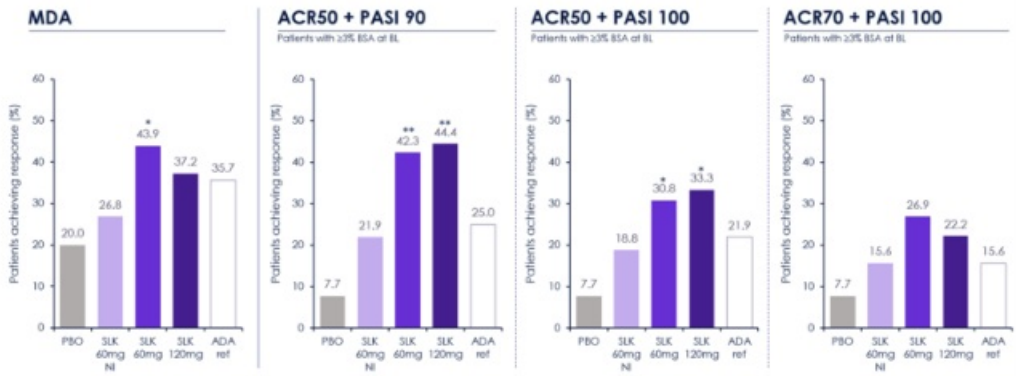
Figure 1. Skin and nail outcomes at W12 in the ARGO trial (ITT-NRI)



***P<0.001, **P<0.01, *P<0.05. *P*-values for PASI 100 are nominal. Missing data were imputed as a non-response. PASI and mNAPSI responses are based on the number of patients at each visit in the full analysis set in each treatment group with BL psoriasis involving ≥3% BSA and mNAPSI>0, respectively.

ADA, adalimumab; BL, baseline; BSA, body surface area; ITT, intention-to-treat; mNAPSI, modified Nail Psoriasis Severity Index; NI, no induction; NRI, non-responder imputation; PASI, Psoriasis Area and Severity Index; PBO, placebo; ref, reference arm; SLK, sonelokimab; W, week.

Figure 2. Multidomain outcomes at W12 in the ARGO trial (ITT-NRI)



**P<0.01, *P<0.05. P-values are nominal. Missing data were imputed as a non-response. ACR+PASI responses are based on the number of patients at each visit in the full analysis set in each treatment group with BL psoriasis involving ≥3% BSA.

ACR, American College of Rheumatology; ADA, adalimumab; BL, baseline; BSA, body surface area; ITT, intention-to-treat; MDA, minimal disease activity; NI, no induction; NRI, non-responder imputation; PASI, Psoriasis Area and Severity Index; PBO, placebo; ref, reference arm; SLK, sonelokimab; W, week.

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Abstract N°: 608

Treatment strategies for patients with psoriatic disease and rheumatoid arthritis coexisting

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Introduction & Objectives:

The number of psoriasis patients in Japan is estimated to be 400,000-500,000, and psoriatic arthritis (PsA) is 10-14% of psoriasis patients. On the other hand, the number of patients with rheumatoid arthritis (RA) is estimated to be 830,000, according to the latest epidemiological survey, and it is not a rare disease. It is estimated that 1-4% of patients with psoriasis also have RA, and up to 28.9% of patients with PsA have RA. Also, the relative risk of RA in patients with psoriasis is 3.02 times that of healthy individuals.

Materials & Methods:

Here, we describe 7 cases of concurrent diagnoses of RA and psoriatic disease, including clinical data, treatment efficacy, and X-ray findings.

Results:

When RA and PsA are suspected, MTX is the anchor drug, and anti-TNFα agents, indicated for both, are the first choice of biologics. Our cases showed that anti-IL-17 agents were as effective as anti-TNFα, but they are only indicated for psoriasis and not for RA. However, IL-17 is involved in the pathogenesis of RA by inducing TNF and causing synovial inflammation, resulting in bone erosion. Also, IL-17 is not present in healthy joints but is elevated in RA patients' serum and synovial fluid.

Conclusion:

1. Anti-TNF agents with MTX as an anchor may be the first choice for treatment.
2. IL-17 is also involved in the pathogenesis of RA, and anti-IL-17 agents are also expected to be effective.
3. Depending on the subject, TNF-α, IL-17, and IL-6 inhibitors may effectively treat joint symptoms. This difference may depend on whether PsA or RA is predominant at the time of treatment.

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Abstract N°: 627

Successful Treatment of Refractory Palmoplantar Pustulosis Using JAK1 Inhibitors and Tyk2 Inhibitors: A Case Series of 10 Patients

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Introduction & Objectives:

Palmoplantar pustulosis (PPP) is a rare, chronic, inflammatory skin disease characterized by recurrent and/or persistent sterile pustules on the palms and/or soles. PPP affects highly functional areas of the body, so affected patients often face significant impairments to their quality of life, and treatment is often challenging due to the limited understanding of the condition's pathogenesis. Elevated serum levels of IFN-α, IFN-γ, and IL-19 have been observed in biopsies of individuals with PPP. Since IFN-α is mediated by Tyk2, IFN-γ is mediated by JAK1, and IL-19 is mediated by both, we sought to assess the therapeutic response of patients with PPP to JAK1 inhibition via abrocitinib or upadacitinib or to Tyk2 inhibition via deucravacitinib.

Materials & Methods:

We conducted a retrospective analysis of 10 PPP patients treated with JAK1 inhibitors (abrocitinib or upadacitinib) or a Tyk2 inhibitor (deucravacitinib) following failure to respond to conventional treatments. Data collected included treatment response, previous treatments, lesion location, smoking status, and comorbidities.

Results:

Ten patients with a diagnosis of PPP were included (80% female, mean age 47.7 ± 10.14, range 32–64), of which 40% had lesions on only the soles of the feet, 20% had lesions on only the palms of the hands, and 40% had lesions on both. Of the 10 patients, 40% were treated with abrocitinib (JAK1 inhibitor), 40% with deucravacitinib (Tyk2 inhibitor), and 20% with upadacitinib (JAK1 inhibitor). Most patients (70%) were smokers, and comorbidities reported included hypothyroidism (40%), psoriatic arthritis (20%), celiac disease (20%), inflammatory bowel disease (10%), rheumatoid arthritis (10%), arthritis not yet diagnosed (10%), systemic lupus erythematosus (10%), and hyperthyroidism (10%). Prior to initiation of treatment with a JAK1 or Tyk2 inhibitor, patients had failed to respond to an average of 2.1 other treatments for PPP, including acitretin (60%), methotrexate (30%), cyclosporine (20%), secukinumab (20%), guselkumab (20%), risankizumab (20%), ixekizumab (20%), apremilast (10%), tildrakizumab (10%), and narrow band UV combined with oral alitretinoin (10%). All patients reported marked improvement in their condition with semi- or complete clearance of lesions by week 16 of treatment.

Conclusion:

To date, there have been only a few case series and reports published on the treatment of PPP with JAK1 inhibitors, and none on the treatment of PPP with Tyk2 inhibitors. Our case series provides compelling evidence that JAK1 and Tyk2 inhibitors are promising treatment options for PPP, including in cases refractory to conventional therapies. Limitations of our study include its retrospective nature and the inclusion of only 10 patients. Further studies are warranted to further investigate the efficacies of JAK1 and Tyk2 inhibitors in PPP.

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Abstract N°: 631

Comparing the Efficacy of Risankizumab Versus Apremilast in Achieving National Psoriasis Foundation's Treatment Target Goals: Results From the Phase 4 IMMpulse Study

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Introduction & Objectives: Despite effective therapies for psoriasis (PsO), nontreatment and undertreatment remain significant issues.** The National Psoriasis Foundation (NPF) has set treatment goals to improve outcomes.** A target response is defined as a reduction of patient's body surface area (BSA) ≤1 and an acceptable response as BSA ≤3 or ≥75% improvement in BSA three months after starting a new treatment. The phase 4 IMMpulse study has demonstrated superior efficacy and safety of risankizumab (RZB) compared to apremilast (APR) in systemic-eligible adult (≥18 years) patients with moderate plaque PsO. This post-hoc analysis evaluated the proportion of patients achieving the NPF target and acceptable responses in the overall IMMpulse population, and among patients with nail and scalp PsO. Herein, we present additional efficacy results for those patients in IMMpulse with and among patients with scalp and nail PsO.

Materials & Methods: Data for this analysis included 3 timepoints and treatment arms. Early response was assessed at week 16 (Period A), where patients received either RZB or APR for 16 weeks. At week 16, stratified by their PASI 75 response, all APR-treated patients were re-randomized and switched to RZB or continued APR. Of those who were PASI 75 non-responders at week 16, we evaluated their efficacy at week 52 (Period B). Data from patients who received continuous RZB or APR throughout the entire study period (0-52 weeks) was also evaluated. Non-responder imputation incorporating multiple imputations to handle missing data due to COVID-19 was used.

Results: Baseline demographics and disease characteristics were similar between the treatment arms. In the overall population, the mean age was 46 years, 65.6% were male, and the mean baseline BSA was 13.1%. The mean baseline BSA among patients with scalp and nail PsO was 13.2% and 13.0 %, respectively.

In Period A, a greater proportion of patients treated with RZB versus (vs.) APR achieved the NPF target (overall, 50.0% vs. 6.8%; scalp, 49.5% vs. 6.2%; nail, 46.8% vs. 6.3%) and acceptable response (overall, 72.9% vs. 14.5%; scalp, 74.2% vs. 13.8%; nail, 62.9% vs. 12.6%; **Figure**) at week 16.

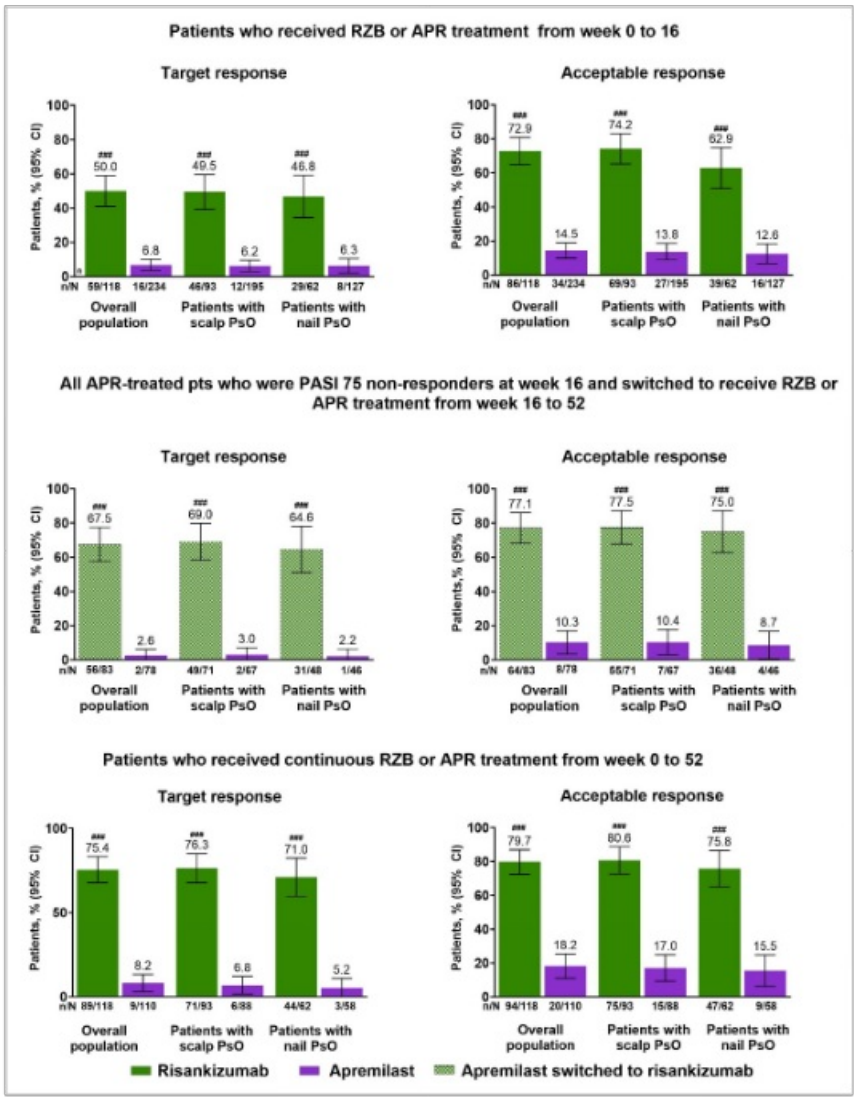
In Period B, among patients who did not achieve PASI 75 with APR at week 16 and switched to RZB, a greater proportion of patients treated with RZB vs. APR achieved the NPF target (overall, 67.5% vs. 2.6%; scalp, 69.0% vs. 3.0%; nail, 64.6% vs. 2.2%) and acceptable response (overall, 77.1% vs. 10.3; scalp, 77.5% vs. 10.4%; nail, 75.0% vs. 8.7%) at week 52.

Similarly, among patients who received continuous RZB vs. APR from week 0-52, a greater proportion of patients achieved the NPF target (overall, 75.4% vs. 8.2%; scalp, 76.3% vs. 6.8%; nail, 71.0% vs. 5.2%) and acceptable response (overall, 79.7% vs. 18.2%; scalp, 80.6% vs. 17.0%; nail, 75.8% vs. 15.5%) at week 52.

All comparisons were nominally significant with a p-value <0.001.

Conclusion: Treatment with RZB was associated with a greater portion of patients with moderate plaque PsO achieving NPF target and acceptable responses compared with APR, including those with scalp and nail involvement.

Figure. The proportion of patients achieving NPF treatment target goals in the overall population, including patients with scalp and nail psoriasis in the IMMpulse study (NCT04908475)



APR, Apremilast; BSA, body surface area; NPF, National Psoriasis Foundation; RZB, Risankizumab

Non-responder imputation incorporating multiple imputations to handle missing data due to COVID-19 was used in the analysis; ###, nominal P-value <0.001. Scalp psoriasis was defined as Psoriasis Scalp Severity Index > 0 at baseline; nail psoriasis was defined as Nail Psoriasis Severity Index > 0 at baseline.

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Abstract N°: 632

Integrated Analysis of Clinical Trial Data to Evaluate Long-Term Safety of Risankizumab in Patients with Psoriatic Disease

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Introduction & Objectives: Risankizumab (RZB), an IL-23 inhibitor, has demonstrated a favorable benefit-risk profile with long-term safety in patients with psoriasis (PsO) and psoriatic arthritis (PsA) with no new safety signals. The objective of this analysis is to provide an updated report on the long-term safety of RZB in patients with PsO and PsA, with additional years of follow-up.

Materials & Methods: Data for this integrated safety analysis were pooled from 21 phase 1-4 clinical trials in PsO and 4 phase 2-3 trials in PsA. Treatment-emergent adverse events (TEAEs) and AEs of safety interest were reported in patients receiving ≥1 dose of RZB. Exposure adjusted event rates were summarized as events per 100 patient years (E/100 PY).

Results: The analysis included 3849 patients with PsO (13,805.2 PY exposure) and 1542 patients with PsA (4,805.7 PY exposure) with a median (range) treatment duration of 3.3 years (84 days – 9.1 years) and 3.8 years (84 days – 5.0 years), respectively.

Rates of TEAEs (144.6 E/100PY), serious AEs (7.3 E/100PY), and AEs leading to discontinuation (1.8 E/100PY) in patients with PsO were similar to rates in patients with PsA (138.2 E/100PY, 8.6 E/100PY, and 1.9 E/100PY, respectively; **Table**).

Excluding COVID-19 related infections, similar rates of infections (42.2 and 32.1 E/100 PY) and serious infections (1.1 and 1.4 E/100PY) were reported among PsO and PsA groups. The most frequently reported infections (excluding COVID-19 infections) were nasopharyngitis (12.2 E/100PY), upper respiratory tract infection (URTI, 6.3 E/100PY) and influenza (1.7 E/100 PY) in PsO and nasopharyngitis (5.5 E/100PY), URTI (4.4 E/100PY), and urinary tract infection (1.7 E/100PY) in PsA. The most frequently reported serious infections (excluding COVID-19 infections) were sepsis (0.1 E/100PY), pneumonia (<0.1 E/100PY), and cellulitis (<0.1 E/100PY) in PsO and pneumonia (0.2 E/100PY), cellulitis (0.1 E/100PY), and urosepsis (<0.1 E/100PY) in PsA. The rates of opportunistic infections excluding tuberculosis (both <0.1 E/100PY) and herpes zoster (0.5 and 0.3 E/100 PY, respectively) were comparable in both PsO and PsA groups, respectively.

Non-melanoma skin cancer (NMSC) rates were 0.6 and 0.4 E/100PY, and malignant tumours excluding NMSC rates were 0.6 and 0.5 E/100PY in PsO and PsA groups, respectively. Adjudicated major cardiovascular event rates were 0.6 and 0.4 E/100PY in PsO and PsA, respectively.

Conclusion: Rates of AEs, AEs of safety interest, and AEs leading to discontinuation remained low and were mostly either consistent with or decreased over time compared to prior long-term safety reporting of RZB in

patients with psoriatic disease. Overall, these results provide further evidence of the safety profile of RZB as a long-term treatment option for patients with psoriatic disease.

Table. Treatment-emergent adverse events in patients with psoriasis and psoriatic arthritis

	Psoriasis (N=3849, PY=13805.2) E (E/100PY) [95% CI]	Psoriatic Arthritis (N=1542, PYS=4805.7) E (E/100PY) [95% CI]
AEs	19963 (144.6) [142.6, 146.6]	6640 (138.2) [134.9, 141.5]
Serious AEs	1012 (7.3) [6.9, 7.8]	412 (8.6) [7.8, 9.4]
AEs leading to discontinuation	254 (1.8) [1.6, 2.1]	89 (1.9) [1.5, 2.3]
AEs leading to death	38 (0.3) [0.2, 0.4]	13 (0.3) [0.1, 0.5]
Infection[a]	5831 (42.2) [41.2, 43.3]	1543 (32.1) [30.5, 33.7]
Nasopharyngitis	1682 (12.2)	266 (5.5)
URTI	874 (6.3)	213 (4.4)
Serious infection[a]	145 (1.1) [0.9, 1.2]	66 (1.4) [1.1, 1.7]
Sepsis	14 (0.1)	3 (<0.1)
Pneumonia	13 (<0.1)	8 (0.2)
Cellulitis	11 (<0.1)	5 (0.1)
Opportunistic infections[b]	13 (<0.1) [0.0, 0.2]	3 (<0.1) [0.0, 0.2]
Tuberculosis (active)	1 (<0.1) [0.0, 0.0]	0
Candida[d]	71 (0.5) [0.4, 0.6]	24 (0.5) [0.3, 0.7]
Herpes zoster	71 (0.5) [0.4, 0.6]	15 (0.3) [0.2, 0.5]
NMSC	77 (0.6) [0.4, 0.7]	21 (0.4) [0.3, 0.7]
Basal cell carcinoma	50 (0.4)	15 (0.3)
Squamous cell carcinoma	18 (0.1)	3 (<0.1)
Malignant tumours excluding NMSC	87 (0.6) [0.5, 0.8]	26 (0.5) [0.3, 0.8]
Breast cancer[d]	13 (<0.1)	6 (0.1)
Prostate cancer[d]	12 (<0.1)	5 (0.1)
Pancreatic carcinoma[d]	5 (<0.1)	0
Adjudicated MACE	77 (0.6) [0.4, 0.7]	20 (0.4) [0.3, 0.6]
Serious hypersensitivity[e]	10 (<0.1) [0.0, 0.1]	4 (<0.1) [0.0, 0.2]
Injection site reactions	372 (2.7) [2.4, 3.0]	37 (0.8) [0.5, 1.1]
Depression[c]	76 (0.6)	29 (0.6)
Suicidal ideation and behavior	10 (<0.1)	5 (0.1)
All deaths[f]	36 (0.3) [0.2, 0.4]	14 (0.3) [0.2, 0.5]

Data cutoff date for this integrated safety analysis was March 25, 2024.]
AE, adverse event; E, event; MACE, major adverse cardiovascular event; NMSC, non-melanoma skin cancer; PY, patient-years; TEAEs, treatment-emergent adverse events; URTI, upper respiratory tract infection.
[a]Excluding COVID-related infections.
The most frequently reported (Top 5) infections among PsO E (E/100PY): nasopharyngitis 1682 (12.2) upper respiratory tract infection 874 (6.3) influenza 228 (1.7), urinary tract infection 225 (1.6), bronchitis 180 (1.3), and gastroenteritis 180 (1.3), and PsA: nasopharyngitis 266 (5.5), upper respiratory tract infection 213 (4.4), urinary tract infection 83 (1.7), bronchitis 83 (1.7), and latent tuberculosis 79 (1.6).
The most frequently reported (Top 5) serious infections among PsO: sepsis 14 (0.1), pneumonia 13 (<0.1), cellulitis 11 (<0.1), appendicitis 9 (<0.1), and diverticulitis 8 (<0.1), and PsA: pneumonia 8 (0.2), cellulitis 5 (0.1), urosepsis 4 (<0.1), appendicitis 3 (<0.1), gastroenteritis 3 (<0.1), and sepsis 3 (<0.1).
[b]Excluding tuberculosis and herpes zoster.
[c]By preferred term.
[d]By group term.
[e]Serious hypersensitivity: PsO, eczema (n=2), Stevens-Johnson syndrome (n=2), urticaria (n=2), angioedema, drug hypersensitivity, erythema multiforme, and hypersensitivity (n=1, each); PsA: anaphylactic reaction, hypersensitivity, immune thrombocytopenia, and swollen tongue (n=1, each).
[f]Includes non-treatment-emergent deaths

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Abstract N°: 639

Excimer light effect on neurogenic inflammation in active versus stable psoriasis lesions

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Introduction & Objectives: Neurogenic inflammation, mediated by T helper 17 cell (Th17) and neurons that release neuropeptides such as substance P (SP), is thought to play a role in the pathogenesis of psoriasis. Excimer light is used in the treatment of psoriasis via induction of T cell apoptosis. The objective of this study is to study the effect of excimer light on active versus stable psoriasis and investigate the levels of substance P and its receptor in both groups.

Materials & Methods: The study included 27 stable and 27 active psoriatic patients as well as 10 matched healthy controls. Clinical examination (in the form of local psoriasis severity index (PSI) and visual analogue scale (VAS)) was done to determine disease severity, level of itching, and quality of life. Tissue levels of SP and neurokinin-1 receptor (NK-1R) were measured by ELISA before and after 9 excimer light sessions in 43 patients.

Results: A statistically significant lower levels of PSI and VAS were reached after therapy with no significant difference between the stable and active groups. The mean tissue levels of SP before therapy were significantly higher than the control group. Lower levels of SP and NK-1 receptor were found after treatment overall and in each group.

Conclusion: Excimer therapy can be effective for both stable and active plaque psoriasis and this effect could be partly through its role on ameliorating the neurogenic inflammation.

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Abstract N°: 646

Mapping of comorbidities in Brazilian patients with psoriasis - Findings from The Global Healthcare Study on Psoriasis

Mia-Louise Nielsen[1], Lara Maul[2], Andre Vicente Carvalho[3], Gleison Vieira Duarte[4], Jacob Thyssen[1], Clara Richter[5], Bruno de Oliveira de Rocha[6], Jaquelini Silva[7], Wagner Galvao Cesar[8], Adriane Reichert Faria[9], Bortoletto Cecilia[10], Ricardo Romiti[11], Fernando Valenzuela[12], Javier Fernandez[12], Thomas Kuendig[5], Johannes Didaskalu[13], Jashin J Wu[14], Simon Francis Thomsen[1], Alexander Egeberg[1], Julia-Tatjana Maul[5]

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Introduction & Objectives:

Several** comorbidities are associated with psoriasis and add to both the physical and psychological burdens of disease. The objective is to investigate comorbidities among Brazilian patients with psoriasis, especially in relation to the severity of psoriasis.

Materials & Methods:

Cross-sectional data from the Global Health Care Study on Psoriasis (GHSP) collected in 27 dermatology centers in Brazil was used.

Patients were stratified based on psoriasis severity and characteristics were reported and compared among groups with t-tests and chi-squared tests.

The relationship between severity of psoriasis, comorbidities, and patient characteristics such as sex and age, was further investigated using univariate and multivariate logistic regressions.

Results:

A total 826 patients (mild psoriasis=371, moderate-to-severe psoriasis=357) were included. Most patients (66.1%) had at least one comorbidity, with obesity (31.2%), dyslipidemia (22.8%), metabolic syndrome (22.2%), and psoriatic arthritis (PsA) (19.3%) being among the most frequent (see Figures 1-3).

More patients with mild psoriasis had PsA (23.7% vs. 16.3%, p=0.012), while obesity and hypertension were more frequent among patients with moderate-to-severe psoriasis (p=0.001 and p=0.032, respectively). The proportion of patients having at least one comorbidity was larger among patients with moderate-to-severe psoriasis compared to mild psoriasis (p=0.011).

Conclusion:

Comorbidities were more common among patients with moderate-to-severe compared to mild psoriasis, both

overall and specifically for obesity and hypertension. However, PsA were observed more frequently among patients with mild disease. It may be beneficial to screen more patients for common comorbidities, especially if their psoriasis is moderate-to-severe.

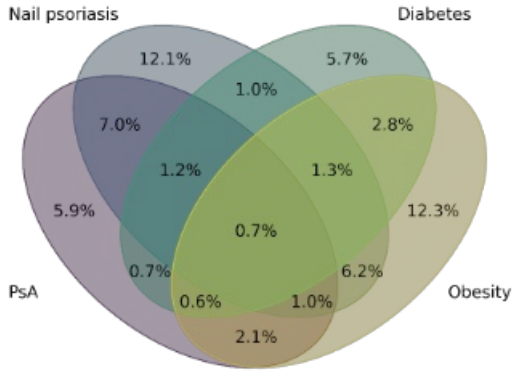


Figure 1:

Figure 2:

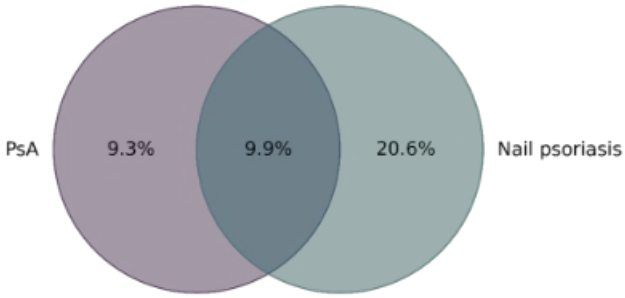
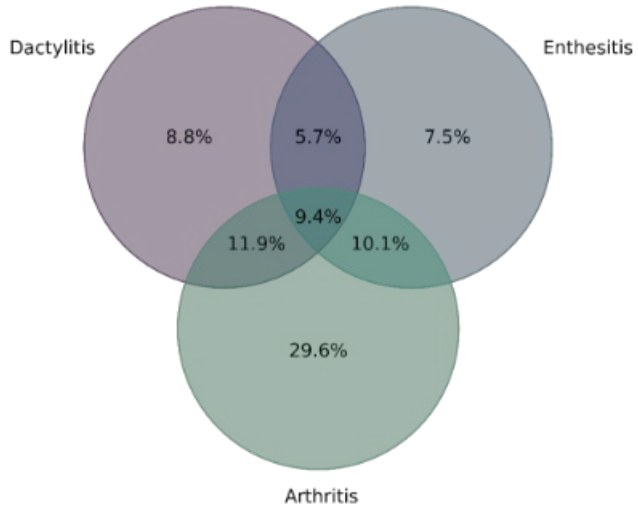


Figure 3:



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Abstract N°: 684

Epidemiology, clinical characteristics, treatment patterns, and mortality of palmoplantar pustulosis in Finland – a population-based national register study

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Introduction & Objectives: Palmoplantar pustulosis (PPP) is a chronic, recurrent, inflammatory skin disease characterized by sterile pustules with erythematous keratotic lesions on the palms and soles. Most PPP patients generally suffer from active disease with high risk of relapses and often have several comorbid conditions, leading to a significant decrease in the quality of life. The aim of the current study is to characterize the epidemiology, clinical characteristics, treatments, and mortality of Finnish PPP patients diagnosed in a specialty care setting.

Materials & Methods: This is a non-interventional, retrospective, population-based register study in which patients with two PPP diagnosis (ICD-10: L40.3) at a dermatology clinic were included. Additionally, two age- and gender-matched control groups were also included; a population with psoriasis vulgaris (PV; ICD-10: L40.0) and a population-based control group without a GPP or PV diagnosis. Diagnosis and comorbidities were assessed using ICD-10 codes and pharmacy dispensed medications by the ATC codes. Data from 1996 to 2021 was collected and the epidemiology of PPP was evaluated by calculating period prevalence and annual incidence rate.

Results: In the present study, 5469 PPP patients were included of which the majority were female (74%) with a mean (SD) age of 50 (13.5) years. The period prevalence of PPP was 87.7 per 100.000 persons and the mean annual incidence rate was 39.5 per 100.000 persons. The prevalence was ~2 times higher in women compared to men (126.6 vs. 46.5) and was the highest in the 50-59 years age category (206.1). The most common comorbidities found among PPP patients were cardiovascular diseases (54.9%) and upper respiratory tract infections (41.1%, Figure 1). The most prescribed PPP-related medications during follow-up are shown in Figure 2. Among PPP patients, 14% died during follow-up and the mortality rate was 1.1 per 100 person years (Figure 3). The most frequent reported causes of death were ischemic heart disease (1.8%) and malignancies of bronchus and lung (1.5%). The survival rate of PPP was 97% at 5 years and 91% at 10 years.

Conclusion: The results of the present study shown a prominent female predominance of PPP with the highest prevalence around the age of 50 years, which is in line with previous studies although epidemiological data in the current literature is limited. The disease is characterized by a high comorbidity burden, increased treatment use and shorter overall survival when compared to matched population-based controls, highlighting the current unmet medical need of this debilitating condition.

Figure 1: Prevalence of selected comorbidities among PPP patients compared to matched control groups.

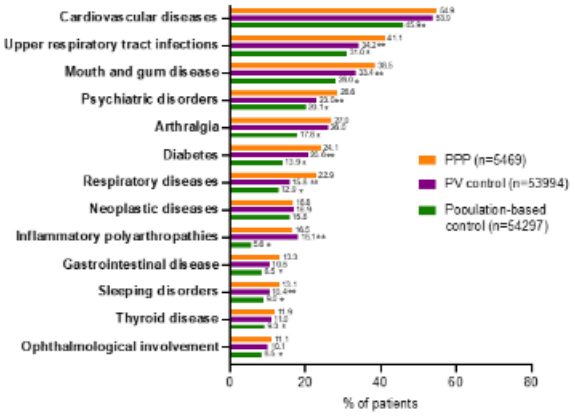


Figure 2: Use of PPP-related medications during follow-up among PPP patients compared to matched control groups

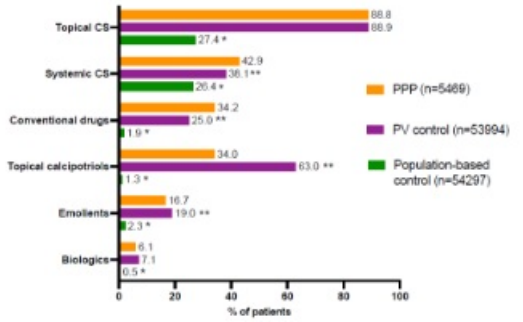
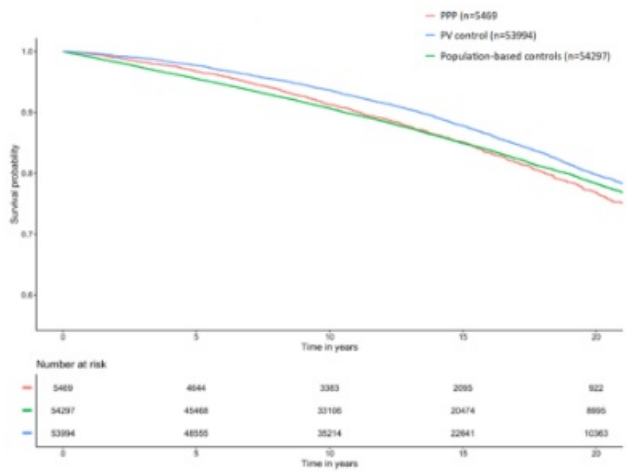


Figure 3: Kaplan-Meier estimates of mortality rates of PPP compared to matched control groups



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Abstract N°: 724

screening for psoriatic arthritis in patients who have psoriasis in primary care, a quality improvement project

Yazmin Bakhtiari*[1], Soo Young Baik[1]

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disorder with an estimated prevalence of 1.3% to 2.2% in the United Kingdom (UK). Psoriatic arthritis (PsA) is recognised to be associated with psoriasis and estimated to affect 30% of patients with psoriasis. Links between PsA, reduced quality of life and increased mortality have been shown. National Institute of Clinical Excellence (NICE) guidelines recommend annual screening of patients with psoriasis utilising the Psoriasis Epidemiology Screening Tool (PEST), a five-item questionnaire, however current screening is very minimal. This project aims to implement PEST to aid early detection of PsA and subsequent referral to rheumatology, in a primary care centre in the UK.

Materials & Methods:

The Plan-Do-Study-Act (PDSA) cycle was adopted. Three sequential PDSA cycles were carried out. Patients were screened with the PEST, whereby a positive result (three or more) indicates further investigation with blood tests and possible rheumatology referral. Patients under the age of 18, known PsA and those already referred to rheumatology were excluded.

Results:

216 patients were recruited, 37 responses were received with 26 scoring three or more and 11~~ scoring less than 3. 17 positive PEST scoring patients consented for bloods, 11 in total had blood tests all of which returned as normal. Overall, screening rate was 17.7% . 71.1% of those screened score positively on the PEST and the referral rate was 0%.

Conclusion:

The PEST is simple and easy to administer in a clinical setting. Barriers to screening rate include issues in language and literacy skills which are prevalent in this city. Little evidence exists looking at PEST in primary care. Our study reflects findings of low screening rates and very low referral rates. Suggestions to screen patients who only have joint complaints could be implemented. It may be worth referring these patients to rheumatology anyway as they may benefit from specialist input. There is further need for research to look at a validated screening tool for PsA in a primary care setting.

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Abstract N°: 760

Impact of Apremilast Treatment on Individual Domains of the Dermatology Life Quality Index Questionnaire in Patients with Psoriasis in Special Areas: 52-Week Results From EMBRACE

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Introduction & Objectives: Psoriasis in special areas impairs quality of life (QoL), even among patients (pts) with limited skin involvement (body surface area [BSA] 1-10%). Treatment guidelines recommend that pts with special area involvement and/or QoL impairment, even those with low BSA, should be considered as candidates for systemic therapy. In the EMBRACE study, the efficacy and safety of apremilast 30 mg BID (APR) was assessed over 52 weeks (wks) in pts with limited skin involvement but occurring in special areas.

Materials & Methods: EMBRACE (NCT03774875) was a phase 4, multinational, randomized, double-blind, placebo (PBO)-controlled, parallel-group trial conducted in Western Europe. Eligible pts had plaque psoriasis (≥6 months prior to enrollment) not controlled by topicals; lack of response, contraindication, or intolerance to conventional first-line systemics; psoriasis in ≥1 special area; Psoriasis Area and Severity Index score ≥3 to ≤10; and Dermatology Life Quality Index (DLQI) score >10. Pts were randomized 2:1 to receive APR or PBO from Wks 0 to 16, after which pts continued to receive APR (APR/APR) or switched from PBO to APR (PBO/APR) until Wk 52. Randomization was stratified by 5 special areas (visible locations [dorsal hand, face, neck, hairline], scalp, nails, genital area, and palmoplantar area). The primary endpoint was DLQI response (≥4-point reduction) at Wk 16. In this post hoc analysis, we report mean percentage change from baseline for each of the 10 DLQI items over 52 wks and mean percentage change from baseline in DLQI total score in subgroups based on special area location, number of special areas (1, 2, and ≥3), and disease duration (<5, ≥5-<10, ≥10-<20, and ≥20 years). Data are summarized descriptively.

Results: Among the 277 pts randomized, mean (SD) baseline DLQI was 18.2 (4.9) (PBO: 18.5 [4.9]; APR: 18.1 [4.9]). Significantly more pts achieved DLQI response at Wk 16 with APR vs PBO (73.3% vs 41.3%; P<0.0001).1 Least squares mean change from baseline in DLQI was also significantly greater with APR vs PBO at Wk 16 (-8.7 vs -3.4; P<0.0001).1 A total of 221 pts (PBO: 69, APR: 152) entered the extension phase and 158 (PBO/APR: 53, APR/APR: 105) completed Wk 52. Among pts who completed Wk 52, mean age at baseline was 50.5 years, 60.8% were men, and mean psoriasis duration was 17.7 years (**Table 1**). The DLQI items with the most impact at baseline were "how itchy, sore, painful, stinging" (Q1), "how embarrassed, self-conscious" (Q2), and "influenced clothes you wear" (Q4) (**Table 1**). Greater improvements were seen in each DLQI item with APR vs PBO at Wk 16 except "prevented working or studying" (Q7a), although this item had a limited sample size (**Figure 1**). At Wk 52, improvements in all DLQI items were maintained in the APR/APR group and similar improvements were seen in the PBO/APR group (**Figure 1**). Greater improvements were seen in DLQI total score with APR vs PBO at Wk 16 regardless of special area type (**Figure 2**), number of special areas involved (**Figure 3**), or disease duration. Improvements were maintained through Wk 52.

Conclusion: In pts with psoriasis in special areas and QoL impairment, greater improvements were seen in almost all DLQI items with APR vs PBO at Wk 16 in a post hoc analysis. APR/APR and PBO/APR pts experienced similar improvements by Wk 52. Improvements in DLQI were consistent regardless of special area location, number of special areas, or disease duration.

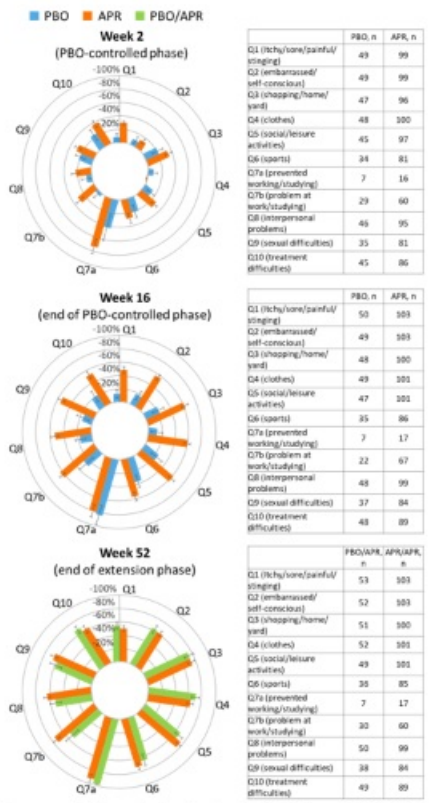
1. Mrowietz U, Barker J, Conrad C, et al.*J Eur Acad Dermatol Venereol.* 2023;37:348-355.

Table 1. Baseline demographics and clinical characteristics

	PBO/APR (n=33)	APR/APR (n=105)
Age, years, mean (SD)	53.5 (12.1)	49.0 (13.3)
Male, n (%)	31 (58.5)	65 (61.9)
BSA, %, mean (SD)	7.7 (4.9)	7.1 (3.9)
Primary manifestation for stratification*, n (%)		
Scalp	20 (29.0)	36 (23.7)
Nails	16 (23.2)	36 (23.7)
Palmoplantar	7 (10.1)	17 (11.2)
Genitals	10 (14.5)	21 (13.8)
Visible locations	16 (23.2)	42 (27.6)
Number of special areas, n (%)		
1	17 (32.1)	37 (35.2)
2	22 (41.5)	44 (41.9)
≥3	14 (26.4)	24 (22.9)
Duration of psoriasis, years, mean (SD)	20.4 (14.2)	16.3 (13.5)
<5 years, n (%)	9 (17.0)	19 (18.1)
≥5 and <10 years, n (%)	4 (7.6)	26 (24.8)
≥10 and <20 years, n (%)	16 (30.2)	29 (27.6)
≥20 years, n (%)	24 (45.3)	31 (29.5)
DLQI (0-30), mean (SD)	17.7 (4.7)	17.9 (4.5)
Primary manifestation subgroup		
Scalp	18.4 (5.0)	17.9 (3.9)
Nails	17.8 (5.0)	17.8 (4.4)
Palmoplantar	18.2 (4.2)	18.6 (5.2)
Genitals	16.3 (4.4)	17.7 (4.1)
Visible locations	18.3 (4.9)	17.9 (4.5)
Number of special areas subgroup		
1	17.0 (4.3)	18.1 (4.8)
2	17.9 (4.7)	17.7 (4.4)
≥3	18.3 (5.4)	18.0 (4.2)
Disease duration subgroup		
<5 years	18.7 (3.7)	18.4 (4.4)
≥5 and <10 years	19.8 (7.9)	17.8 (4.9)
≥10 and <20 years	18.0 (5.5)	17.6 (4.1)
≥20 years	16.8 (4.0)	18.0 (4.7)
DLQI item (0-3), n mean (SD)		
Q1: How itchy, sore, painful, stinging	2.5 (0.7)	2.4 (0.7)
Q2: How embarrassed, self-conscious	2.3 (0.7)	2.3 (0.7)
Q3: Interfered with shopping, home, yard	1.7 (0.8)	1.7 (0.8)
Q4: Influenced clothes you wear	2.2 (0.8)	2.1 (0.8)
Q5: Affected social, leisure activity	1.9 (0.9)	1.9 (0.7)
Q6: Made it difficult to do any sports	1.2 (1.0)	1.4 (1.0)
Q7a: Prevented working or studying	0.4 (1.0)	0.5 (1.1)
Q7b: If no, problem at work or studying†	1.3 (0.6)	1.2 (0.7)
Q8: Problem with partner, friends, relatives	1.6 (0.8)	1.7 (0.7)
Q9: Caused any sexual difficulties	1.3 (1.1)	1.6 (1.0)
Q10: How much of a problem is treatment	1.8 (1.0)	1.6 (1.0)
Number of prior conventional systemic therapies, n (%)		
0	10 (18.9)	26 (24.8)
1	21 (39.6)	38 (36.2)
2	12 (22.6)	18 (17.1)
≥3	10 (18.9)	23 (21.9)
Number of prior biologic therapies, n (%)		
0	46 (86.8)	97 (92.4)
1	6 (11.3)	7 (6.7)
2	0	1 (1.0)
≥3	1 (1.9)	0

Patients who completed Week 52.
*For the purposes of stratification, if a patient presented with multiple special areas, they were allocated to the special area group which was most severe, as determined by the patient.
†PBO: n=40, APR: n=85.
APR, apremilast; DLQI, Dermatology Life Quality Index; PBO, placebo; SD, standard deviation.

Figure 1. Mean percentage change from baseline in each DLQI item over time



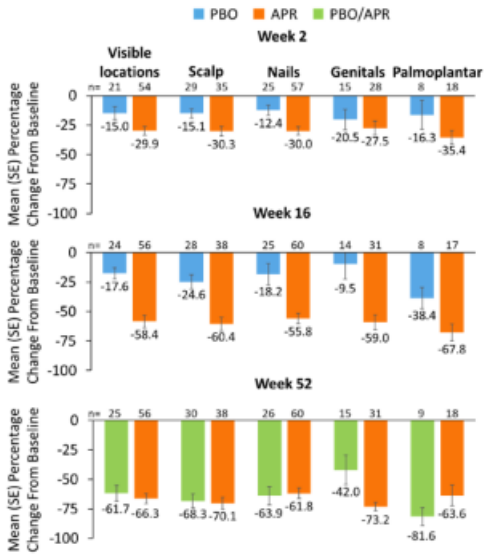
	PBO, n	APR, n
Q1 (Itchy/sore/painful/stinging)	49	99
Q2 (embarrassed/self-conscious)	49	99
Q3 (shopping/home/yard)	47	96
Q4 (clothes)	48	100
Q5 (social/leisure activities)	45	97
Q6 (sports)	34	81
Q7a (prevented working/studying)	7	16
Q7b (problem at work/studying)	29	60
Q8 (interpersonal problems)	46	95
Q9 (sexual difficulties)	35	81
Q10 (treatment difficulties)	45	86

	PBO, n	APR, n
Q1 (Itchy/sore/painful/stinging)	50	103
Q2 (embarrassed/self-conscious)	49	103
Q3 (shopping/home/yard)	48	100
Q4 (clothes)	49	101
Q5 (social/leisure activities)	47	101
Q6 (sports)	35	86
Q7a (prevented working/studying)	7	17
Q7b (problem at work/studying)	22	67
Q8 (interpersonal problems)	48	99
Q9 (sexual difficulties)	37	84
Q10 (treatment difficulties)	48	89

	PBO/APR, n	APR/APR, n
Q1 (Itchy/sore/painful/stinging)	53	103
Q2 (embarrassed/self-conscious)	52	103
Q3 (shopping/home/yard)	51	100
Q4 (clothes)	52	101
Q5 (social/leisure activities)	49	101
Q6 (sports)	38	85
Q7a (prevented working/studying)	7	17
Q7b (problem at work/studying)	30	60
Q8 (interpersonal problems)	50	99
Q9 (sexual difficulties)	38	84
Q10 (treatment difficulties)	49	89

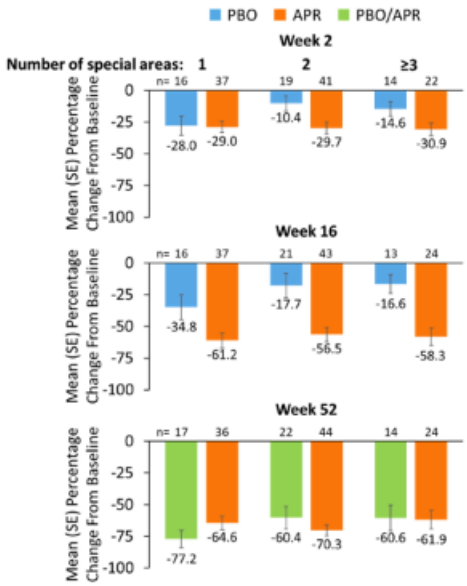
Shown are mean (SE) percentage change from baseline. Patients who completed Week 52. Data as observed.
Q1: How itchy, sore, painful, stinging; Q2: How embarrassed, self-conscious; Q3: Interfered with shopping, home, yard; Q4: Influenced clothes you wear; Q5: Affected social, leisure activity; Q6: Made it difficult to do any sports; Q7a: Prevented working or studying; Q7b: Problem at work or studying; Q8: Problem with partner, friends, relatives; Q9: Caused any sexual difficulties; Q10: How much of a problem is treatment.
APR, apremilast; DLQI, Dermatology Life Quality Index; PBO, placebo; SE, standard error.

Figure 2. Mean percentage change from baseline in DLQI total score over time by special area location



Patients who completed Week 52. Data as observed.

Figure 3. Mean percentage change from baseline in DLQI total score over time by number of special areas



Patients who completed Week 52. Data as observed.

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Abstract N°: 824

Apremilast Benefit in Early Oligoarticular Psoriatic Arthritis: 48-Week Data From FOREMOST

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Introduction & Objectives: Approximately 40% of patients (pts) with psoriasis (PsO) have psoriatic arthritis (PsA).1 PsA typically develops after skin symptoms,1 with dermatologists often the first healthcare providers to see pts with early oligoarticular (oligo; ≤4 joints affected) PsA. Most PsA clinical trials exclude early oligo PsA, resulting in limited evidence to inform treatment decisions. Apremilast is an oral phosphodiesterase-4 inhibitor approved for PsO and PsA. We report changes in joint, nail and skin involvement with apremilast 30 mg BID (APR) vs placebo (PBO) for up to 48 weeks (wks) from FOREMOST, the first multicenter, randomised, double-blind, PBO-controlled phase 4 trial in early oligo PsA.

Methods: FOREMOST (NCT03747939) enrolled pts with early PsA (duration ≤5 years) and limited joint involvement (>1 to ≤4 swollen joint count [SJC] and tender joint count [TJC]; 66–68 joints assessed).2 Pts were randomised 2:1 to APR or PBO for 24 wks (PBO pts switched to receive APR at Wk 16, if no improvement in SJC, or at Wk 24; APR pts continued on APR), followed by an extension phase in which all pts received APR through Wk 48. Primary endpoint was modified Minimal Disease Activity (MDA-Joints; sentinel joints affected at baseline [BL]) at Wk 16. Post hoc analyses assessed SJC and TJC, disease progression (switch from ≤4 to >4 active joints), nail visual analog scale (VAS) and skin clearance (body surface area [BSA] of 0%) through Wk 48.

Results: 308 pts were randomised (APR: n=203; PBO: n=105 [24 switched to APR at Wk 16]): mean (SD) PsA duration, 9.9 (10.2) months; mean (SD) age, 50.9 (12.5) years; mean (SD) SJC, 2.6 (0.7); mean (SD) TJC, 3.2 (0.8); mean (SD) nail VAS (n=212), 30.2 (26.0); mean (SD) BSA, 6.7% (11.8%). Twice as many pts achieved MDA-Joints at Wk 16 with APR *vs* PBO (33.9% *vs* 16.0%; *p*=0.0008).2 Mean SJC and TJC improved with APR and worsened with PBO (BL to Wk 16), with the treatment difference observed by Wk 12 and sustained improvements observed through Wk 48 in pts who continued or switched to APR (Fig 1A-B). In the PBO group, over one-third of pts with 2-4 affected joints at BL experienced disease progression, as shown by joint count (JC) >4 at Wk 16; sustained treatment benefit was observed when these pts switched to APR, with fewer moving to JC >4 through Wk 48 (Fig 1C). Compared with PBO, rapid/greater improvements in nail VAS were observed with APR (Fig 2) and a higher proportion of pts achieved skin clearance (Fig 3A-B). In pts with higher skin involvement (BSA>3%) at BL, seven times as many achieved skin clearance with APR *vs* PBO (Fig 3B; 2.6% vs 18.9%). Pts randomised to PBO showed rapid improvements in nail VAS and skin clearance after switching to APR and overall improvements in nail VAS and skin clearance were maintained with up to 48 wks of APR treatment. No new safety signals were reported.

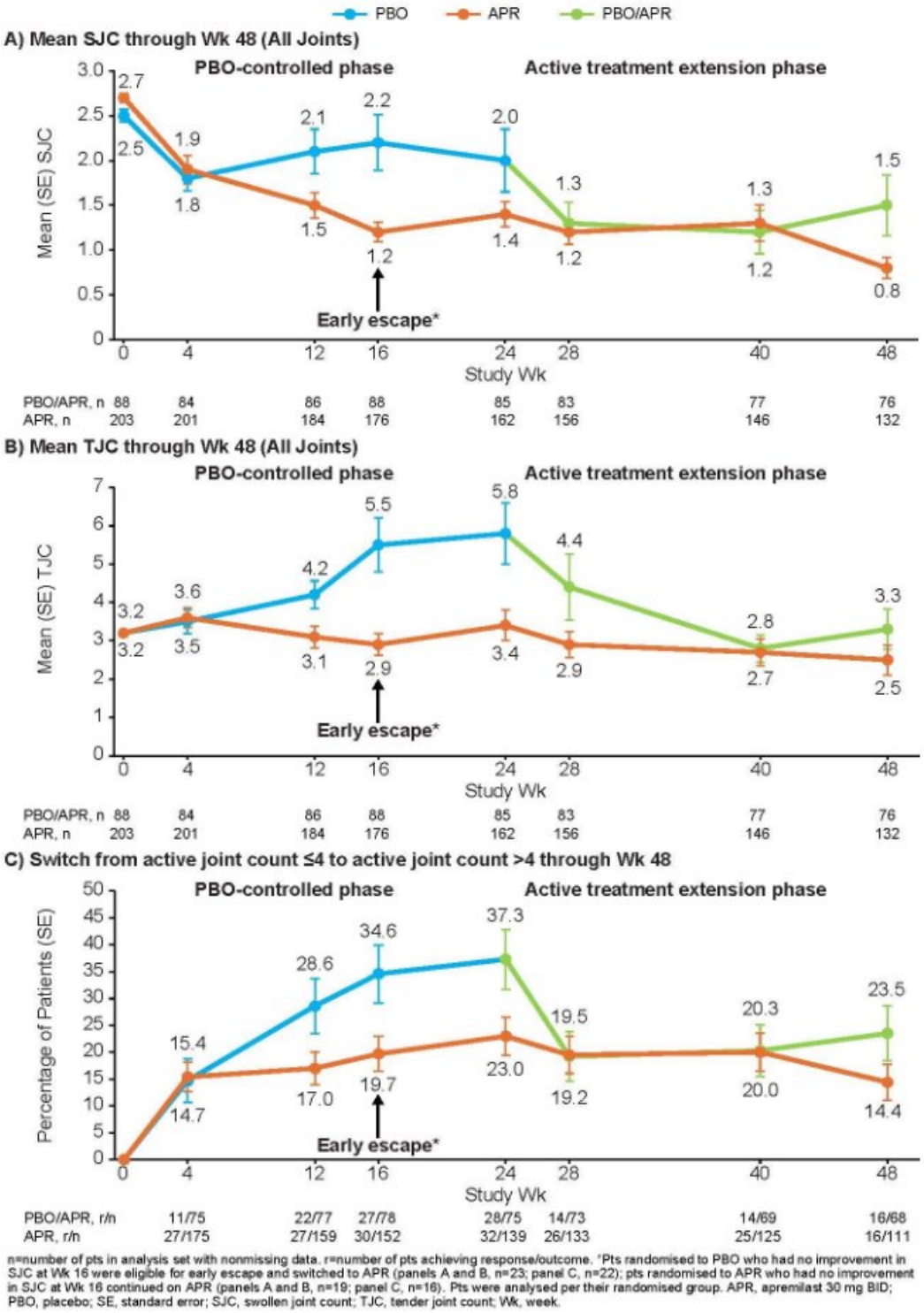
Conclusion: APR demonstrated early and sustained benefits in early oligo PsA vs PBO. The number of swollen and tender joints, nail involvement and skin clearance improved in pts who received APR and worsened in pts who received PBO from BL to Wk 16, with sustained improvements among pts who received continuous APR up to Wk 48 and improvements in pts who switched from PBO to APR. These findings demonstrate that early use of APR

in pts with early oligo PsA can manage multiple aspects of the disease, including nail, joint and skin involvement.

References

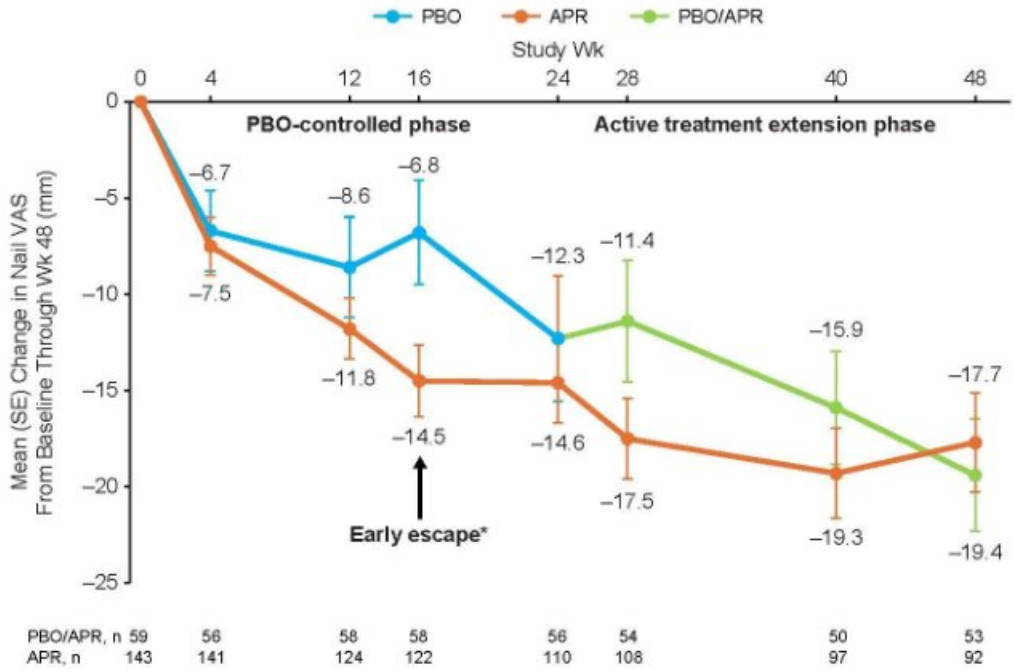
1. Kasiem FR, et al. *Scand J Rheumatol*. 2021;50:124-131.
2. Mease P, et al. *Arthritis Rheumatol*. 2023;75(Suppl 9):1691 (abstract).

Figure 1. Swollen and Tender Joint Counts through Wk 48 in FOREMOST



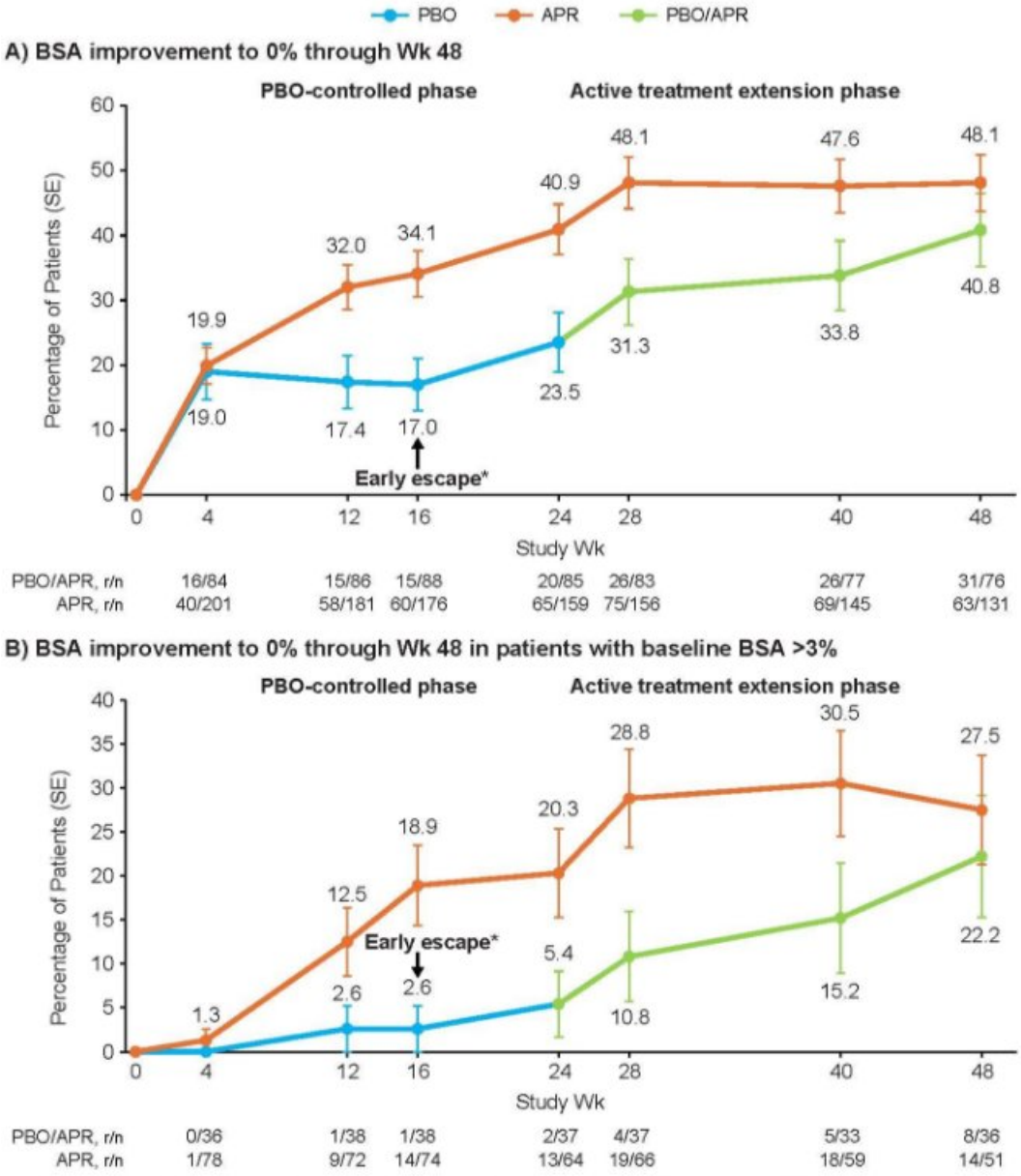
n=number of pts in analysis set with nonmissing data. r=number of pts achieving response/outcome. *Pts randomised to PBO who had no improvement in SJC at Wk 16 were eligible for early escape and switched to APR (panels A and B, n=23; panel C, n=22); pts randomised to APR who had no improvement in SJC at Wk 16 continued on APR (panels A and B, n=19; panel C, n=16). Pts were analysed per their randomised group. APR, apremilast 30 mg BID; PBO, placebo; SE, standard error; SJC, swollen joint count; TJC, tender joint count; Wk, week.

Figure 2. Improvement in nail involvement through Wk 48 in FOREMOST



n=number of pts in analysis set with nonmissing data. *Pts randomised to PBO who had no improvement in SJC at Wk 16 were eligible for early escape and switched to APR (n=18); pts randomised to APR who had no improvement in SJC at Wk 16 continued on APR (n=15). Pts were analysed per their randomised group. APR, apremilast 30 mg BID; PBO, placebo; SE, standard error; SJC, swollen joint count; VAS, visual analog scale; Wk, week.

Figure 3. Improvements in skin involvement through Wk 48 in FOREMOST



n=number of pts in analysis set with nonmissing data. r=number of pts achieving response/outcome. *Pts randomised to PBO who had no improvement in SJC at Wk 16 were eligible for early escape and switched to APR (panel A, n=24; panel B, n=11); pts randomised to APR who had no improvement in SJC at Wk 16 continued on APR (panel A, n=19; panel B, n=11). Pts were analysed per their randomised group. APR, apremilast 30 mg BID; BSA, body surface area; PBO, placebo; SE, standard error; SJC, swollen joint count; Wk, week.

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Abstract N°: 834

Fatigue and Pain in Patients With Psoriasis and Oligoarticular Psoriatic Arthritis and Improvements on Apremilast Treatment: 48-Week Data From FOREMOST

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Introduction & Objectives: Approximately 40% of patients (pts) with psoriasis (PsO) develop psoriatic arthritis (PsA).1 Dermatologists typically see pts with early oligoarticular (oligo) PsA, which, despite limited (≤4) joint involvement, is associated with high disease burden, including fatigue and pain.1-3 Hence, dermatologists have an opportunity to identify pts presenting with fatigue and pain related to early oligo PsA. The 12-item PsA Impact of Disease (PsAID-12) is a multi-dimensional pt-reported outcome (PRO) measuring symptoms and impact of PsA and captures key PsA features highly relevant to dermatologists including fatigue, pain, and skin involvement.2 Apremilast is an oral immunomodulating phosphodiesterase-4 inhibitor approved for PsO and PsA. We describe fatigue and pain burden in the FOREMOST oligo PsA study population, and pt-reported benefits of apremilast 30 mg BID (APR) vs placebo (PBO) for up to 48 weeks (wks).

Methods: FOREMOST (NCT03747939), a randomised controlled trial, compared APR vs PBO in pts with early (duration ≤5 years) oligo PsA (>1 but ≤4 tender joint count and swollen joint count; 66-68 joints assessed).4 Pts were randomised 2:1 to APR or PBO for 24 wks (early escape at Wk 16) followed by an extension phase in which all pts received APR through Wk 48. Pts with early escape were analysed per randomisation. PROs included PsAID-12 (0 [best health state]-10 [worst health state]) and Short Form (SF)-36 (0-100; higher values=better health state) questionnaires. We report post hoc analyses of PsAID-12 Total, Fatigue and Pain scores, PsAID-12 related disease activity (remission/low disease activity), and SF-36 Physical Function, Bodily Pain and Vitality Scores.

Results: 308 pts were randomised (APR, n=203; PBO, n=105, 24 switched to APR at Wk 16): mean (SD) PsA duration, 9.9 (10.2) months; mean (SD) age, 50.9 (12.5) years. At baseline, most pts reported high disease activity in PsAID-12 (Total, Fatigue and Pain [Fig 1]). At Wk 16, pts reported lower disease activity and greater improvements in PsAID-12 Fatigue and Pain scores for APR vs PBO (Fig 2-3); twice as many pts achieved a minimum clinically important difference (MCID; ≥3 point increase in PsAID-12 Total score) for APR vs PBO (Fig 4). Pts continuing APR or switched from PBO to APR maintained improvements in PsAID-12 Total, Fatigue and Pain scores, and lower disease activity up to Wk 48 (Fig 2-4). Mean SF-36 Physical Function, Bodily Pain and Vitality scores for APR vs PBO were 43.2 vs 41.6, 44.4 vs 41.2, and 47.2 vs 44.4, respectively, at Wk 16; in pts continuing APR or switched from PBO to APR, these scores were 44.3 vs 43.9, 45.0 vs 45.3 and 47.9 vs 47.9, respectively, at Wk 48. At Wk 16, more pts achieved the MCID of a ≥5-point increase in Vitality score5 for APR vs PBO; pts continuing APR or switched from PBO to APR maintained this improvement up to Wk 48 (Fig 5).

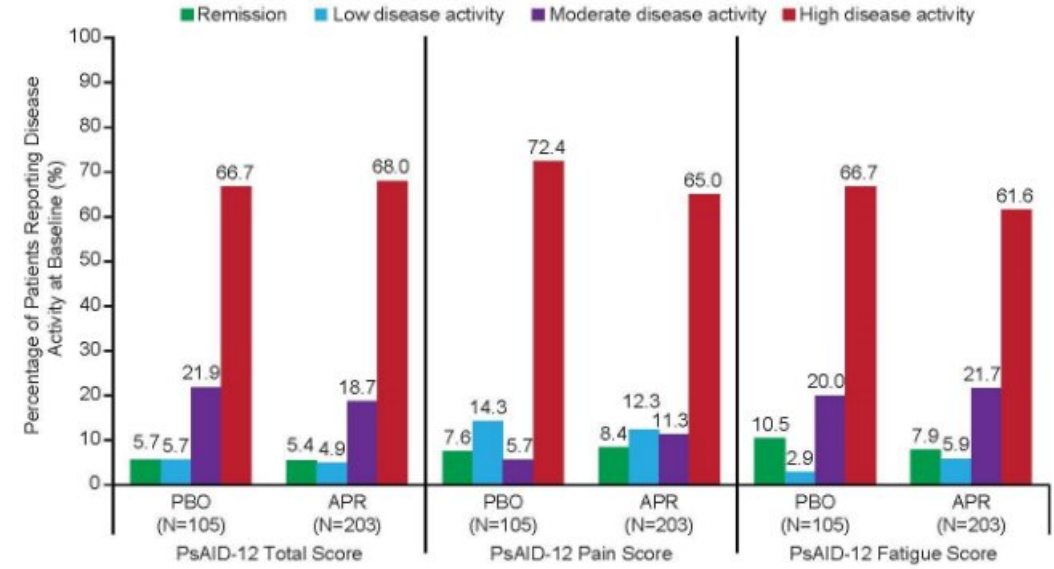
Conclusion: Patients with early oligo PsA enrolled in the FOREMOST study reported high disease activity, overall and related to fatigue and pain, demonstrating fatigue and pain are highly relevant to disease burden. Early treatment with APR reduced pt-reported fatigue and pain, with these treatment benefits sustained through 48

weeks.

References

1. Kasiem FR, et al. *Scand J Rheumatol.* 2021;50:124-131.
2. Gossec L, et al. *RMD Open.* 2024;10:e003548.
3. Krajewska-Włodarczyk M, et al. *Reumatologia.* 2017;55:125-130.
4. Mease P, et al. *Arthritis Rheumatol.* 2023;75(Suppl 9):1691 (abstract).
5. Deodhar A, et al *Rheumatol Ther* 2023;10:983-999.

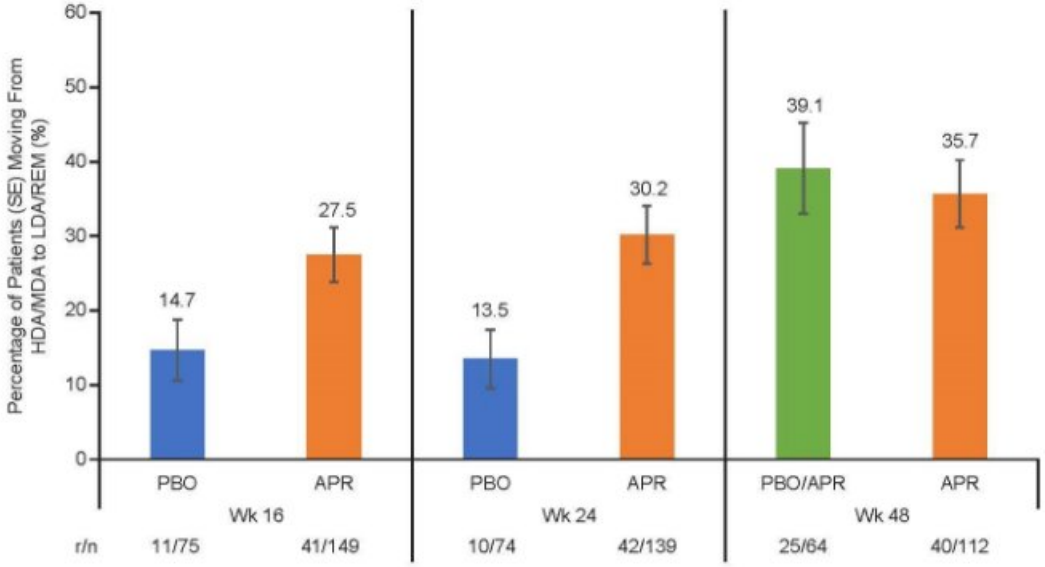
Figure 1. PsAID-12 disease activity at baseline, summarized for Total, Pain and Fatigue score



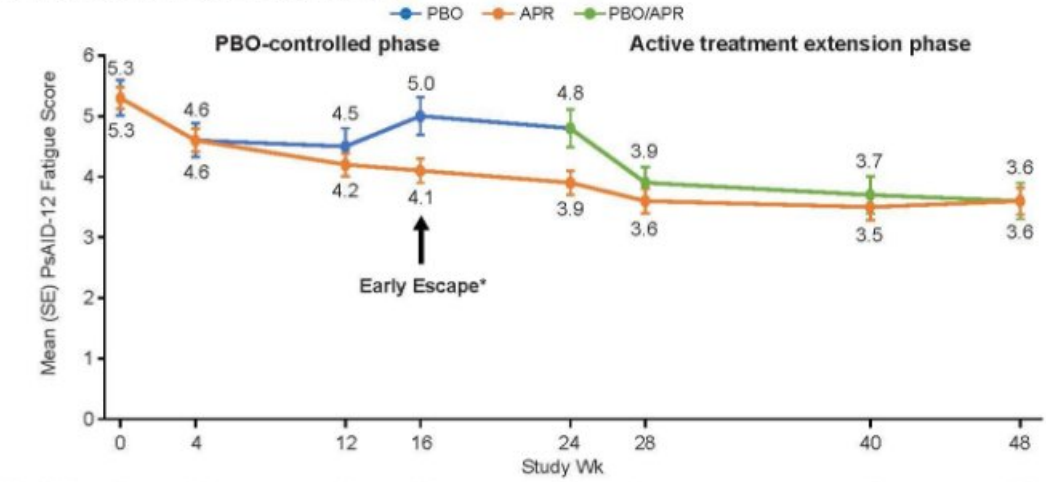
N=number of pts in the analysis set. APR, apremilast 30 mg BID; PBO, placebo; PsAID, Psoriatic Arthritis Impact of Disease; pt, patient.
PsAID-12 Total score: ≤1.15=Remission, >1.15 to ≤1.95=Low disease activity, >1.95 to ≤3.60=Moderate disease activity, >3.60=High disease activity.
PsAID-12 Pain score: ≤2=Remission, 3=Low disease activity, 4=Moderate disease activity, ≥5=High disease activity.
PsAID-12 Fatigue score: ≤1=Remission, 2=Low disease activity, 3 or 4=Moderate disease activity, ≥5=High disease activity.

Figure 2. PsAID Fatigue score over time

A) Patients with moderate-high disease activity at baseline reporting remission or low disease activity at Wks 16, 24 and 48*



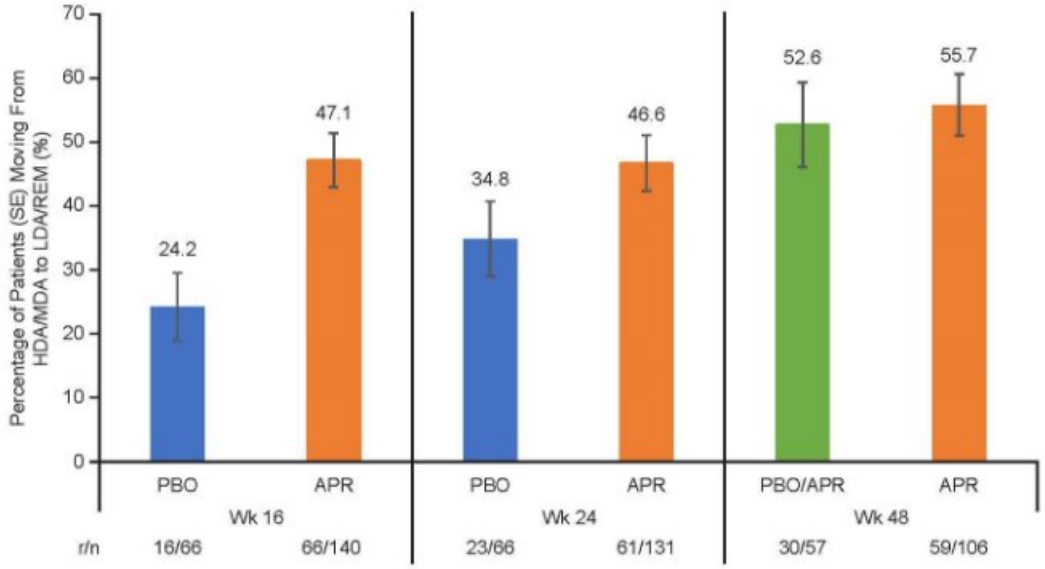
B) Mean Fatigue score through Wk 48



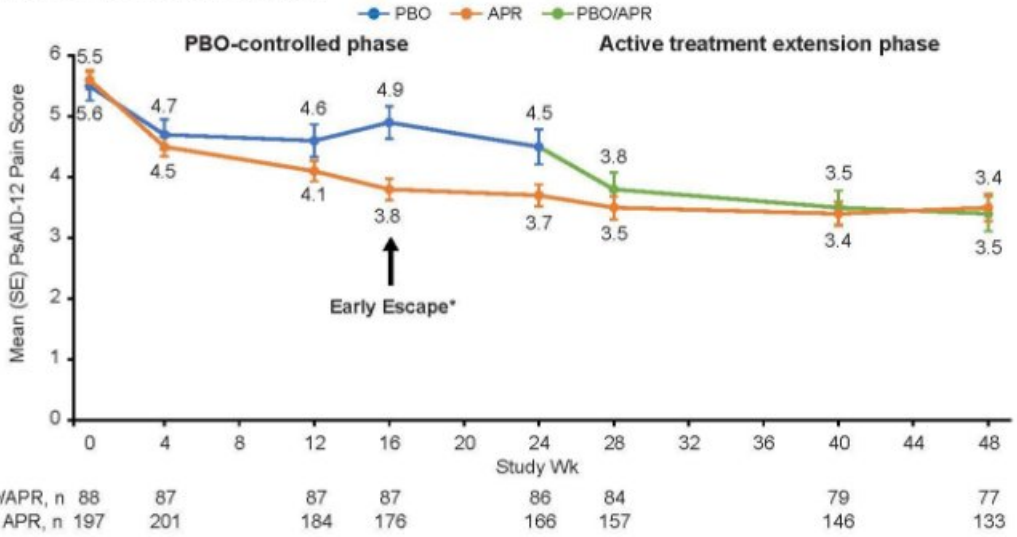
n=number of pts in analysis set with nonmissing data. r=number of pts moving from MDA/HDA at baseline to REM/LDA. *Pts randomised to PBO who had no improvement in SJC at Wk 16 were eligible for early escape and switched to APR (panel A, n=20; panel B, n=24); pts randomised to APR who had no improvement in SJC at Wk 16 continued on APR (panel A, n=16; panel B, n=19). Pts were analysed per their randomised group. APR, apremilast 30 mg BID; HDA, high disease activity (PsAID Fatigue score ≥5); LDA, low disease activity (PsAID Fatigue score=2); MDA, moderate disease activity (PsAID fatigue score=3 or 4); PBO, placebo; PsA, psoriatic arthritis; PsAID, PsA Impact of Disease; pt, patient; REM, remission (PsAID Fatigue score ≤1); SE, standard error; SJC, swollen joint count; Wk, Week.

Figure 3. PsAID Pain score over time

A) Patients with moderate-high disease activity at baseline reporting remission or low disease activity at Wks 16, 24 and 48*

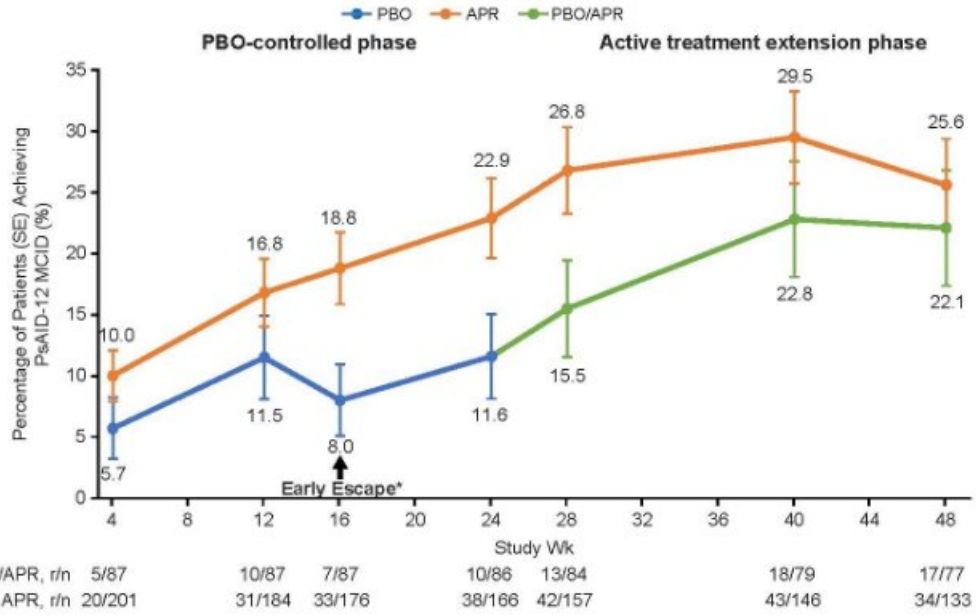


B) Mean Pain score through Wk 48



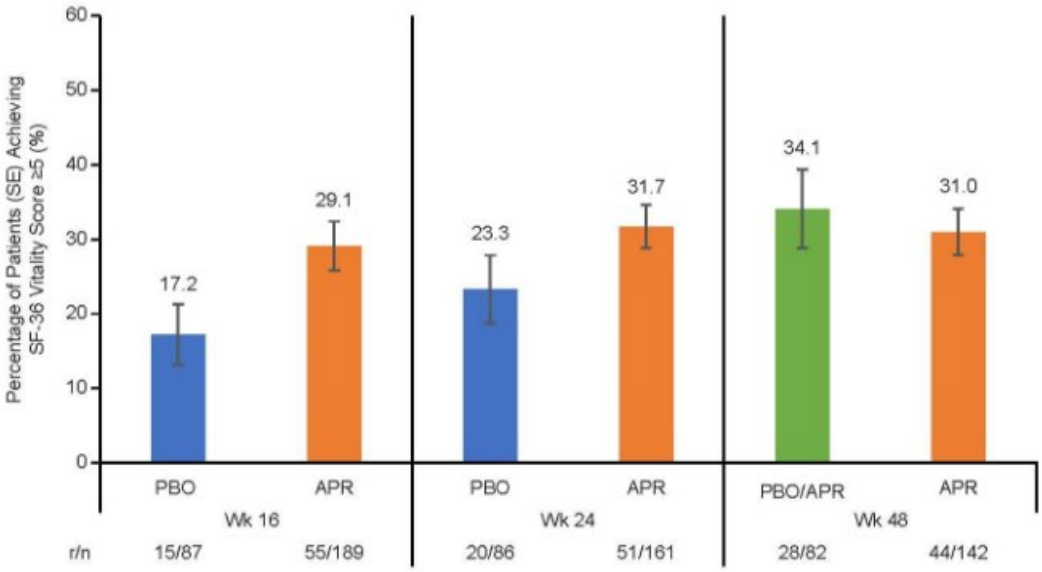
n=number of pts in analysis set with nonmissing data. r=number of pts moving from MDA/HDA at baseline to REM/LDA. *Pts randomised to PBO who had no improvement in SJC at Wk 16 were eligible for early escape and switched to APR (panel A, n=18; panel B, n=24); pts randomised to APR who had no improvement in SJC at Wk 16 continued on APR (panel A, n=15; panel B, n=19). Pts were analysed per their randomised group. APR, apremilast 30 mg BID; HDA, high disease activity (PsAID Pain score ≥5); LDA, low disease activity (PsAID Pain score=3); MDA, moderate disease activity (PsAID Pain score=4); PBO, placebo; PsA, psoriatic arthritis; PsAID, PsA Impact of Disease; pt, patient; REM, remission (PsAID Pain score ≤2); SE, standard error; SJC, swollen joint count; Wk, Week.

Figure 4. Achievement of PsAID-12 MCID (3-point improvement in total score)



n=number of pts in analysis set with nonmissing data. r=number of pts achieving PsAID-12 MCID. *Pts randomised to PBO who had no improvement in SJC at Wk 16 were eligible for early escape and switched to APR (n=24); pts randomised to APR who had no improvement in SJC at Wk 16 continued on APR (n=19). Pts were analysed per their randomised group. APR, apremilast 30 mg BID; MCID, minimum clinically important difference; PBO, placebo; PsA, psoriatic arthritis; PsAID, PsA Impact of Disease; pt, patient; SE, standard error; SJC, swollen joint count; Wk, Week.

Figure 5. Achievement of SF-36 Vitality score MCID (≥5 point improvement in norm-based score)*



n=number of pts in analysis set with nonmissing data. r=number of pts achieving SF-36 Vitality score MCID. *Pts randomised to PBO who had no improvement in SJC at Wk 16 were eligible for early escape and switched to APR (n=24); pts randomised to APR who had no improvement in SJC at Wk 16 continued on APR (n=18). Pts were analysed per their randomised group. APR, apremilast 30 mg BID; MCID, minimum clinically important difference; PBO, placebo; pt, patient; SF-36, Short Form 36; SE, standard error; SJC, swollen joint count; Wk, Week.

EADV CONGRESS
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Abstract N°: 857

The economic impact of ustekinumab in the treatment of psoriasis: a targeted literature review

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Introduction & Objectives:

Ustekinumab is an interleukin (IL)-12/23 inhibitor biologic that is used to treat patients with psoriasis (PsO). Clinical and real-world evidence has demonstrated its efficacy and safety among patients; however, its high cost may result in reimbursement restrictions that impact access and use. The objective of this literature review was to understand the economic impact of ustekinumab's reference product in the treatment of patients with PsO.

Materials & Methods:

A literature search was conducted in MEDLINE for economic models that evaluate the economic impact of ustekinumab or included ustekinumab in its analysis. Key terms: "budget impact model", "cost-effective*", "cost-utility", "cost per responder", "economic model", and "psoriasis" were searched from January 1st, 2018, until Mar 1st, 2024. Only studies published in English were eligible for inclusion.

Results:

A total of 56 hits were screened for inclusion, resulting in 17 relevant studies that explored the economic impact of ustekinumab in PsO. Seven articles were conducted from the US payer perspective, two from the Japense, and one each from the German, Philippine, Chinese, French/German, Australian, Italian, Spanish, and Dutch payer perspective. The economic models included budget impact models (n = 2), cost-effectiveness analyses (n = 8), cost per responder (n = 6), and a cost-utility analysis (n = 1). Of the included studies, two found ustekinumab was the lowest-costing biologic (Dutch and Spanish payers) using a patient simulation and cost per responder analysis, respectively. Notably, the patient simulation analysis did not include newer mechanisms of action, whereas the cost per responder analysis also evaluated ixekizumab and secukinumab (Spanish payer perspective). However, more recent cost per responder analyses for payers in Italy, and France/Germany found that ustekinumab incurred the highest cost per responder compared to other biologics included in the model (eg, golimumab and risankizumab). Moreover, all cost-effectiveness analyses demonstrated that ustekinumab was not a cost-effective therapy at the current willingness to pay thresholds for several payers. An analysis from the Philippine payer perspective noted that the effectiveness of ustekinumab was highly similar to the most cost-effective treatments; however, it was associated with higher unit drug costs, highlighting that its price negatively affected the incremental cost-effectiveness ratio. No studies tested the possible cost-effectiveness of an ustekinumab biosimilar which would positively influence the cost associated with ustekinumab treatment.

Conclusion:

This literature review demonstrated that ustekinumab is typically among the most expensive therapies to treat patients with PsO leading to low probabilities of cost-effectiveness across several studies. As the economic burden for PsO is rising globally, newer cost-saving therapeutic options such as biosimilars may provide savings that could expand patient access.

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Abstract N°: 888

Exploring bimekizumab for psoriasis treatment: Multicentre perspectives from Canada

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Exploring bimekizumab for psoriasis treatment: Multicentre perspectives from Canada

Introduction & Objectives: Biologic therapies are essential in managing moderate-to-severe psoriasis by targeting immune pathways involved in disease pathogenesis. Bimekizumab, a dual IL-17A and F inhibitor, received Canadian approval in 2022 for the treatment of moderate-to-severe plaque psoriasis based on the data from four pivotal clinical trials. However, real-world evidence from Canadian centres is limited. We conducted a chart analysis to evaluate the effectiveness, safety, and impact on quality of life (QOL) of bimekizumab in patients with psoriasis.

Materials & Methods: We retrospectively reviewed charts of patients with moderate-to-severe psoriasis treated with bimekizumab across 7 Canadian outpatient dermatology clinics.

Results: Data from 154 patients were included in the analysis. The primary reasons for prescribing bimekizumab were previous failure of other biologics (54%) and expected efficacy and safety of bimekizumab (27%). The mean patient age was 53.9 years. The patients predominantly had plaque psoriasis and the mean Psoriasis Area and Severity (PASI) score at baseline was 10.8. Psoriatic arthritis was the most common comorbidity (40%). A total of 73% had psoriasis at 1 or more of the 4 special sites (face, hands, feet, or genitals). The median treatment duration was 8.5 months. Most patients (84%) were on an every-8-week maintenance schedule.

Bimekizumab treatment led to improvement in psoriasis in most patients. Improvement was observed already by 3 months of treatment, with rates of 71% for PASI75, 62% for PASI90, and 52% for PASI100. These improvements were maintained throughout the follow-up period (scores at last assessment 72%, 60%, and 47%, respectively). Additionally, the proportion of patients with PASI scores of ≤2 increased markedly by 3 months, indicating a substantial reduction in disease severity. Body Surface Area (BSA) and Physician Global Assessment (PGA) data were in line with these observations (Fig. 1).

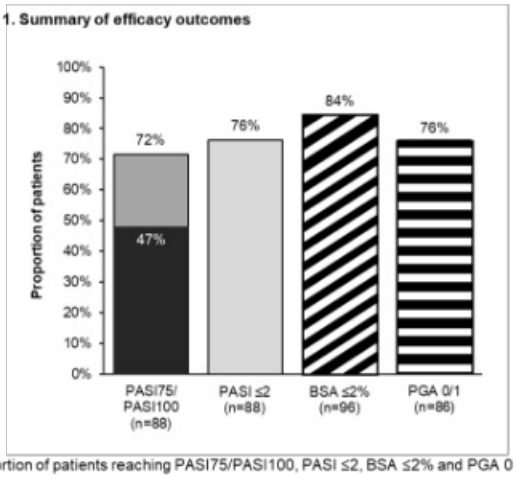
Bio-naïve patients had higher baseline PASI scores. However, both bio-naïve and bio-experienced patients had a sharp decrease in PASI scores within 3 months of treatment initiation, with similar improvement maintained over time. There were no statistically significant differences in the relative reduction in PASI scores or the proportion of patients with PASI scores of ≤2 between the two groups (Fig. 2).

Patients experienced improved QOL with bimekizumab treatment, as reflected in reduced Dermatology Life Quality Index (DLQI) scores. There was a significant correlation between DLQI and PASI, BSA, and PGA scores, indicating that improvements in psoriasis were associated with better QOL.

Bimekizumab was generally well tolerated. Oral candidiasis was the most common adverse event (23%). Sixteen percent of patients discontinued bimekizumab, primarily due to lack of efficacy (14 patients) or mild or moderate recurrent oral candidiasis (6 patients). Patients who discontinued tended to be bio-experienced and to have more severe disease and higher DLQI scores.

Conclusion: In real-world practice, bimekizumab demonstrated effectiveness and safety in line with clinical trials. Patients experienced significant improvement in psoriasis severity and QOL, with manageable adverse events. Our findings support bimekizumab's use in patients with moderate-to-severe psoriasis, regardless of their previous experience with biologics.

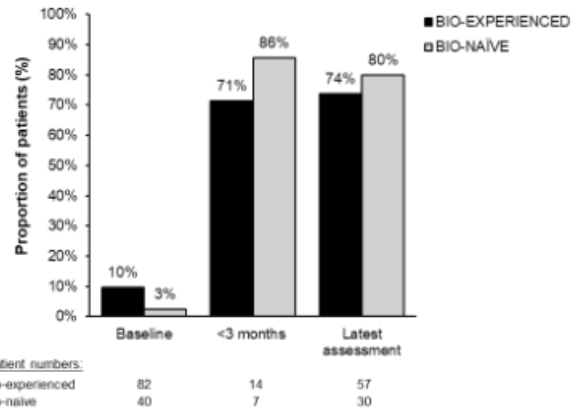
Figure 1. Summary of efficacy outcomes



Proportion of patients reaching PASI75/PASI100, PASI ≤2, BSA ≤2% and PGA 0 or 1 out of all patients with the available data at the latest assessment.

BSA = Body Surface Area; PASI = Psoriasis Area and Severity Index; PGA = Physician Global Assessment.

Figure 2. Proportion of patients with PASI scores of ≤2



Patient numbers:			
Bio-experienced	82	14	57
Bio-naive	40	7	30

Percentages are calculated from the number of patients who had PASI score of ≤2 out of all patients with data at the specified timepoint.

PASI = Psoriasis Area and Severity Index.

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Abstract N°: 945

Nail Involvement in Psoriasis and Psoriatic Arthritis: Clinical Characteristics and Implications

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Introduction & Objectives:

Nail involvement is frequent in patients with psoriasis (Pso) and psoriatic arthritis (PsA) and there is a relationship between nail involvement and inflammation of the enthesis. The main objective of the present study is to describe the clinical characteristics of nails from patients with psoriasis and psoriatic arthritis with nail dystrophy.

Materials & Methods:

A cross-sectional study including consecutive patients with PsO and PsA was carried out. The study patients were divided into 2 groups, totaling 60 participants. Group 1: patients with psoriasis vulgaris and onychodystrophy; Group 2: patients with psoriatic arthritis and onychodystrophy; All patients were submitted to dermatological clinical analysis.

Inclusion criteria: The selected individuals will consist of adult patients aged 18 and above, with no age cutoff, of both genders. Participants must be volunteers who are well-informed and have agreed to the collection of clinical information and materials after reading and completing the informed consent form. Exclusion criteria were patients who did not provide informed consent, those with positive results in direct mycological exams or nail lesion cultures for fungi and/or bacteria, individuals with a history of trauma in fingernails in the last 6 weeks, local glucocorticoid** injections in the distal interphalangeal (DIP) joints.

The study adhered to the principles outlined in the Declaration of Helsinki and complied with local regulations. Ethical approval for the study was granted by the Hospital’s Local Ethics Committee

Results:

The average NAPSI (Nail Psoriasis Severity Index) overall was 25.00 (range 6 to 97 mm, SD 15.64), with the score being 28 in patients with psoriasis and onychodystrophy (group 1) and 22 in the group with arthritis and onychodystrophy (group 2). There was no significant difference between groups 2 and 4 regarding the NAPSI variable (p=0.12). The most frequent nail clinical findings in groups 1 and 2 were onycholysis in 87 nails (79.09%) and oil spots in 49 nails (44.54%), with no significant difference between the two groups (p=0.28). The most frequent clinical findings of nail matrix lesions in groups 1 and 2 were cup-shaped depressions in 87 nails (78.39%) and leukonychia in 40 nails (36.00%). There was no significant difference between groups 1 and 2 regarding the nail matrix clinical variable (p=0.88).

Conclusion:

In conclusion, our study provides valuable insights into the clinical characteristics of nail involvement in patients with psoriasis and psoriatic arthritis presenting with nail dystrophy. Despite the distinct underlying conditions, both groups exhibited similar patterns of nail involvement, with no significant differences observed in the Nail Psoriasis Severity Index (NAPSI) scores or specific nail clinical findings between patients with psoriasis alone and those with psoriatic arthritis. These findings underscore the importance of comprehensive dermatological assessment in patients with psoriatic disease, as nail dystrophy appears to be a common manifestation regardless

of the presence of joint involvement. Further research is warranted to elucidate the precise mechanisms underlying nail involvement in psoriatic conditions and to develop targeted therapeutic interventions aimed at improving both dermatological and rheumatological outcomes in affected individuals.

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Abstract N°: 982

Long-term Safety and Efficacy of Ebdarokimab in Patients with Moderate to Severe Plaque Psoriasis: Results from a Single Arm, Open Label, Multicenter Phase III Clinical Study

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Introduction & Objectives:

Interleukin-12 (IL-12) and interleukin-23 (IL-23) are two essential cytokins involved in the immune-mediated inflammatory disorders of psoriasis. Anti-IL-12/IL-23 therapy has been developed for the treatment of psoriasis. AK101 is a fully human monoclonal antibody (mAb) targeting IL-12/IL-23 pathway, and specifically binds to the P40 subunit of both IL-12 and IL-23, resulting in inhibition of the signaling of IL-12 and IL-23 cytokines. This study was aimed to evaluate the long-term safety and efficacy of AK101 in Chinese patients with moderate to severe plaque psoriasis.

Materials & Methods:

A total of 950 subjects with age ≥ 18 years old were planned to enroll. Subjects (group 1) who received AK101 treatment in the previous study (a 16 weeks, double blind, placebo controlled study) continued to receive AK101 in this study. With AK101 135mg at week 16, followed by maintenance treatment every 12 weeks, and follow-up until week 52. Subjects (group 2) from placebo group in the previous study received AK101 135mg at week 16/week 20 in this study, followed by maintenance treatment every 12 weeks, and follow-up until week 52. Subjects who directly participated in this study (group 3) received AK101 135mg treatment at week 0/4. Followed by maintenance treatment every 12 weeks, and follow-up until week 52.

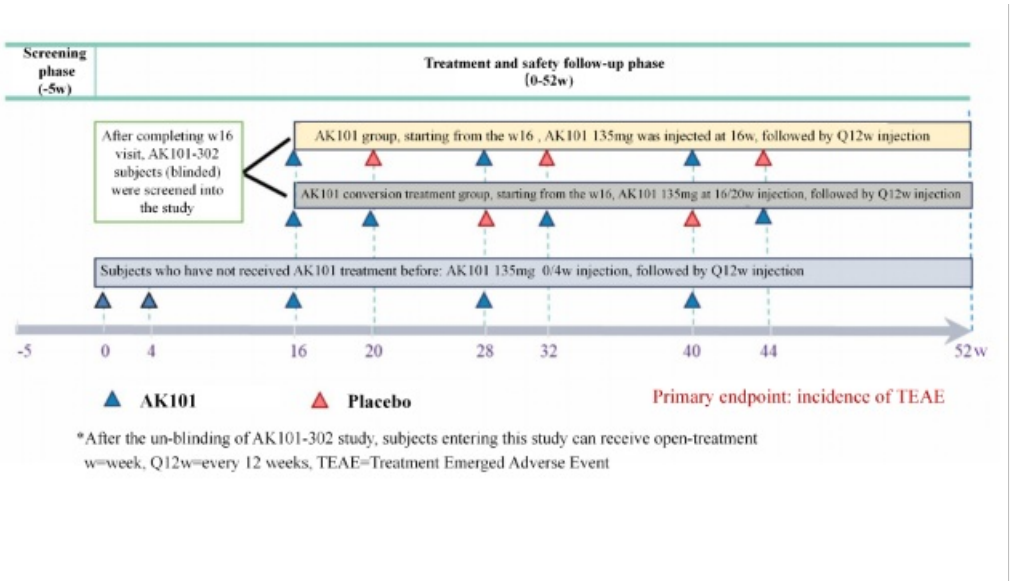

Figure 1 Study design

Results:

Efficacy: The≥75% improvement in Psoriasis Area and Severity Index (PASI75) and
Static Physicians Global Assessment (sPGA) 0/1 response rates of group 1 at week16 were 80.5% and 66.0%,

respectively. The improvement in PASI75 and sPGA0/1 response rates of group 1 subjects were consistently maintained until week 52. After switching to AK101 at week 16, the PASI score of subjects in group 2 decreased. The response rates of PASI75 and sPGA0/1 at week 32 were 81.4% and 71.1%, respectively, the response rates maintained until week 52. The response rates of PASI75 and sPGA0/1 at week 16 of group 3 were 69.5% and 59.1%, respectively, which were consistent with the results from group 1. All subjects were followed up to week 28 at least, and showed a stable long-term efficacy.

Safety: A total of 788 (82.9%) subjects experienced at least one Treatment-Emergent Adverse Event (TEAE), and 314(33.1%) subjects had TEAE related to study drug (TRAE). The incidence of TEAE in group 1 (89.1%) and group 2 (85.6%) was slightly higher than group 3 (79.3%); The incidence of TRAE among different groups is similar. The majority of TEAE/TRAE were classified as mild and moderate. 32(3.4%) subjects experienced Serious Adverse Event (SAE), and 1 (0.1%) death was reported due to traffic accident(unrelated to study drug).

Conclusion:

AK101 was generally safe and well tolerated, with good improvement in PASI 75 and sPGA0/1 response in Chinese subjects with moderate to severe plaque psoriasis.

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Abstract N°: 1013

Adiponectin and risk of psoriasis: Observational and Mendelian randomization studies in up to 900,000 individuals

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Introduction & Objectives:

Psoriasis is a common chronic inflammatory skin disorder often associated with obesity. Adiponectin, an anti-inflammatory protein-hormone produced and secreted by the adipose tissue, may be a link between obesity and psoriasis. We hypothesised that low plasma adiponectin is associated with an increased risk of psoriasis in observational and causal genetic studies.

Materials & Methods:

In observational analyses, we used information on plasma adiponectin and psoriasis in 30,045 individuals from the Copenhagen General Population Study. In one-sample Mendelian randomization analyses, we used genetic information on adiponectin and psoriasis in 107,308 individuals from the Copenhagen General Population Study. In two-sample Mendelian randomization analyses, we used genetic information on adiponectin from the ADIPOGen consortium and genetic information on psoriasis in 373,338 and 462,933 individuals from the FinnGen study and UK Biobank, respectively.

Results:

In observational analyses, a one-unit log-transformed higher plasma adiponectin was associated with hazard ratios for psoriasis of 0.67 (95% confidence interval: 0.48–0.94) in an age and sex adjusted model and 0.95 (0.66–1.35) in a multivariable adjusted model including obesity measures. In genetic one-sample Mendelian randomization analysis, a one-unit log-transformed higher plasma adiponectin was associated with a causal risk ratio for psoriasis of 1.33 (0.77–2.32) in the Copenhagen General Population Study. In genetic two-sample Mendelian randomization analyses, a one-unit log-transformed higher plasma adiponectin was associated with causal risk ratios for psoriasis of 0.96 (0.81–1.14) in FinnGen study and 1.00 (1.00–1.01) in the UK Biobank.

Conclusion:

Low plasma adiponectin is associated with increased risk of psoriasis in age and sex adjusted observational analyses; however, this was not the case after adjustment for obesity measures or in causal genetic analyses.

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Abstract N°: 1014

psoriatic arthritis, previous exposure to a biologic therapy, body mass index and onset of psoriasis young age were independent factors of secukinumab discontinuation in patients with psoriasis

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Introduction & Objectives:

Secukinumab (SEC) is a recombinant fully human monoclonal antibody against interleukin (IL) – 17. The literature comprises limited data on choosing the ideal biologic therapy for each patient with psoriasis (PsO). Therefore, it may be useful to know possible factors that may affect treatment response at the beginning of a treatment. So, the aim of this study was to predict possible factors that may influence SEC discontinuation in patients with PsO. Therefore, when these factors are identified, it can be predicted in which patient the long-term treatment may not be possible for SEC. Here, we aimed to define factors associated with SEC discontinuation.

Materials & Methods:

Retrospective analysis of 109 patients with chronic plaque PsO who initiated treatment with SEC were enrolled. Patients were categorized into two groups according to the presence of continuation or discontinuation of SEC therapy. Comparisons were made between these two patient groups. Sixty-four patients were ongoing SEC treatment for PsO, however in 45 patients SEC treatment was discontinued. The majority of patients discontinued SEC due to secondary lack of efficacy and subsequently adverse effects and emergence of a malign tumor.

Results:

Kaplan - Meier analysis showed that age of disease onset, body mass index (BMI), history of psoriatic arthritis (PsA), gender and previous exposure to biologic therapy was significantly different between the two patient groups ($p=0.027$, $p=0.003$, $p<0.001$, $p=0.02$ and $p<0.001$, respectively; **Table 1**). Cox regression analysis showed that age of disease onset, BMI, history of PsA, previous biologic therapy use increased the risk of SEC discontinuation 3.6 fold and 2.3 fold ($p=0.001$, %95CI:1.7-7.6 and $p=0.032$, %95CI:1.1-5.0, respectively; **Table 2**). Additionally, According to the results of ROC analysis, BMI above 26.5 or age of disease onset below 26.5 significantly reduces SEC survival.($p=0.016$, %95CI: 0.2 – 0.9 and $p=0.004$, %95CI: 1.4 – 6.1; **Table 2**).

Conclusion:

The present study revealed that the history of PsA, previous exposure to biologic therapy, onset of PsO young age and BMI were independent predictors of SEC discontinuation.

Table 1. Comparisons of the study parameters in patient groups exhibiting SEC continuation and SEC discontinuation by Kaplan – Meier analysis

Parameter	SEC continuation (n=64)	SEC discontinuation (n=45)	P value
Age of disease onset, mean (±SD)	27.61 (±12.1)	21.67 (±11.51)	**0.027**
BMI, mean (±SD)	26.63 (±4.5)	29.97 (5.53)	**0.003**
Gender, M/F	35/29	21/24	**0.02**
Smoking status (current smoker/ex-smoker/never smoked)	24/16/24	24/6/15	0.418
History of PsA (present/absent)	18/46	31/14	**<0.001**
Nail involvement (present/absent)	25/39	23/22	0.617
Previous exposure to biologic therapy (present/absent)	24/40	33/12	**<0.001**

SD=Standard deviations; SEC=Secukinumab; BMI=Body Mass Index; M/F=Male/Female; PsA=Psoriatic Arthritis. P<0.05 indicates statistical significance and is shown in bold.

Table 2. Cox regression analysis for variables in patient groups exhibiting SEC continuation and SEC discontinuation.

Variable	HR (95% CI)	P value
Previous exposure to biologic therapy	2.3 (1.4 – 5.1)	**0.012**
History of PsA	3.6 (1.7 - 7.6)	**0.001**
BMI	0.4 (0.2 - 0.9)	**0.016**
Age of Disease Onset	2.9 (1.4 – 6.1)	**0.004**

HR=Hazard Ratio; CI=Confidence Interval; PsA=Psoriatic Arthritis; BMI=Body Mass Index. P<0.05 indicates statistical significance and is shown in bold.

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Abstract N°: 1045

Sutterella wadsworthensis as a hallmark of the gut microbiome in patients with severe psoriasis

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Introduction & Objectives: Intestinal dysbiosis may play a role in immune-mediated diseases. There is growing interest in understanding the influence of the microbiome not only on the etiopathogenesis of psoriasis, but also on therapeutic strategies and potential targets.

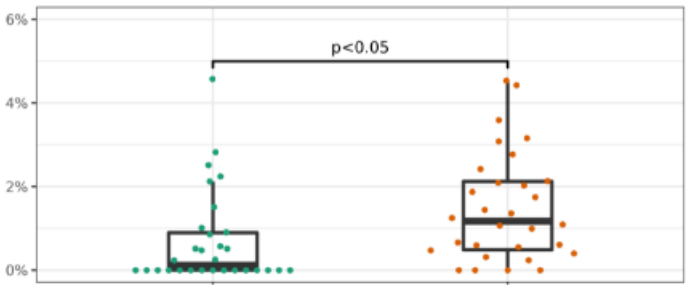
The aim was to compare the intestinal microbiome of patients with severe plaque psoriasis with individuals without psoriasis and without a positive family history in a metropolitan region in South America.

Materials & Methods: 16S rRNA V3/V4 gene sequencing and bioinformatics analyzes were performed with total DNA extracted from stool samples from 30 patients with severe plaque psoriasis and 30 age- and sex-matched controls from the same geographic location. The de novo taxonomic classification was based on similarity, using an algorithm called LCA (lowest common ancestor) to determine the lowest possible taxonomic level.

Results: 60 patients had their intestinal microbiome studied. The groups (30 Pso x 30 Controls) were similar, with no difference in terms of age, sex, comorbidities and body mass index ($p > 0.05$). In terms of alpha diversity (Shannon index), a lower median was observed among patients with psoriasis, but this difference was not statistically significant ($p = 0.16$). On the other hand, beta diversity analysis (Bray-Curtis) showed different clustering of the gut microbiome in severe psoriasis and controls ($p = 0.031$). The Firmicutes/Bacteriodetes ratio was higher in psoriasis ($p = 0.05$). The adjusted differential abundance showed increased expression of the genus Sutterella ($p < 0.01$) and the species Sutterella wadsworthensis ($p < 0.05$) in the psoriasis group (Graphs 1 to 3)

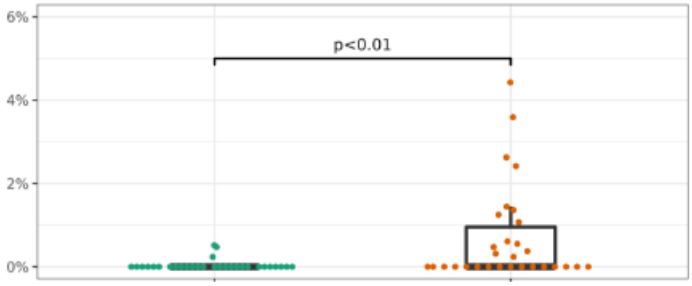
Conclusion: This study shows different compositions of the gut microbiome in patients with severe psoriasis, including overexpression of *Sutterella wadsworthensis*. *Sutterella* has been linked to IBD and appears to play an important role in IgA and intestinal epithelial integrity. This is one of the few studies carried out in this local population and the comparison with the of other publications highlights the heterogeneity of the populations studied. Knowledge of the microbiome brings opportunities for intervention through diet, pre- and probiotics. making it possible to predict the prognosis.

Graph 01: Adjusted differential abundance – Family Sutterellaceae controls x cases ($p < 0.05$)



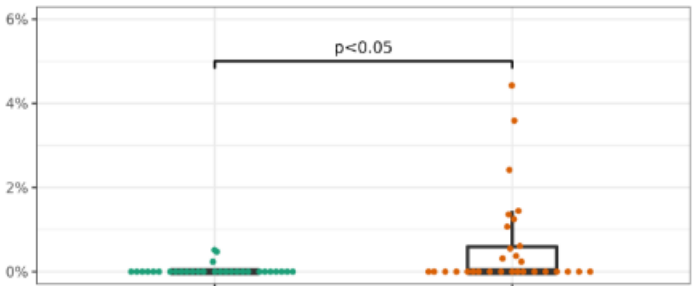
Controls (No psoriasis: green) / Cases (Psoriasis: orange)

Graph 02: Adjusted differential abundance – Genus Sutterella controls x cases ($p < 0.01$)



Controls (No psoriasis: green) / Cases (Psoriasis: orange)

Graph 03: Adjusted differential abundance –Species *Sutterella wadsworthensis* controls x cases **(*p* < 0,05)**



Controls (No psoriasis: green) / Cases (Psoriasis: orange)

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Abstract N°: 1067

Characterization of patients with atopic dermatitis based on flare patterns and severity of disease – a Danish population-based study

Mia-Louise Nielsen[1], Lea Nymand[1], Arnau Domenech[2], Kristian Gaarn Du Jardin[2], Ismail Kasujee[2], Simon Francis Thomsen[1], Alexander Egeberg[1], David Thein[1]

[1]Bispebjerg Hospital, Department of dermatology, Denmark, [2]Almirall

Introduction & Objectives:

Flaring is often observed in patients with atopic dermatitis (AD) but is rarely considered in severity classification or treatment decisions, and yet severe or frequent flares may contribute substantially to the burden of disease.

The objective of this study was to characterize patients with AD based on flare patterns and investigate how flare patterns correlate with disease severity, treatment satisfaction, and quality of life.

Materials & Methods:

The study was based on data from the Danish Skin Cohort and included patients who had active AD and had reported their number of flares within the past 12 months.

Numerical variables were summarized in medians and interquartile ranges (IQRs), while categorical variables were reported as frequencies and percentages.

Differences between strata were evaluated using the chi-squared tests.

Results:

A total of 1557 patients were included, of whom 57 reported 0 flares, 698 reported 1-5 flares, 324 reported 6-10 flares, and 478 reported >10 flares during the past 12 months. Severity measured by the Patient-Oriented Scoring of Atopic Dermatitis (PO-SCORAD) as well as impairment of life quality measured by the Dermatology Life Quality Index (DLQI) were higher among patients with more flares (PO-SCORAD, median (IQR): 13.0 (5.6-22.3), 29.7 (20.8-40.6), 36.3 (26.7-47.6), and 42.9 (30.7-55.6), respectively for the four strata, and DLQI, median (IQR): 1.0 (0.0-2.0), 3.0 (1.0-7.0), 4.0 (1.8-9.0), and 7.0 (3.0-11.0)). Current treatment satisfaction was higher among patients with no flares. However, 36.8%, 24.6%, and 23.7% of patients with 1-5, 6-10, and >10 flares reported being extremely or very satisfied with their current treatment.

Conclusion:

A large number of yearly flares were often accompanied by a higher severity of AD and impairment of life quality compared to a more stable disease course with fewer flares. However, a large proportion of patients with many flares experienced only moderate impairment of life quality and high treatment satisfaction. An improved understanding of flare patterns in AD could benefit clinical decision-making and ensure that flaring is sufficiently accounted for in treatment guidelines, hence decreasing the potential undertreatment of patients with mild AD but severe flaring.

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Abstract N°: 1113

Tapinarof cream (1% daily) in conjunction with a biologic to treat chronic plaque psoriasis

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Introduction & Objectives: Patients with moderate to severe plaque psoriasis do not always respond adequately to biologics alone, necessitating the addition of topical therapy, one example of a combination that can enhance treatment effect. While steroids are most commonly used topically, they have their limitations. Topical tapinarof is a novel, first-in-class, small-molecule, aryl hydrocarbon receptor-modulating agent that downregulates interleukin-17 and normalizes the skin barrier. Data from phase 3 studies demonstrated that tapinarof cream was safe and efficacious and maintained its effect for a median of approximately 4 months after discontinuation (Bagel et al *J Am Acad Dermatol*. 2023;89:936-944; Strober et al *J Am Acad Dermatol*. 2022;87:800-806; Lebwohl et al *N Engl J Med*. 2021;385:2219-2229). The objective of this prospective, open-label, single-center study was to assess the effectiveness, safety, and remittive (or maintenance) effect of tapinarof cream when added to an ongoing biologic therapy in patients with chronic plaque psoriasis.

Materials & Methods: Enrolled males and females (age ≥18 years) with moderate to severe plaque psoriasis (body surface area [BSA] ³3%) who had been receiving a biologic for at least 24 weeks applied tapinarof cream (1%) daily for 12 weeks. Patients were followed up to week 16 to assess a remittive effect after tapinarof was discontinued at week 12. The primary endpoint was the proportion of patients who achieved the National Psoriasis Foundation (NPF) treat to target (TTT) goal of BSA £1% at week 12. Secondary endpoints and quality of life outcomes, as well as safety, were also evaluated.

Results: Thirty patients were enrolled (mean age 55.4 years; 67% male); 20 completed 16 weeks. The biologics patients were concurrently receiving inhibited the activity of IL-23 (63.3%; guselkumab, risankizumab, tildrakizumab), IL-17 (30%; ixekizumab, secukinumab), and IL-17/IL-23 (6.7%; ustekinumab). The proportion of patients reaching the NPF TTT goal of BSA £1% increased over time when topical tapinarof was added to a biologic, to 52.4% at week 12, and was 40% at week 16, 4 weeks after discontinuing tapinarof cream. Mean %BSA and mean scores for physician global assessment (PGA), BSAxPGA, psoriasis area severity index (PASI), dermatology life quality index (DLQI), and worse-itch numeric rating scale (WI-NRS) also improved with tapinarof plus biologic up to week 12 and were maintained until week 16 (**Table**). Few adverse events (AEs), no serious AEs, and no AE discontinuations were reported.

Conclusion: Adding daily tapinarof cream to an existing biologic was tolerable and helped patients achieve the NPF treatment goal. This approach may prevent the need for switching biologics when patients do not respond, preserving the safety and cost associated with their current biologic.

Table: Patient outcomes (mean ± SD) with tapinarof cream plus ongoing biologic at week 12 (combination effect) and week 16 (remittive effect after tapinarof therapy)
Outcome
%BSA
PGA
PGAxBSA
PASI
DLQI
WI-NRS

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Abstract N°: 1135

A Multicenter Randomized Double-blind Vehicle-controlled Parallel Group Phase 2 Study Evaluating the Safety and Efficacy of GN-037 Cream in patients with Mild to Moderate Plaque Psoriasis

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Introduction & Objectives:

Topical therapies including corticosteroids are used in almost all patients with psoriasis for first-line and maintenance treatment as monotherapy or in combination with other agents. However, there is an unmet need to develop novel formulations containing lower concentrations of commonly prescribed highly potent corticosteroids such as clobetasol 17-propionate (CP) to provide a better benefit-risk ratio. Therefore, a novel topical cream combination product (GN-037) with a lower CP concentration (0.036%) together with urea (9.48%), salicylic acid (4.74%) and retinoic acid (0.0012%) was developed with different activities in mind such as moistening, desquamation of lesions and inhibition of skin decolorization. The present multicenter randomized double-blind vehicle-controlled parallel group Phase 2 study (NCT05706870) aimed to investigate the safety and efficacy of GN-037 in patients with mild to moderate plaque psoriasis (MMPP).

Materials & Methods:

Patients (aged 18–65 y) with MMPP for ≥6 mo with 3–12% affected body surface area (BSA), Investigator Global Assessment (IGA) score of 2 or 3, and receiving the last treatment for psoriasis 4 weeks or before at baseline (BL) were eligible. Patients (N=190) randomized (2:2:1 ratio) to receive GN-037 or CP or vehicle (V) cream twice daily

to a selected body target lesion identified at BL for 4 weeks. Primary endpoint was treatment success defined as % of patients with at least 2 grade improvement in IGA score and IGA score equating to 0 or 1 evaluated at weeks 2, 4, 6 and 8 in each arm compared to BL. Other endpoints/assessments included ≥75% improvement in the Psoriasis Area Severity Index (PASI-75) score, improvement in the healing of the target lesion (>50%) and mean changes in BSA compared to BL. Safety and treatment emergent adverse events (TEAEs) were evaluated throughout the study and mean plasma CP concentrations were measured in all patients.

Results:

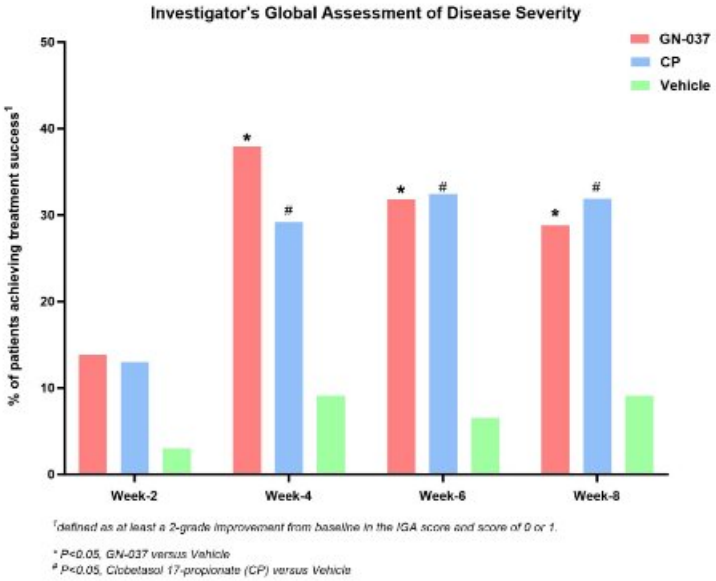
Efficacy assessments were analysed in the per-protocol population at weeks 2, 4, 6 and 8 compared to BL and safety assessments were conducted in the safety population. GN-037 demonstrated statistically significant superiority over vehicle throughout the study. At week 4, treatment success was achieved in 37.9% of patients in GN-037 arm compared with 29.2% and 9.1% in CP (*P*=0.366) and V (*P*=0.006) arms, respectively. GN-037 was also superior to V in reducing the signs of erythema, plaque elevation and scaling. At least 2 grade improvement compared to BL was achieved by 57.6% (erythema, *P*=0.008 vs V), 72.7% (plaque elevation, *P*=0.001 vs V) and 80.3% (scaling, *P*=0.006 vs V) of patients in GN-037 arm. PASI-75 was achieved in 31.8%, 31.9% and 6.1% of patients and mean changes in affected BSA were –2.2, –1.8, and -0.5 in GN-037, CP and V arms, respectively. Plasma CP was detectable only in 5 patients (7.6%) in GN-037 and 2 patients (2.8%) in CP arms. In those patients mean plasma CP concentrations were 129.98 and 124.71 pg/mL in GN-037 and CP arms, respectively. TEAEs were similar among the arms and most frequent observed TEAEs were PASI increase in all arms (5.5% in GN-037, 7.2% in CP and 7.5% in V arms). Skin reactions were rare in all arms and skin atrophy was not observed.

Conclusion:

GN-037 was more effective than V in achieving primary and secondary end points at week 4. Safety data did not reveal any new safety concerns with the combination cream product. Therefore, 4 weeks of GN-037 treatment demonstrated an excellent efficacy and safety profile in patients with MMPP. **

Table 1. Summary of Baseline Characteristics

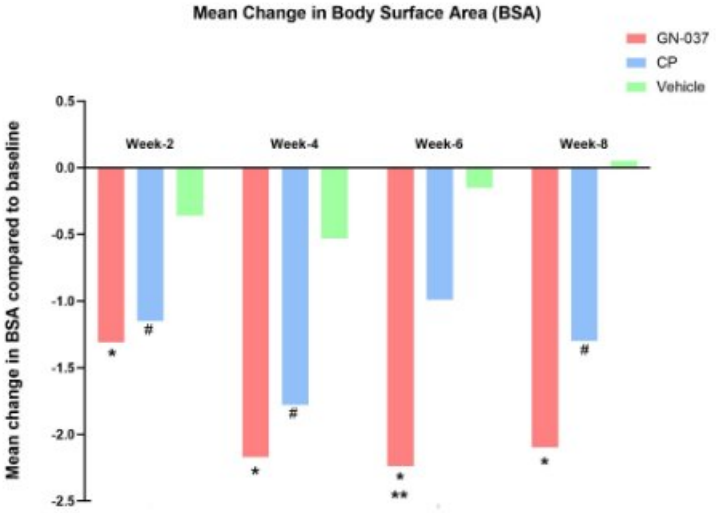
Variables	GN-037 (n=66)	Clobetasol 17-propionate (n=72)	Vehicle (n=33)
IGA, n (%)			
2-Mild	31 (47.0)	30 (41.7)	16 (48.5)
3-Moderate	35 (53.0)	42 (58.3)	17 (51.5)
% BSA affected by psoriasis			
Median	5	5.5	5
Range	3-12	3-12	3-12
Size of target lesion (cm^2)			
Median	22	20.5	20
Range	16-100	16-100	16-80
Age (years)			
Median	41	39	41
Range	20-63	20-64	18-64
Gender, n (%)			
Female	31 (47.0)	27 (37.5)	14 (42.4)
Male	35 (53.0)	45 (62.5)	19 (57.6)



[1]defined as at least a 2-grade improvement from baseline in the IGA score and score of 0 or 1.

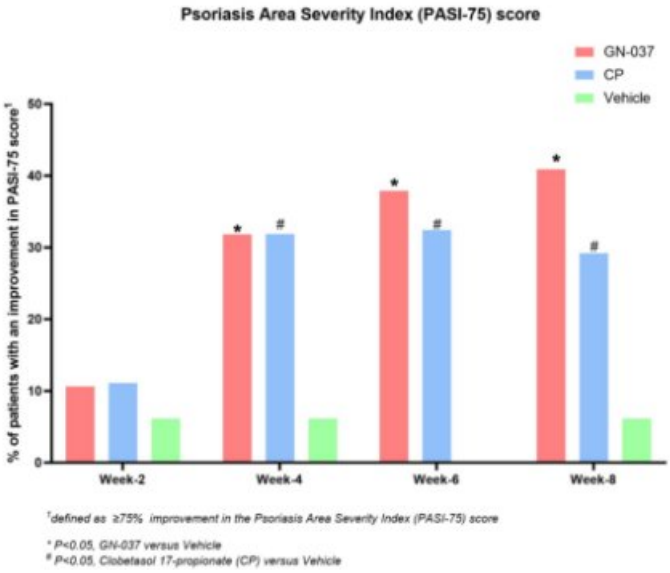
* P<0.05, GN-037 versus Vehicle
# P<0.05, Clobetasol 17-propionate (CP) versus Vehicle

Figure 1. Treatment success in Investigator's Global Assessment of Disease Severity



* P<0.05, GN-037 versus Vehicle
# P<0.05, Clobetasol 17-propionate (CP) versus Vehicle
**P<0.05, GN-037 versus CP

Figure 2. Mean Change in Body Surface Area (BSA)



[1]defined as ≥75% improvement in the Psoriasis Area Severity Index (PASI-75) score

* P<0.05, GN-037 versus Vehicle
# P<0.05, Clobetasol 17-propionate (CP) versus Vehicle

Figure 3. Improvement in Psoriasis Area Severity Index (PASI-75) Score

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Abstract N°: 1186

A 52-week real-life experience of risankizumab in Turkish patients with chronic plaque psoriasis: a single centre, retrospective study

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Introduction & Objectives: The observations on the short- and long-term efficacy and safety of risankizumab in Turkish patients with psoriasis are limited.

Materials & Methods: Patients with chronic plaque psoriasis who were treated with risankizumab for at least 16 weeks were enrolled. The demographic and clinical characteristics of the patients, previous therapies, psoriasis area severity index (PASI) at baseline, PASI90 and PASI100 responses, Physician's General Assessment (PGA) scores at 4th, 16th, and 52nd weeks were retrospectively recorded.**

Results: Of the patients, 26 (55.3%) were female and 21 (44.7%) were male. The mean age was 46.5±12.8 years (range: 20-72). Twenty-three (48.9%) of the patients were bio-naïve, 24 (51.1%) were bio-experienced, and 15 (31.9) were obese. The baseline median PASI was 9.2. Twenty-nine patients (61.7%) completed 52 weeks of treatment. The percent of PASI90/PASI100/PGA0 responses at the 4th, 16th and 52nd weeks were 19.4/13.9/13.9; 76.6/70.2/68.1; 86.2/72.4/72.4, respectively. The median week of total clearance of psoriasis was week 12. While the 16th-week PASI values of bio-naive patients were significantly lower than those of bio-experienced patients (p=0.008), there was no difference in regard of PASI values at the baseline, 4th, and 52nd weeks (p>0.05). The PASI100 and PGA0 responses of bio-naive patients at week 16 were significantly higher than those of bio-experienced patients (p values: 0.014; 0.007, respectively); however, the values of 4th and 52nd-weeks were not different between the two groups (p>0.05). PASI values, PASI90, PASI100, and PGA0 responses at baseline, 4th, 16th, and 52nd weeks did not significantly differ between obese and non-obese patients (all p>0.05).**

Conclusion: Risankizumab efficiently and safely treated patients with chronic plaque psoriasis within 52 weeks. Although efficacy appears to favour bio-naive patients at week 16, the 52-week treatment provides similar efficacy regardless of whether the patient is bio-naive or bio-experienced.

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Abstract N°: 1266

Treatment Satisfaction Across Different Therapeutic Modalities of Filipino Patients with Moderate-to-Severe Plaque-Type Psoriasis in a Tertiary Government Hospital: A Cross-Sectional Study

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Introduction & Objectives:

Psoriasis is a chronic, inflammatory skin disease that affects a multitude of people worldwide. The objective of this study was to measure the treatment satisfaction, medication adherence, and dermatological quality of life of Filipino patients treated with topical medications, phototherapy, and systemic agents for plaque-type psoriasis.

Materials & Methods:

A survey questionnaire composed of the Treatment Satisfaction Questionnaire for Medications (TSQM 1.4), Morisky Medication Adherence Scale-4 (MMAS), and Psoriasis Disability Index (PDI) was completed by patients with moderate to severe plaque-type psoriasis in a tertiary dermatology outpatient clinic. Measured domains of satisfaction included effectiveness, side effects, convenience, and global satisfaction. Objective measure of disease severity was assessed using the Psoriasis Area Severity Index (PASI).

Results:

Results showed moderate to high levels of treatment satisfaction, medium level of medication adherence, and minimal impairment of quality of life across all treatment modalities. A significant correlation was found between convenience satisfaction scores and educational attainment. Satisfaction for effectiveness and convenience were significantly correlated with medication adherence. Global satisfaction scores significantly correlated with disease severity. Satisfaction with side effects had a significant correlation with quality of life.

Conclusion:

These findings highlight the continuing role of all three treatment modalities in the treatment of psoriasis in a low-resource setting. Giving close attention to medication side effects, regimen convenience, and the impact these have on quality of life can help foster a more patient-centered approach to management.

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Abstract N°: 1380

Deucravacitinib in plaque psoriasis: 4-year safety and efficacy results from the phase 3 POETYK PSO-1, PSO-2, and LTE trials

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Introduction & Objectives:

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was superior to placebo and apremilast in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) parent trials in moderate to severe plaque psoriasis. Upon completion of these trials, patients could enroll in the ongoing POETYK long-term extension (LTE) (NCT04036435) trial. As previously reported, patients treated with deucravacitinib maintained long-term efficacy responses through 3 years with no new safety signals versus Year 2. Here, we report safety and efficacy of deucravacitinib for an additional year through 4 years (Week 208; cutoff date of November 1, 2023).

Materials & Methods:

PSO-1 and PSO-2 randomized patients 1:2:1 to oral placebo, deucravacitinib 6 mg once daily (QD), or apremilast 30 mg twice daily. At Week 52, patients enrolled in the LTE trial received open-label deucravacitinib 6 mg QD. Safety was evaluated in patients who received ≥1 dose of deucravacitinib. Exposure-adjusted incidence rate (EAIR) per 100 person-years (PY) was calculated as 100*(# of patients with an adverse event [AE])/(total exposure time for all patients at risk [time to initial AE occurrence for patients with AE+total exposure time for patients without AE]). Efficacy outcomes included ≥75%/≥90% reduction from baseline in Psoriasis Area and Severity Index (PASI 75/90) and static Physician Global Assessment score of 0 (clear) or 1 (almost clear) (sPGA 0/1). Efficacy was analyzed as previously reported using modified nonresponder imputation (mNRI) in patients who received continuous deucravacitinib treatment from Day 1 of the parent trial and were enrolled and treated in the LTE trial. As-observed data and results by treatment failure rules imputation were also analyzed.

Results:

A total of 1519 patients received ≥1 dose of deucravacitinib, with cumulative exposure from parent trial randomization of 4392.8 PY. EAIRs/100 PY were decreased or comparable from the 1-year to 4-year cumulative period, respectively, for AEs (229.2, 131.7), serious AEs (5.7, 5.0), deaths (0.2, 0.3), discontinuation due to AEs (4.4, 2.2), herpes zoster (0.8, 0.6), malignancies (1.0, 0.9), major adverse cardiovascular events (0.3, 0.3), and venous thromboembolism (0.2, 0.1). In patients receiving continuous deucravacitinib treatment as described above (n = 513), clinical response rates were maintained from Year 3 (PASI 75, 73.8% [95% CI, 69.6, 78.0]; PASI 90, 49.0% [95% CI, 44.4, 53.7]; sPGA 0/1, 55.2% [95% CI, 50.5, 59.9]) to Year 4 (PASI 75, 71.7% [95% CI, 67.0, 76.3]; PASI 90, 47.5% [95% CI, 42.6, 52.4]; sPGA 0/1, 57.2% [95% CI, 52.1, 62.2]) by mNRI, with similar results with other data imputation methodology.

Conclusion:

Deucravacitinib demonstrated a consistent safety profile through 4 years with that at 3 years, which was reported earlier, with no emergence of new or long-term safety signals. Efficacy was maintained through 4 years in patients treated continuously with deucravacitinib from Day 1 in the POETYK PSO-1/PSO-2 trials. These data support the long-term safety and durable efficacy profile through 4 years of treatment with deucravacitinib, a first-in-class TYK2 inhibitor treatment for psoriasis.

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Abstract N°: 1402

Deucravacitinib efficacy in special areas of scalp, fingernails, and palms/soles in plaque psoriasis: results from a phase 3 trial

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Introduction & Objectives:

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was significantly more efficacious than placebo and apremilast in two global, 52-week, phase 3 trials, and maintained long-term efficacy through 2 years with no new safety signals in an ongoing long-term extension (LTE) trial. This study was designed to evaluate the efficacy of deucravacitinib 6 mg once daily through Week 52 in patients with scalp, fingernail, and palmoplantar involvement at baseline of any severity, including limited involvement, in the phase 3 POETYK PSO-1 trial (NCT03624127) in patients with moderate to severe plaque psoriasis.

Materials & Methods:

The analysis included patients from this trial who either (1) received continuous deucravacitinib from Day 1 through Week 52 or (2) were randomized to placebo at Day 1 and crossed over to deucravacitinib at Week 16. Efficacy outcomes for scalp (Psoriasis Scalp Severity Index [PSSI]), fingernail (modified Nail Psoriasis Severity Index [mNAPSI]), and palmoplantar (palmoplantar Psoriasis Area and Severity Index [pp-PASI]) areas were performed separately by Physician Global Assessment scores of 1 or 2 (limited involvement) or ≥1 (1-4) in the respective body areas at baseline. The Clopper-Pearson method was used to calculate 95% confidence intervals. Nonresponder imputation was used to impute missing data.

Results:

Baseline patient demographics and clinical characteristics were generally similar between the limited versus any involvement subgroups, respectively, in scalp (n=110 vs n=440, respectively), fingernail (n=117 vs n=194), and palmoplantar (n=35 vs n=61) areas. Response rates at Week 16 in scalp, fingernail, and palmoplantar areas of involvement were greater in patients receiving deucravacitinib treatment than in patients receiving placebo through Week 16, regardless of extent of baseline involvement in the respective special areas (**Table**). Response rates at Week 52 were maintained with deucravacitinib in patients who received continuous deucravacitinib treatment and were improved in patients who crossed over from placebo to deucravacitinib at Week 16 in both subgroups (**Table**). At Week 52, patients who crossed over from placebo to deucravacitinib achieved response rates similar to those who received continuous deucravacitinib treatment, regardless of extent of baseline involvement in these special areas.

Conclusion:

Deucravacitinib maintained clinical efficacy through 52 weeks in patients with scalp, fingernail, and palmoplantar psoriasis, regardless of extent of involvement in these areas at baseline. These findings further support the use of

deucravacitinib for treatment of the hard-to-treat special areas, specifically the scalp, fingernail, and palmoplantar areas, in patients with plaque psoriasis.

Table. Efficacy outcomes at Week 16 and Week 52 (NRI)

Response rate, % of patients[a] (95% CI)	Continuous deucravacitinib		Placebo to deucravacitinib	
	Baseline score 1 or 2	Baseline score ≥1	Baseline score 1 or 2	Baseline score ≥1
Scalp	n=79	n=288	n=31	n=152
PSSI 75				
Week 16	60.8 (49.1-71.6)	67.7 (62.0-73.1)	22.6 (9.6-41.1)[b]	19.7 (13.7-27.0)[b]
Week 52	65.8 (54.3-76.1)	68.1 (62.3-73.4)	67.7 (48.6-83.3)[c]	70.4 (62.5-77.5)[c]
PSSI 90				
Week 16	55.7 (44.1-66.9)	57.3 (51.4-63.1)	19.4 (7.5-37.5)[b]	13.2 (8.2-19.6)[b]
Week 52	60.8 (49.1-71.6)	59.4 (53.5-65.1)	61.3 (42.2-78.2)[c]	58.6 (50.3-66.5)[c]
Fingernail	n=82	n=125	n=35	n=69
mNAPSI 75				
Week 16	18.3 (10.6-28.4)	18.4 (12.0-26.3)	8.6 (1.8-23.1)[b]	8.7 (3.3-18.0)[b]
Week 52	40.2 (29.6-51.7)	37.6 (29.1-46.7)	34.3 (19.1-52.2)[c]	31.9 (21.2-44.2)[c]
Palmoplantar	n=22	n=40	n=13	n=21
pp-PASI 75				
Week 16	63.6 (40.7-82.8)	62.5 (45.8-77.3)	7.7 (0.2-36.0)[b]	14.3 (3.0-36.3)[b]
Week 52	72.7 (49.8-89.3)	70.0 (53.5-83.4)	46.2 (19.2-74.9)[c]	52.4 (29.8–74.3)[c]

[a]Patients from POETYK PSO-1 who were randomized to and received continuous deucravacitinib treatment from Day 1 or who were randomized to placebo and crossed over from placebo to deucravacitinib at Week 16. [b]Response rate in placebo-randomized patients at Week 16 prior to crossing over to deucravacitinib treatment. [c]Response rate after crossover to deucravacitinib treatment at Week 16. CI, confidence interval; PSSI 75/90, ≥75%/≥90% reduction from baseline in Psoriasis Scalp Severity Index; mNAPSI 75, ≥75% reduction from baseline in modified Nail Psoriasis Severity Index; NRI, nonresponder imputation; pp-PASI 75, ≥75% reduction from baseline in palmoplantar Psoriasis Area and Severity Index.

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Abstract N°: 1406

Paradoxical arthritis induced by IL-17A antagonist in a patient with plaque psoriasis.

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Introduction & Objectives:

Psoriasis is a chronic inflammatory disorder that involves skin and joints. Its therapeutic arsenal as immunobiologicals which have a substantial impact on the disease. Secukinumab, an inhibitor of interleukin fraction A (IL-17A), has demonstrated remarkable efficacy in psoriasis, however it is possible that there may be the presentation of paradoxical reactions. We define a paradoxical reaction to an immunobiological, when a medication that is indicated to treat a certain disease, when used for another conditoin, can trigger that disease. We aim to report a case of a patient who developed inflammatory arthritis after starting therapy with secukinumab, diagnosed as paradoxical arthritis (PsA).

Materials & Methods:

We present a 33-year-old woman with severe plaque psoriasis without comorbidities. Treatment with methotrexate was initiated at 14 years old, with a loss of response after the 24th month. We transitioned to etanercept, with a good response for 8 years, followed by recurrence of lesions Afterward, a loss of clinical response prompted the initiation of secukinumab, achieving a PASI 90 response by the 8th week. By the 26th week, she began experiencing joint pain, primarily in the fingers, accompanied by morning stiffness lasting approximately 2 hours. Based on imaging and clinical findings, a diagnosis of paradoxical psoriatic arthritis with secukinumab was established. Subsequently, secukinumab was discontinued, and adalimumab was initiated, resulting in complete resolution of arthralgia after 12 weeks. Currently, the patient maintains a PASI score of 0 with no joint pain.

Results:

With the advancement of targeted therapies, paradoxical reactions have been increasingly reported, with cytokine imbalances induced by drugs being postulated as a potential mechanism. In the case of psoriasis, anti-TNF drugs are most commonly associated with paradoxical reactions. Paradoxical reactions induced by immunobiologicals commonly manifest as psoriasis and paradoxical arthritis. Although limited studies relate secukinumab to the development of PsA, it is postulated that the intestinal microbiota may play a role in joint inflammation and bone remodeling in psoriatic disease Given that IL-17 inhibitors directly impact the intestinal microbiota composition, this mechanism may contribute to triggering PsA, in addition to the well-established mechanism of IL-17 action on TNF levels.

Differentiating between inadequate and true paradoxical reactions, such as the onset or exacerbation of PsA, can be challenging. Recent studies suggest that early-onset arthritis likely results from cytokine imbalances induced by medication, while late-onset cases may stem from reduced efficacy of the biological agent at the joint level, preventing its clinical expression. A review described paradoxical PsA in a psoriasis patients treated with ustekinumab ranging from 3 days to 28 months since the onset of the medication. Despite the different mechanism of action of the drug in our case, the concept remains the same; thus, we believe it represents a paradoxical reaction due to proposed mechanisms and the drug’s known action in improving joint symptoms.

Conclusion:

Overall, this case underscores the importance of vigilance for paradoxical reactions in patients receiving immunobiological therapy for psoriasis and highlights the need for further research to better understand the mechanisms underlying these phenomena, specially with Secuquinumab.

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Abstract N°: 1429

Efficacy and safety of SYHX1901 in moderate-to-severe plaque psoriasis: a multicenter, randomized, double-blinded, placebo-controlled, phase 2 trial

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Introduction & Objectives:

SYHX1901 is an oral, high-efficiency JAK/TYK2 inhibitor under investigation for treatment of multiple immune-mediated inflammatory diseases. Here we presented the efficacy and safety of SYHX1901 in moderate-to-severe plaque psoriasis in a phase 2 study.

Materials & Methods:

This study enrolled adults (aged 18–75 years) with moderate-to-severe plaque psoriasis, defined as psoriasis involving ≥10% of the body surface area (BSA), a psoriasis area and severity index (PASI) score ≥12 and a static physician global assessment (sPGA) score ≥3. Patients had to be diagnosed with plaque psoriasis at least 6 months prior to screening. Patients were randomized (1:1:1:1) to placebo or SYHX1901 60 mg, 90 mg, or 180 mg orally once a day for 12 weeks. Randomization was stratified by previous biologic use (yes/no). The primary efficacy endpoint was the proportion of patients with a 75% reduction in PASI score from baseline (PASI 75 response) at week 12. Secondary endpoints were other efficacy outcomes including the proportion of subjects who achieved PASI 50, PASI 90, sPGA of 0 or 1, dermatology life quality index (DLQI) of 0 or 1, and PASI improvement at each visit, adverse event (AE), as well as pharmacokinetic profiles.

Results:

A total of 135 patients were screened and 93 patients were randomly assigned to treatment with placebo (n=23), SYHX1901 60 mg (n=23), 90 mg (n=23) and 180 mg (n=24) and received at least one dose of treatment. Baseline disease characteristics were similar across all four groups, with mean (SD) PASI score of 20.39 (8.7) and mean BSA involvement of 31.95% (15.57). 29% of patients had a sPGA score of 4.

At week 12, significantly greater proportion of patients achieved PASI 75 in SYHX1901 60 mg group (47.8%), 90 mg group (52.2%) and 180 mg group (54.2%) than in the placebo group (4.3%, all p value < 0.05), with

percentage difference versus placebo of 43.77% (95% CI 21.58, 65.96) for SYHX1901 60 mg group, 46.55% (95% CI 24.46, 68.64) for 90 mg group and 49.78% (95% CI 28.19, 71.38) for 180 mg group. Superiority of SYHX1901 versus placebo was also achieved for PASI 50 at week 12 (69.6%, 60.9% and 83.3% versus 13.0%, *p* value <0.01). The proportions who achieved the PASI 90, sPGA of 0 or 1 and DLQI of 0 or 1 at week 12 were numerically higher with SYHX1901 versus placebo (13.0%, 30.4% and 25.0% versus 0% for PASI 90; 8.7%, 30.4% and 33.3% versus 0% for sPGA of 0 or 1; 26.1%, 34.8% and 29.2% versus 8.7% for DLQI of 0 or 1).

Overall treatment emergent AEs (TEAEs) rate was 65.2%, 73.9%, and 87.5% for SYHX1901 60 mg, 90 mg, and 180 mg group, compared with 82.6% for placebo group. Most TEAEs were grade 1-2, only three patients (two in 60 mg group and one in 90 mg group) experienced grade 3 TEAEs and all resolved after medical intervention. Upper respiratory tract infection, nasopharyngitis, hyperlipidemia and palpitation were more common in SYHX1901 group than in placebo group. No herpes zoster, tuberculosis, opportunistic infection, cardiovascular events were observed.

Conclusion:

Data from this phase II study indicate that SYHX1901 is well tolerated and efficacious in the treatment of moderate-to-severe plaque psoriasis. Further studies with large sample and long-term treatment are warranted to validate the findings.

ClinicalTrials.gov Identifier: NCT05858047

Figure 1. Proportions of patients achieving PASI 75 over time in the SYHX1901 60 mg (*n*=23), 90 mg (*n*=23), 180 mg (*n*=24) and placebo (*n*=23) groups. PASI, psoriasis area and severity index.

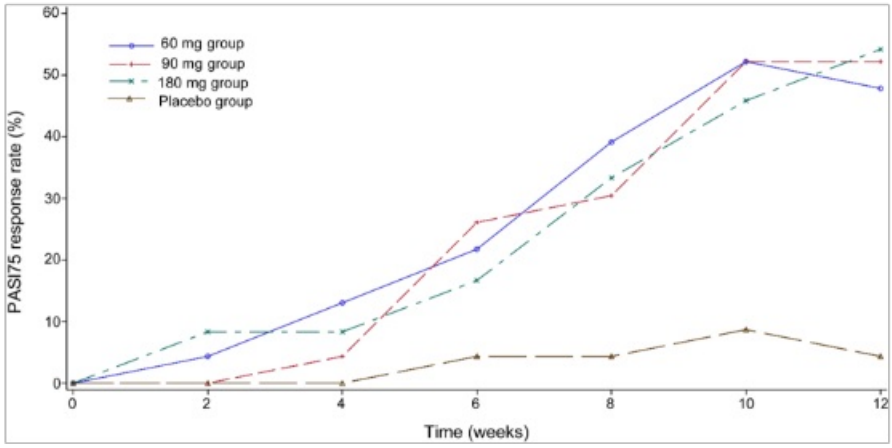
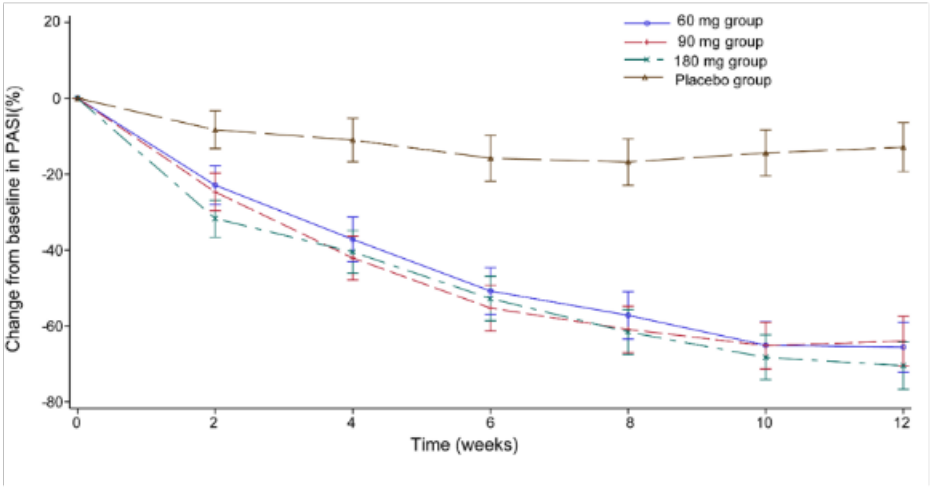


Figure 2. Change from baseline in PASI over time in the SYHX1901 60 mg (*n*=23), 90 mg (*n*=23), 180 mg (*n*=24) and placebo (*n*=23) groups. PASI, psoriasis area and severity index.



EADV CONGRESS
AMSTERDAM 25-28 SEPTEMBER 2024
EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 1458

Severity of psoriasis in patients with psoriatic arthritis treated with the Treat-to-Target strategy: data from long-term follow-up

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Introduction & Objectives: The main principles of the Treat-to-target (T2T) strategy are presented in the EULAR guidelines for the treatment and management of patients (pts) with psoriatic arthritis (PsA). The goal of PsA therapy is to achieve remission and/or minimal disease activity (MDA). The aim of the study is to assess the severity of skin and nail psoriasis in PsA pts treated with the T2T strategy.

Materials & Methods: This study assessed 53 (M/F–25/28) PsA pts fulfilling CASPAR criteria, who were treated according to T2T at the early stage within 24 mos. Mean age 45±12 yrs, median (Me) PsA duration 90 [72;99] month (mos), psoriasis Me 132 [96,180] mos, Me follow-up 81 [61;91] mos. During 24 mos of T2T strategy all pts were taking Methotrexate (MTX) monotherapy at a dose of 20-25 mg/wk, if remission or MDA was not achieved after 3-6 mos, combined therapy with MT+biological DMARDs was added. When T2T study was stopped all pts were treated according to the standard care based on a PsA activity. At baseline, at 24 mos of T2T and after 5 yrs from ending T2T study (7 yrs follow-up) all pts underwent standard clinical examination, including skin psoriasis by BSA (%) assessment, presence of nail psoriasis, DAPSA activity index for PsA. M±SD, Me [Q25; Q75] were performed. Changes were analyzed with the Wilcoxon Signed Rank Test. All $p<0.05$, were considered to indicate statistical significance.

Results: At baseline, Me DAPSA activity was 29.3 [24,3;36], after 2 yrs of treatment with T2T, a significant improvement in activity was revealed - Me DAPSA 24 mos T2T 4 [0.7;21] (Wilcoxon, p=0,000). After 7 yrs follow-up Me DAPSA 10.8 [2,7;21] (Wilcoxon, p=0.000). Assessment of psoriasis skin lesions: at baseline Me BSA was 1,5 [0,5;5], 64,1% (34) pts had mild psoriasis severity (BSA ≤ 3%). At 24 mos of treated with T2T Me BSA was 0,5 [0;2] (Wilcoxon, p-value <0.05). After 7 yrs follow-up 75,5% (40) pts had mild psoriasis severity (BSA ≤ 3%), Me BSA 1 [0,2;4]. There were no significant differences in the assessment of BSA after 7 years of follow-up in comparison with the baseline (Wilcoxon, p=0,5). Wilcoxon signed-rank test showed significant change in evaluation of the presence of nail psoriasis: at baseline was revealed in 69,8% (37) pts and at 24 mos T2T 34% (18) pts, p=0,000. At 7 yrs follow-up nail psoriasis was detected in 64,2% (34) pts and there was no significant difference in comparison with the baseline, p=0,5.

Conclusion: Treatment according to the T2T strategy showed good results in pts with PsA in disease activity in the long term. However, skin and nail lesions with psoriasis showed no improvement at long-term follow-up, after more than 7 years of PsA. Improvement in psoriasis was noted only during the first 2 years of regular follow-up and treatment, according to the basic principles of the T2T strategy and after switching from T2T treatment to the standard care, psoriasis damage to the skin and nails increases.

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Abstract N°: 1459

analysis of leukocytogram parameters and biochemical parameters in patients with severe psoriasis

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Introduction & Objectives: to analyze laboratory abnormalities depending on the severity of the course of psoriasis.

Materials & Methods: 168 (100%) patients with Psoriasis(Ps) 122 (72.6%) men and 46 (27.3%) women. Only skin manifestations of Ps were in 139 (82.7%), out of 168 patients, psoriatic arthritis (PsA) was registered in 29 (17.2%) out of 168.

Results: The analysis of laboratory data revealed in the general clinical analysis of blood in patients with only skin manifestations of psoriasis, the mean value of the leukocyte level is 10.5 ± 3.5., The level of eosinophils is 2.9 ± 2.27., The level of neutrophils is 60.9 ± 71.2., Lymphocytes 27.9 ± 8.8., Erythrocytes 4.6 ± 0.5., Platelets 255.8 ± 62.6., Hemoglobin 142.0 ± 13.0 and erythrocyte sedimentation rate (ESR) -14.2 ± 10.4.

When analyzing laboratory data in the biochemical blood test, the average ALT value was 24.7 ± 13.0., AST 22.3 ± 7.3., Bilirubin 13.2 ± 4.6., Total protein 71.3 ± 8, 5., urea 4.6 ± 1.5., Glucose 5.7 ± 1.1.

When analyzing laboratory data in the general clinical analysis of blood in patients with established psoriatic arthritis, the following was revealed: the average value of the leukocyte level is 11.5 ± 3.5., The level of eosinophils is 3.0 ± 2.2., The neutrophil level is 60.2 ± 19, 1., lymphocytes 28.4 ± 8.8., Erythrocytes 4.6 ± 0.5., Platelets 255.3 ± 63.0., Hemoglobin 142.3 ± 12.87., And erythrocyte sedimentation rate (ESR) 20.2 ± 10.3.

The analysis of laboratory data in the biochemical blood test revealed an average ALT value of 24.4 ± 13.1., AST 22.6 ± 7.4., Bilirubin 13.4 ± 4.6., Total protein -71.5 ± 8, 8., urea -4.6 ± 1.5., Glucose-5.7 ± 1.0.

Conclusion: the level of leukocytes, eosinophils, platelets, erythrocytes, neutrophils, lymphocytes in all 168 (100%) patients was in the normal range. The level of hemoglobin, leukocytes and ESR was usually normal or higher than normal. We found that in almost all patients there are rather high (upper normal) indices for hemoglobin, leukocytes and ESR. It is likely that in psoriasis erythropoiesis is stimulated and a systemic inflammatory response is noted. Also, high (upper limits of the norm) were also revealed by the biochemical parameters of ALT, AST, blood glucose levels, which reliably reveals metabolic risks in patients with psoriasis.

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Abstract N°: 1462

Study on the effectiveness and safety of Interleukin-17 inhibitor and Interleukin-23 inhibitor treatments for psoriasis

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[1]Hacettepe Hastanesi, Türkiye, [2]Yüksekova, Yüksekova, Türkiye

Introduction & Objectives:

Biological therapies are utilized in the treatment of patients with moderate to severe plaque psoriasis(PsO), unstable PsO, and psoriatic arthritis(PsA) who don't respond to conventional systemic treatments, for whom these treatments are contraindicated, or aren't tolerated. Biological agents used to treat PsO include TNF inhibitors(inh), IL-12/23 inh, IL-17 inh, and more recently, IL-23 inh. The aim of our study is to evaluate the effectiveness and reliability of the treatments being used in PsO patients who are taking IL-17 and/or IL-23 inh in real-world settings.

Materials & Methods:

Our study included patients diagnosed with PsO who have been using IL-17 and/or IL-23 inh treatments for at least 1 year between the dates of Nov 1, 2021, and Aug 1, 2023, in our clinic. The Psoriasis Area Severity Index(PASI) and body surface area(BSA) calculations were conducted for patients at the beginning of the study, after 3 months, and at the 1-year mark.

Results:

A total of 32 patients with PsO, including 16 males(50%) and 16 females(50%) with an average age of 43.75, were included in our study. The patients' ages ranged from 23 to 69. Eight patients(25%) were being treated with Ixekizumab(IXE), eight patients(25%) were receiving Secukinumab(SEK), six patients(18.8%) were receiving Risankizumab(RIS), and ten patients(31.3%) were receiving Guselkumab(GUS) treatments. Additionally, twelve patients(37.5%) had a diagnosis of PsA.

The average PASI score at the beginning of treatment and at the 1-year follow-up for patients was 11.46 and 0.69, respectively, while the average VYA score was 16% and 1.2%. Among the patients who achieved a PASI 100 response, 2(12.5%) were active smokers. In contrast, among the 16 patients who did not achieve a PASI 100 response, 11(68.7%) were active smokers. A statistically significant relationship was discovered between PASI response and pack-years of smoking($p<0.001$).

There is a statistically significant relationship was found between PASI response and previous use of an IL-17 inh ($p=0.008$). Patients who had not previously used an IL-17 inh showed a significantly better response to PASI compared to patients who had used it in the study. A statistically significant relationship was found between body mass index(BMI) and PASI response which was higher in the low and normal weight categories compared to the overweight categories($p=0.038$). No significant relationship was found between PASI response and gender($p=1$), presence of PsA($p=0.216$), or duration of PsO disease($p=0.200$).

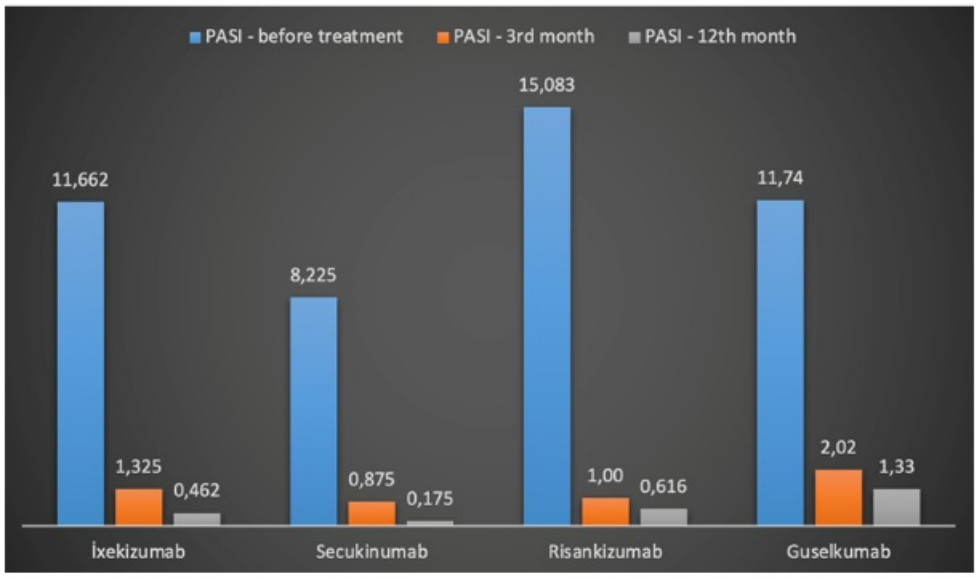
At the beginning of treatment and within the first year, the average PASI scores table is shown in Table 1. In terms of treatment continuity and safety, the treatment of one patient was discontinued due to anti-HIV positivity while receiving SEK, another patient switched to IXE treatment in the 9th month of RIS treatment due to secondary unresponsiveness. Despite these changes for those two patients, the remaining 32 patients in our study continued

with their medications without any safety issues that required treatment discontinuation.

Conclusion:

In our study, IL-23 inh have been found to be effective and safe, similar to IL-17 inh. In our clinic, the treatment that has been found to be most effective in terms of PASI response and PASI involvement in real-life data of patients followed and treated is evaluated as SEC in terms of treatment responses in the first year, followed by IXE, RIS, and GUS treatments respectively.

Table 1:Average PASI values and drugs



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Abstract N°: 1463

A novel Fatty Acid Binding Protein 5 (FABP5) inhibitor shows efficacy in preclinical models of psoriasis

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Introduction & Objectives:

Fatty acid-binding protein (FABP) 5, also known as epidermal FABP, was first discovered in psoriatic lesions (Madsen et al., 1992). FABP5 regulates keratinocyte homeostasis, and is upregulated in psoriasis tissue (Takahashi-Shishido et al., 2021). Knock-out of FABP5 is beneficial in preclinical psoriasis models (Dallaglio et al., 2013). Our aim was to assess whether Artelo's novel oral FABP5 inhibitor ART26.12 is efficacious in psoriasis.

Materials & Methods:

In vitro, recombinant human epidermis was stressed with a cytokine mix (IL17, IL22, and TNFalpha) co-administered with vehicle, a JAK1 inhibitor I (CAS-No 457081-03-7; 10 μM), or ART26.12 (1, 3, or 10 μM) for 48 hrs. Change in the mRNA levels of 64 relevant genes were compared against two housekeeping genes. *In vivo*, male Balb/C mice were given either vehicle, BMS-986165 (Deucravacitinib, tyrosine kinase 2 inhibitor) (10 mg/kg p.o. QD), or ART26.12 (25 or 100 mg/kg p.o. BID) for two days prior to application of imiquimod (IMQ, 62.5 mg of a 5% cream for 7 days on their back), and throughout IMQ treatment.

Results:

In vitro, the cytokine mix upregulated genes related to innate immunity (eg DEFB4A, S100A7) and cytokine markers (especially IL8), as well as reducing differentiation markers (KRT10 and LOR)(Fig1A). The JAK1 inhibitor I largely reversed this effect. ART26.12 reduced genes related to the JAK/STAT pathway (PIAS3 and SOCS3; $p<0.001$), keratinocyte proliferation (KRT14, TP63; $p<0.001$), and chemokines and cytokines (CXCl10, TNF, IL1R1; $p<0.001$). The highest concentration of ART26.12 also upregulated genes related to anti-microbial peptides and innate immunity (eg CAMP, DEFB4A, TLR2, RNA SE7, SLP1, PI3; $p<0.01$). *In vivo*, the psoriasis area severity index (PASI) scores in the IMQ-vehicle group were near maximum by day 7 (Fig1B and C). Oral treatment with BMS-986165 attenuated PASI scores on day 6 and 7. Oral treatment with ART26.12 (25 mg/kg) reduced PASI scores on day 6 ($p<0.05$) and 7 ($p<0.001$). The higher dose of ART26.12 (100 mg/kg) reduced scores on day 7 ($p<0.05$). All drugs worked by attenuating skin scaling and thickness, with no effect on erythema. ART26.12 also reduced histopathological signs of damage (reduced hyperkeratosis, parakeratosis, inflammatory infiltrates, and epidermal acanthosis).

Conclusion:

In* models of skin inflammation, The FABP5 inhibitor ART26.12 had a positive effect on *in vitro* gene profiling and attenuated the effects of IMQ *in vivo*. These data suggest that ART26.12 shows promise as a novel oral treatment for psoriasis, and possibly other dermatological conditions where FABP5 is also known to be elevated.

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Abstract N°: 1465

Clinical Review of Bimekizumab in a tertiary centre

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Introduction & Objectives:

Bimekizumab is a humanized anti-IL(interleukin) 17A and F monoclonal antibody approved for the treatment of moderate-severe plaque psoriasis. Efficacy and safety data are lacking in the clinic setting and needed to assess its use in people ineligible for randomised controlled trials.

Materials & Methods:

This retrospective study reviewed all patients prescribed bimekizumab (n=68) in a tertiary centre; recording baseline Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI) and subsequent response at 16 – 24 weeks. Adverse events were also captured.

Results:

Mean age was 48.8 years (range 23-74) with mean treatment duration of 14.8 months. In our cohort 88.2% of patients were previously treated with at least one biologic, 48.5% with two to four biologics and 14.7% with five or more biologics.

All patients followed label induction dosing. Fifty-two patients received Q8 maintenance regimen; three patients received Q4 maintenance regimen whilst thirteen patients switched from Q8 to Q4 after week 16.

Baseline and 16-24 week PASI scores were recorded for 56 out of 68 patients with 1 patient stopping treatment before week 16, 3 patients not reaching that time point and 8 patients reaching the time window awaiting clinical review.

At 16-24 weeks 85.7%, 78.6% and 50.0% (n=56) achieved PASI 75, 90 and 100 respectively.

In patients who were previously exposed to at least one IL-17 inhibitor (n=33), 91.0%, 84.9% and 48.4% achieved PASI 75, 90 and 100 respectively. At 16-24 weeks, 56.0% of patients achieved a DLQI 0 or 1.

Adverse events occurred in 44.1% (30/68) of our cohort with 32.4% (22/68) developing candida infection. This was predominantly oral 86.4% (19/22) with some patients having additional sites involved; 7 developed genital and 3 developed oesophageal candidiasis.

Oesophageal candida was diagnosed via endoscopy for one patient while two other patients were diagnosed clinically with resolution of symptoms on oral fluconazole. No patients discontinued bimekizumab due to candidiasis. No patients developed suicidal ideation or inflammatory bowel disease (IBD).

Three patients (4.4%) permanently stopped treatment due to ineffectiveness (n=1), myeloma from pre-existing MGUS (n=1) and persistent diarrhoea, tenesmus, and abdominal pain (n=1); IBD was excluded by gastroenterology via colonoscopy.

Conclusion:

This clinical review demonstrates a high level of effectiveness for bimekizumab in a cohort of patients who had failed multiple prior biologics including IL17s. Bimekizumab was generally well tolerated with a small proportion of patients discontinuing treatment. However, almost one third of our cohort developed candidiasis, which may reflect the greater level of co-morbid disease and vulnerability to candida of the initial population treated with bimekizumab in our centre.

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Abstract N°: 1470

Nail psoriasis patients: demographic and clinical characteristics compared to psoriasis patients with no nail affection: A detailed retrospective archive based cohort analysis.

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Introduction & Objectives:

Nail psoriasis (PsN) is a distinctive type of psoriasis (Ps) that affects a variable proportion of psoriasis The treatment of nail psoriasis is challenging. Tthis retrospective cohort study was designed to compare psoriasis patients with nail involvement and psoriasis patients with no nail affection

Materials & Methods:

This retrospective, archive-based study included the files of all patients with psoriasis between December 2015 to August 2020.

The data required to be fulfilled in every patient's file to be qualified for the study included patient history, family history of psoriasis and history of any associated systemic, dermatological diseases, general examination findings, results of the baseline lab investigations. Psoriatic arthritis was diagnosed by a rheumatologist in suspected patients after answering a 5 questions screening questionnaire. We excluded patients with incomplete records and those with associated diseases that may cause nail changes

Files were split into two groups: patients with nail affection (PsN) and patients with no nail affection (Ps).

Results: A total of 2888 psoriasis patients were included in the analysis, 2363 patients didn't have clinical nail affection (Ps) while 525 patients had psoriasis with nail affection (PsN). Table 1

Conclusion:

Nail psoriasis affects male patients more frequently, this was in accordance with previous studies that suggested that this might be explained by koebnerization caused by the higher proportion of males in jobs requiring manual work, however, our findings did not validate this hypothesis as in manual workers didn't show significantly more nail affection than patients whose occupations require no manual work.

Duration and severity of psoriasis: nail affection in the present cohort is associated with longer duration of skin psoriasis, "younger age at onset?". and a significantly higher severity (higher PASI and body surface area) and more disability than psoriasis patients without nail affection. It affects fingernails more frequently than toenails.

Diabetes, metformin treatment and nail affection

Although diabetes didn't seem to negatively impact nail psoriasis within the current psoriasis patient's cohort, yet surprisingly metformin was associated with significantly more nail affection.

PsN and PsA:

In this study, PsN was associated with significantly more joint affection, Radiological studies using magnetic resonance imaging (MRI) suggested that PsA might actually be an extended inflammatory response or a

kobnerizing effect that originated primarily in the nail and extended to the DIP

Association with special areas

In the present cohort, nail psoriasis group shows a significantly higher percentage of both scalp psoriasis, flexural psoraisis as well as palmoplantar psoriasis

Smoking and nail psoriasis:

In the current study, the number of smokers was significantly higher among patients with nail psoriasis than psoriasis patients with no nail involvement, moreover; smoking was also found as an independent risk factor for nail psoriasis.

		P
	Ps group (No. =2354)	PsN group (No. = 522)
Age	41.12 ± 15.61	44.82 ± 15.59
	Male	1234 (52.2%)
	Female	1129 (47.8%)
Psoriasis duration	8.56 ± 9.12	11.44 ± 10.72
Type	Classic	1973 (83.4%)
	Scalp	935 (39.5%)
	Flexural	232 (9.8%)
	Palmoplantar	205 (8.7%)
	Erythrodermic	54 (2.3%)

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Abstract N°: 1476

Evaluation Of Intestinal Inflammation With Fecal Calprotectin In Psoriasis Patients

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Evaluation Of Intestinal Inflammation With Fecal Calprotectin In Psoriasis Patients

Introduction & Objectives: Psoriasis is not only a disease limited to the skin, but can occur with comorbidities such as psoriatic arthritis, metabolic syndrome, cardiovascular events, inflammatory bowel disease, and mood disorders. Inflammatory bowel disease, one of these comorbidities, is a recurrent, chronic inflammatory disease of the gastrointestinal system. It has genetic bases and pathogenesis mechanisms that overlap with psoriasis. Fecal calprotectin is a marker directly indicating intestinal inflammation that has been frequently used in the diagnostic process of inflammatory bowel disease. In this study, we aimed to evaluate the intestinal inflammation with fecal calprotectin level in psoriasis patients without a diagnosis of inflammatory bowel disease, and explore the association between fecal calprotectin and psoriasis characteristics.

Materials & Methods: Eighty psoriasis patients over the age of 18 who admitted to our clinic between June 2022 and February 2023; eighty age/sex-matched healthy volunteers were included as the control group. All of the included people were not using any immunosuppressive therapy in the last 6 months, without pregnancy, active infection or malignancy. Demographic data, gastrointestinal complaints using the Turkish version of Gastrointestinal Symptom Rating Scale and psoriasis characteristics were recorded. Fecal calprotectin was studied using Euroimmun Calprotectine ELISA (Lübeck, Germany). All obtained results were recorded. Statistical analysis was performed using the IBM SPSS V23 statistical package program.

Results: The median calprotectin level of the patient group (235.0 [11.2-2100.0] µg/g) was significantly higher than that of the control group (44.6 [6.7-711.6] µg/g). When the distribution of the groups according to the 50 µg/g, recommended by the kit company, and 250 µg/g, defined as significant inflammation, the number of people exceeding both thresholds was significantly higher in the patient group (95% vs 48.8%, 47,5% vs 5%, respectively). It was determined that the fecal calprotectin level was correlated with the maximum and current PASI, maximum and current BSA values. The mean of Gastrointestinal Symptoms Rating Scale scores was significantly higher in patient group. No correlation was found between fecal calprotectin level and Gastrointestinal Symptoms Rating Scale score in the patient group.

Conclusion: According to fecal calprotectin measurement, there is significant intestinal inflammation in psoriasis patients compared to the control group. It is not known that the elevation of fecal calprotectin that we detected in psoriasis patients clearly indicates the risk of inflammatory bowel disease. However, high fecal calprotectin levels may be a warning sign for coexistence with inflammatory bowel disease in psoriasis patients. Fecal calprotectin level was found to be associated with psoriasis severity. For this reason, fecal calprotectin level measurement comes into prominence especially in patients with severe psoriasis. In patients with psoriasis, fecal calprotectin may be elevated independently of gastrointestinal complaints. Measurement of fecal calprotectin levels in psoriasis patients may influence our choice of systemic treatment.

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Abstract N°: 1566

Data from the Belgian Psoriasis Registry BePso predicts treatment response in specific patient groups

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Introduction & Objectives: Psoriasis, a chronic autoimmune skin disorder, poses a key challenge in research. Affecting roughly 2% of the population worldwide, this condition manifests variably, partly influenced by individual phototypes. As the number of the therapies has increased, Belgium decided to establish its own registry. Systematically analysing the evolution of psoriasis through follow-ups data may lead to a better understanding of patient profiles and facilitate personalized treatment.

Materials & Methods: Patients diagnosed with psoriasis included in the Belgian Psoriasis Registry and who attend follow-up consultations were included in the study. Collected data included socio-demographic change, lifestyle change, psoriasis related characteristics, treatment specifics and treatment change, as well as associated diseases.

Results: 205 patients were included. Patients were classified as responders if their PASI score decreased by more than 75% between the initial visit and the follow-up (PASI75).

47% of patients responded with a PASI75 to their treatment. In the short term, 50% of patients treated with biotherapies, 30.5% on systemic conventional therapies, and 32.25% on topicals/phototherapy responded with a PASI75 to their treatment. At long-term follow-up, an increase in response was observed in patients receiving biotherapies, as well as in patients undergoing systemic conventional therapy (55,5%).

Patients who receive treatment shortly after the onset of their first lesions have better responses (p-value <0.0001).

Non-responders reported significantly more triggers for their psoriasis flares, particularly with cold weather and infection (p-value 0.035 and 0.034 respectively), while responders reported more Koebner Phenomenon as a trigger of their psoriasis flares (p-value 0.08).

We also found a higher prevalence of anxiety in responders (p-value 0.045).

Responders also have a significantly higher prevalence of scalp and palmoplantar phenotype (p-value 0.033 and 0.023 respectively).

Conclusion: We observed the importance of promptly treating patients after the onset of their first lesions to ensure the best possible response, particularly in younger patients. Transitioning towards a management strategy that prioritizes early intervention with biotherapy, using a step-down approach rather than a step-up approach, could potentially enhance the number of responders and potentially reduce costs of treatment.

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Abstract N°: 1574

Treatment Satisfaction with JNJ-77242113 in Patients with Moderate-to-Severe Plaque Psoriasis: 1-Year Results from the FRONTIER 1 & 2 Studies

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Introduction & Objectives: JNJ-77242113 (JNJ-2113), a targeted oral peptide that inhibits IL-23 signaling by binding the IL-23 receptor, demonstrated superior efficacy vs placebo (PBO) in moderate-to-severe psoriasis in the Phase 2 FRONTIER 1 trial [1]. Rates of near-complete/complete skin clearance achieved through Week (W)16 of FRONTIER 1 were maintained through W52 in FRONTIER 2, the long-term extension of FRONTIER 1, with 100mg BID yielding the highest response rates [2]. Here, we evaluated treatment satisfaction with JNJ-2113 through W52 in FRONTIER 1 & 2.

Materials & Methods: FRONTIER 1 pts were randomized (1:1:1:1:1:1:1; 41-43 pts/arm) to receive JNJ-2113 25mg once daily (QD), 25mg twice daily (BID), 50mg QD, 100mg QD, 100mg BID, or PBO through W16. In FRONTIER 2, FRONTIER 1 pts continued the same JNJ-2113 dosing regimen (25mg QD [n=35]; 25mg BID [n=40]; 50mg QD [n=39]; 100mg QD [n=40]; 100mg BID [n=38]); PBO pts crossed over to JNJ-2113 100mg QD (PBO→100mg QD [n=35]). Patient satisfaction was measured with Treatment Satisfaction Questionnaire for Medication-9 items (TSQM-9), comprising 3 domains (effectiveness, convenience, global satisfaction) of 3 items each. Domain scores are the sum of item scores transformed to a 0-100 scale. Effectiveness domain scores of 33.3, 66.7, 83.3 indicate average responses of dissatisfied, satisfied, very satisfied, respectively, on the 3 domain items. Least squares mean (LSM) scores (95% confidence interval [CI]) were calculated with mixed models for repeated measures (MMRM) over time.

Results: As early as W8 (1st timepoint assessed), and through W16, treatment effectiveness satisfaction scores were higher in JNJ-2113 vs PBO groups (Fig 1). Specifically, JNJ-2113-treated pts (except in 25mg QD & BID) were satisfied with treatment effectiveness at W16 (LSM [CI]: 70.8 [63.1-78.6]-79.1 [71.2-87.0]), whereas PBO pts indicated dissatisfaction (32.6 [24.7-40.4]; Fig 1). Treatment effectiveness satisfaction scores were generally maintained across JNJ-2113 groups through W52, at which time pts in the 100mg BID group reported being very satisfied (LSM [CI]: 83.3 [74.9-91.8]; Fig 1). Following PBO→100mg QD, pts shifted from dissatisfied at W16 to satisfied at W52 (LSM [CI]: 73.4 [64.8-82.0]; Fig 1). Consistent patterns were found for global satisfaction over time (Fig 2). No differences vs PBO in the convenience domain scores were observed across JNJ-2113 groups (mean score=61-74 across arms and timepoints), likely owing to consistent modes of oral administration and study blinding [1].

Conclusion: Higher satisfaction scores were reported for treatment effectiveness and global satisfaction in JNJ-2113 vs PBO groups as early as W8, with maintenance of satisfaction through W52. JNJ-2113 100mg BID-treated

pts indicated being very satisfied with treatment effectiveness at W52.

References:

\1. Bissonnette R., et al. *N Engl J Med* 2024;390(6):510-21.

\2. Ferris L.K., et al. A Phase 2b, Long-term Extension, Dose-ranging Study of Oral JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis: FRONTIER 2. Presented at: AAD Annual Meeting; March, 2024; San Diego, CA, USA.

Figure 1: Patient satisfaction with treatment effectiveness at W8, W16, and W52
LSM data are presented for W8, W16, and W52, error bars correspond to ± 95% CI. LSM scores were estimated with MMRM, adjusting for treatment group, visit, treatment group by visit interaction, baseline weight category (≤90 vs >90kg), baseline weight category by visit interaction, baseline TSQM domain score, and baseline TSQM domain score by visit interaction.

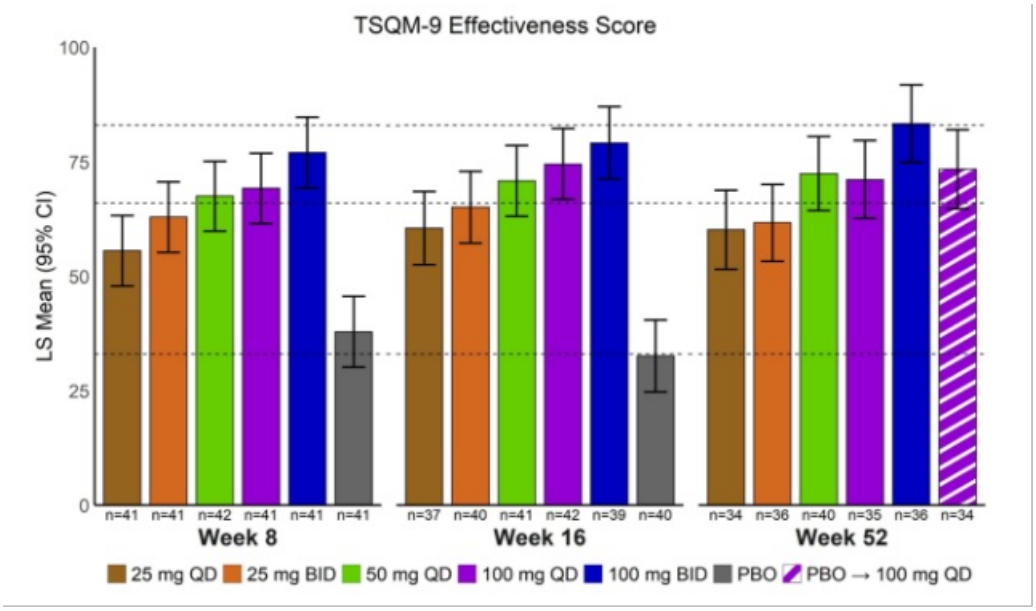
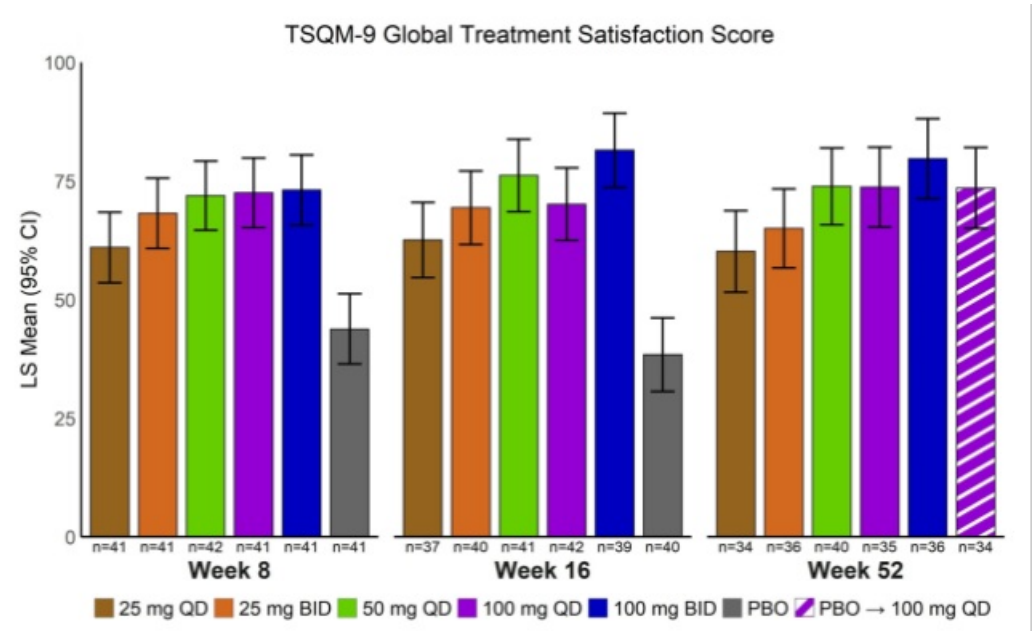


Figure 2: Global treatment satisfaction at W8, W16, and W52
LSM data are presented for W8, W16, and W52, error bars correspond to ± 95% CI. LSM scores were estimated with MMRM, adjusting for treatment group, visit, treatment group by visit interaction, baseline weight category (≤90 vs >90kg), baseline weight category by visit interaction, baseline TSQM domain score, and baseline TSQM domain score by visit interaction.



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Abstract N°: 1613

Can the calcipotriol/betamethasone dipropionate (CAL/BDP) cream be used for the treatment of moderate to severe plaque psoriasis?

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Introduction & Objectives: The fixed-dose combination of calcipotriol (CAL), a vitamin D analogue, and the corticosteroid betamethasone dipropionate (BDP), is suggested as the first-line topical treatment in mild to moderate psoriasis, as well as for severe cases requiring systemic treatment. Conventional formulations with the CAL/BDP fixe-dose combination, including ointment, gel or foam, may result in low adherence as they can be perceived as sticky, greasy and inconvenient by patients. A novel aqueous cream formulation of the CAL/BDP fixed-dose combination based on the polyaphron dispersion (PAD) technology was designed for a more convenient topical treatment of plaque psoriasis.1-2 Two phase III clinical trials (MC2-01-C2 and MC2-01-C7) demonstrated similar safety and tolerability of CAL/BDP cream compared to CAL/BDP gel, but with greater efficacy, patient acceptance and adherence.3 A *post-hoc* pooled analysis of the phase III trials revealed greater treatment efficacy in patients with moderate to severe psoriasis.4 However, as the CAL/BDP cream is indicated for the topical treatment of mild to moderate psoriasis, there is limited evidence in the use of CAL/BDP cream for treating moderate to severe plaque psoriasis.

Materials & Methods: We report one case in which CAL/BDP cream was used to successfully treat moderate to severe plaque psoriasis in our site.

Results:* A 24-year-old male with no personal or family history of psoriasis who developed pruritic erythematous-scaly plaques on his right forearm following a tattoo procedure, which subsequently spread to involve the scalp, face, ears, trunk and limbs. The patient received some topical treatments but they were discontinued due to lack of efficacy. CAL/BDP cream was prescribed off-label prior to systemic treatment to treat all involved areas, including an off-label application on the face. After two weeks of CAL/BDP cream treatment, significant improvement was observed, characterized by marked reduction in plaque infiltration, erythema, scaling and pruritus. The patient reported an improvement in his quality of life and good adherence to treatment given the positive outcomes.

Conclusion:* CAL/BDP cream demonstrated efficacy and a rapid onset of action in treating a case of moderate to severe psoriasis. Symptoms significantly improved, leading to enhanced quality of life reported by the patient. The good adherence and positive satisfaction with CAL/BDP cream stands out in contrast to the patient's previous experience with topical treatments.*

References: 1Taylor A, et al. Ann Pharmacother. 2023;57(3):341-347. 2Torres T, et al. Dermatol Ther (Heidelb). 2023;13(10):2153-2169. 3Pinter A, et al. J Eur Acad Dermatol Venereol. 2023:37 Suppl 1:14-19. 4Stein Gold L, et al. Dermatol Ther (Heidelb). 2023;13(9):2031-2044.

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Abstract N°: 1631

Bimekizumab impact on clinical markers of liver fibrosis and key liver parameters in patients with moderate to severe plaque psoriasis: Long-term pooled data from BE BRIGHT

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Introduction & Objectives:

Patients with psoriasis are at an increased risk of liver fibrosis;1 reports suggest treatments which inhibit interleukin (IL)-17F in addition to IL-17A may reduce this risk.2 A previous study found that clinical markers of liver fibrosis, and the key liver enzymes alanine transaminase (ALT) and aspartate transaminase (AST), did not increase over 2 years of bimekizumab (BKZ) treatment.3 Here, changes in liver parameters are reported through 4 years of BKZ treatment.

Materials & Methods:

Data were pooled from the 52-week BE VIVID, and 56-week BE SURE and BE READY phase 3 trials, and their open-label extension (OLE) BE BRIGHT.4–7 Included patients were randomised to BKZ 320 mg every 4 weeks (Q4W) to Week 16, received BKZ Q4W or every 8 weeks (Q8W) thereafter and entered the OLE. Data are reported for BKZ dose groups combined (BKZ Total).

In line with American Academy of Dermatology guidelines,8 liver fibrosis severity was determined by levels of clinical markers at baseline: Fibrosis-4 Index (FIB-4, <1.3 [low risk of liver fibrosis]9 and >1.659 [high risk of liver fibrosis])10 and Aspartate Aminotransferase to Platelet Ratio Index (APRI, <0.5 [absence of advanced fibrosis] and ≥0.5 [presence of advanced fibrosis]).11 FIB-4 and APRI scores, and ALT, AST, and platelet levels are reported through 4 years (Week 196/200) by baseline liver fibrosis risk.

Results:

Overall, 771 patients received continuous BKZ and entered the OLE. In patients with high baseline liver fibrosis risk (FIB-4 >1.659; N=34), FIB-4 scores (mean ± standard deviation [SD]) trended towards a decrease from baseline (2.17 ± 0.45) to Week 16 (1.99 ± 0.70) and remained consistent to Year 4 (1.89 ± 0.76; **Figure 1**). Mean FIB-4

scores remained consistent from baseline (0.71 ± 0.26) to Year 4 (0.76 ± 0.34) in patients with low baseline fibrosis risk (FIB-4 <1.3; N=658). Similar trends were observed for mean ALT and AST levels, whilst platelet counts remained consistent over 4 years in both risk groups (**Table 1**).

Mean APRI scores also trended towards a decrease from baseline (0.70 ± 0.26) to Week 16 (0.56 ± 0.31) and remained consistent to Year 4 (0.62 ± 0.61) in patients with baseline APRI ≥0.5 (N=60; presence of advanced fibrosis, **Figure 2**). In those without advanced fibrosis at baseline (APRI <0.5; N=711), APRI scores remained consistent (baseline: 0.25 ± 0.09; Year 4: 0.29 ± 0.14).

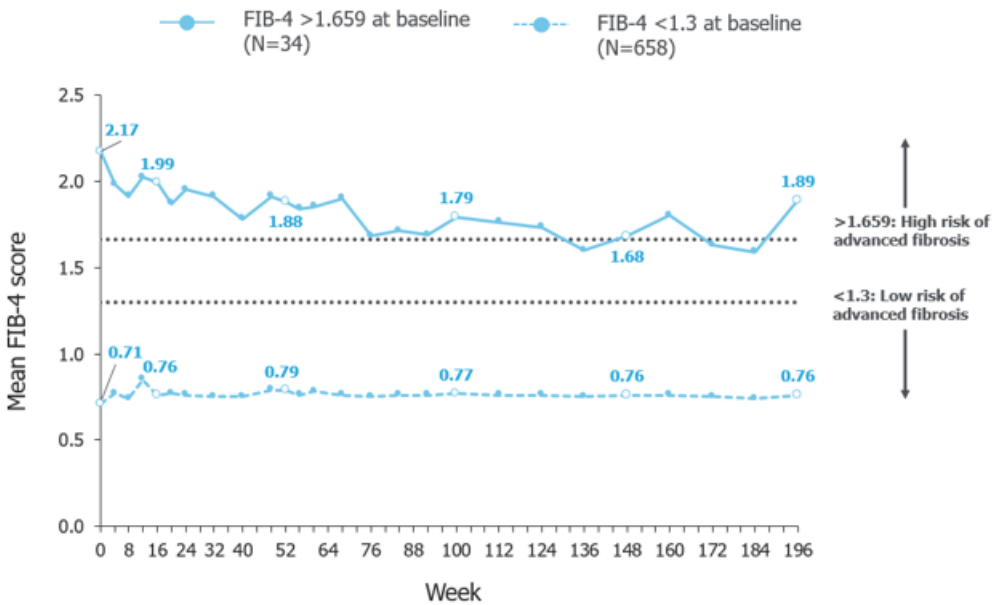
Conclusion:

Clinical markers of liver fibrosis trended towards a reduction over 4 years in BKZ-treated patients with high risk of liver fibrosis at baseline and remained consistent in those with low risk. Similar trends were observed for levels of the key liver enzymes ALT and AST, whilst platelet counts remained consistent over 4 years, regardless of risk of fibrosis at baseline. These findings should be viewed in context of the small sample size in the high-risk groups.

References:

1. Ogdie A. J Invest Dermatol 2018;138:760–7; **2.** Matsuda KM. Cytokine 2024;178:15687; **3.** Lebwohl M. J Am Acad Dermatol 2024;S0190-9622(24)00568-1; **4.** Reich K. Lancet 2021;397:487–98, NCT03370133; **5.** Warren RB. N Engl J Med 2021;385:130–41, NCT03412747; **6.** Gordon KB. Lancet 2021;397:475–86, NCT03410992; **7.** Strober B. Br J Dermatol 2023;188:749–59, NCT03598790; **8.** Menter A. J Am Acad Dermatol 2020;82:1445–86; **9.** EASL. J Hepatol 2021;75:659–89; **10.** Yoneda M. J Gastroenterol 2013;48:1051–60; **11.** Wai CT. Hepatology 2003;38:518–26.**

Figure 1. Absolute FIB-4 scores in BKZ-treated patients stratified by liver fibrosis risk at baseline (as defined by FIB-4 score)



BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 52 data presented here are from the Week 52 assessment in BE VIVID and the Week 56 assessment in BE SURE and BE READY, respectively. Data presented after Week 52 are from the BE BRIGHT OLE. BKZ: bimekizumab; FIB-4: fibrosis-4.

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Table 1. Key liver parameters in BKZ-treated patients stratified by liver fibrosis risk at baseline (as defined by FIB-4 score)

Mean ± SD (n)	BKZ Total N=771	
	Baseline FIB-4 score	
Absolute ALT levels (units/L)	**<1.3 (n=658)**	**>1.659 (n=34)**
Baseline	27.38 ± 17.45 (n=658)	39.65 ± 30.59 (n=34)
Week 16	29.08 ± 18.94 (n=646)	32.79 ± 23.76 (n=33)
Year 4 (Week 196/200)	31.97 ± 21.92 (n=531)	30.85 ± 16.98 (n=27)
Absolute AST levels (units/L)	**<1.3 (n=658)**	**>1.659 (n=34)**
Baseline	22.03 ± 8.35 (n=658)	43.50 ± 26.93 (n=34)
Week 16	23.01 ± 8.28 (n=647)	35.00 ± 21.42 (n=33)
Year 4 (Week 196/200)	24.30 ± 13.51 (n=538)	30.30 ± 11.68 (n=27)
Platelet count ($x10^9$/L)	**<1.3 (n=658)**	**>1.659 (n=34)**
Baseline	273.22 ± 64.48 (n=658)	194.35 ± 33.45 (n=34)
Week 16	263.88 ± 61.82 (n=648)	196.85 ± 36.26 (n=33)
Year 4 (Week 196/200)	260.01 ± 60.48 (n=524)	195.22 ± 45.95 (n=27)

ALT: alanine transaminase; AST: aspartate transaminase; BKZ: bimekizumab; FIB-4: fibrosis-4; SD: standard deviation.

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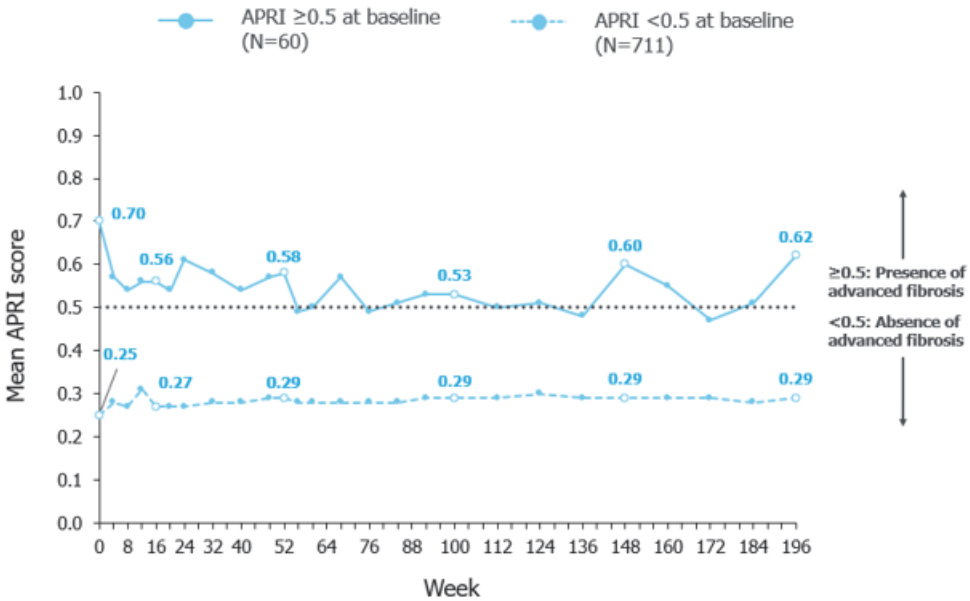
Figure 2. Absolute APRI scores in BKZ-treated patients with presence and absence of advanced liver fibrosis at baseline (as defined by APRI score)



BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 52 data presented here are from the Week 52 assessment in BE VIVID and the Week 56 assessment in BE SURE and BE READY, respectively. Data presented after Week 52 are from the BE BRIGHT OLE. APRI: Aspartate Aminotransferase to Platelet Ratio Index; BKZ: bimekizumab; OLE: open-label extension.

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Abstract N°: 1655

High Disease Control and State of Remission With Risankizumab in Patients With Moderate-to-Severe Psoriasis During the 6-Year LIMMitless Study

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EADV 2024 Encore Abstract - LIMMitless Remission Analysis Week 304 – (IFPA 2024)

Encore Abstract (IFPA 2024)

Introduction & Objectives:

Psoriasis is a chronic, inflammatory skin condition that impairs patients' quality of life. Psoriasis often requires longterm treatment; however, data on long-term uninterrupted disease control with biologic therapies are very limited. Risankizumab, a humanized immunoglobulin G1 monoclonal antibody that specifically inhibits interleukin 23 by binding to its p19 subunit, is approved to treat moderate-to-severe psoriasis and active psoriatic arthritis. To evaluate the long-term durability of response with risankizumab treatment and the ability of risankizumab to maintain uninterrupted disease control in patients with moderate-to-severe psoriasis.

Materials & Methods:

LIMMitless (NCT03047395) was a phase 3, global, multicenter, open-label extension study evaluating the long-term efficacy and safety of risankizumab 150 mg for moderate-to-severe psoriasis through up to 304 weeks of continuous treatment. Adult patients randomized to receive risankizumab 150 mg who completed 1 of 5 double-blind, placebo-controlled phase 2/3 studies (UltIMMa-1, UltIMMa-2, SustaIMM, IMMvent, or NCT03255382) were eligible to enroll in LIMMitless, in which patients continued open-label risankizumab 150 mg once every 12 weeks. Durability of response was assessed as the proportion of patients who achieved ≥90%/100% improvement in Psoriasis Area and Severity Index (PASI 90/PASI 100) or Dermatology Life Quality Index score of 0 or 1 (DLQI 0/1) at week 52 and maintained the corresponding responses at weeks 100/160/208/252/304. Additional efficacy assessments included the proportion of patients with high disease control (defined as no loss of PASI 90 or DLQI 0/1) or state of remission (defined as no loss of PASI 100) at any visit after week 52 through >1/>2/>3/>4/>5 years. Results are presented for all patients and those with (bio-experienced) or without (bio-naïve) prior biologic therapy. Data are reported as observed cases with no imputation for missing data.

Results:

A total of 897 patients enrolled in LIMMitless and 661 (73.7%) completed the study. At baseline of LIMMitless (week 52 of treatment), PASI 90, PASI 100, and DLQI 0/1 were achieved by 86.3% (n/n = 766/888), 58.3% (n/n = 518/888), and 77.9% (n/n = 680/873) of patients, respectively. Among patients who achieved the corresponding

outcomes at week 52, PASI 90, PASI 100, and DLQI 0/1 were maintained at week 304 by 93.3%, 78.0%, and 91.4% of patients, respectively; similar trends were observed for bio-experienced and bio-naïve patients (**Table 1**). The proportion of patients with high disease control for >1/>2/>3/>4/>5 years was 89.3%/80.9%/75.4%/72.7%/68.0% for PASI 90 and 93.8%/88.4%/81.7%/78.3%/66.2% for DLQI 0/1 (**Table 2**). State of remission for >1/>2/>3/>4/>5 years was achieved by 70.5%/54.1%/45.6%/41.2%/37.1% of patients. High disease control and state of remission results for bio-experienced and bio-naïve patients were comparable to the overall population. Long-term risankizumab safety has been reported elsewhere.

Conclusion:

Patients with moderate-to-severe psoriasis who achieve treatment goals after 52 weeks of risankizumab therapy can maintain a high level of long-term durability, high disease control, and a state of remission for up to 5 additional years.

Table 1. Proportion of patients who maintained efficacy over time during the LIMMitless open-label extension study (OC)

	Maintenance of clinical response					
Patients, n/n (%)	**Week 52**	**Week 100**	**Week 160**	**Week 208**	**Week 256**	**Week 304**
PASI 90						
Overall	766/766 (100)	685/731 (93.7)	630/681 (92.5)	464/497 (93.4)	559/614 (91.0)	491/526 (93.3)
Bio-experienced	260/260 (100)	234/252 (92.9)	209/234 (89.3)	153/168 (91.1)	190/212 (89.6)	173/193 (89.6)
Bio-naïve	453/453 (100)	405/429 (94.4)	376/399 (94.2)	267/283 (94.3)	331/357 (92.7)	318/333 (95.5)
PASI 100						
Overall	518/518 (100)	411/496 (82.9)	373/461 (80.9)	274/338 (81.1)	320/416 (76.9)	277/355 (78.0)
Bio-experienced	170/170 (100)	130/164 (79.3)	113/154 (73.4)	78/114 (68.4)	99/138 (71.7)	89/125 (71.2)
Bio-naïve	311/311 (100)	251/298 (84.2)	234/273 (85.7)	167/191 (87.4)	198/245 (80.8)	188/230 (81.7)
DLQI 0/1						
Overall	680/680 (100)	602/652 (92.3)	—[a]	409/450 (90.9)	497/545 (91.2)	427/467 (91.4)
Bio-experienced	225/225 (100)	204/221 (92.3)	—[a]	133/145 (91.7)	167/185 (90.3)	151/171 (88.3)
Bio-naïve	409/409 (100)	361/388 (93.0)	—[a]	240/264 (90.9)	295/320 (92.2)	276/296 (93.2)

DLQI 0/1, Dermatology Life Quality Index score of 0 or 1; OC, observed cases; PASI 90/100, ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index.

[a]DLQI was not assessed at week 160.

Table 2. Proportion of patients with high disease control (no loss of PASI 90 or DLQI 0/1 at any visit after week 52) or state of remission (no loss of PASI 100 at any visit after week 52) over time during the LIMMitless open-label extension study (OC)

	Duration of response[a]				
Patients, n/n (%)	**>1 year**	**>2 years**	**>3 years**	**>4 years**	**>5 years**
No loss of PASI 90					
Overall	458/513 (89.3)	415/513 (80.9)	387/513 (75.4)	373/513 (72.7)	349/513 (68.0)
Bio-experienced	166/191 (86.9)	148/191 (77.5)	137/191 (71.7)	129/191 (67.5)	119/191 (62.3)
Bio-naïve	292/322 (90.7)	267/322 (82.9)	250/322 (77.6)	244/322 (75.8)	230/322 (71.4)
No loss of PASI 100					
Overall	241/342 (70.5)	185/342 (54.1)	156/342 (45.6)	141/342 (41.2)	127/342 (37.1)
Bio-experienced	84/128 (65.6)	69/128 (53.9)	55/128 (43.0)	46/128 (35.9)	40/128 (31.3)
Bio-naïve	157/214 (73.4)	116/214 (54.2)	101/214 (47.2)	95/214 (44.4)	87/214 (40.7)
No loss of DLQI 0/1					
Overall	411/438 (93.8)	387/438 (88.4)	358/438 (81.7)	343/438 (78.3)	290/438 (66.2)
Bio-experienced	151/158 (95.6)	141/158 (89.2)	130/158 (82.3)	121/158 (76.6)	104/158 (65.8)
Bio-naïve	259/279 (92.8)	246/279 (88.2)	228/279 (81.7)	222/279 (79.6)	186/279 (66.7)

DLQI 0/1, Dermatology Life Quality Index score of 0 or 1; OC, observed cases; PASI 90/100, ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index.

[a]Duration of response was assessed in patients who reached year 4 or beyond and had ≤ 5% missing data; total duration includes responses achieved from week 0 through week 304. If a patient had a missing record at a visit but achieved the response before and after the visit, the patient was considered as no loss of response at that visit.

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Abstract N°: 1677

Visfatin, Omentin-1 and Lipid Profile in Egyptian Patients with Psoriasis Vulgaris: Relation to Disease Severity

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Introduction & Objectives

In psoriatic patients an increased risk of cardiovascular abnormalities, dyslipidemia, atherosclerosis, obesity and cerebral stroke have been found (Dsouza and Kuruville 2013)

Visfatin has been proposed as marker of endothelial dysfunction and an initial and crucial step in progression of atherosclerotic process and may play a significant role in psoriasis pathophysiology (Vanhoutte 2009)

Omentin is produced mainly by stromal vascular cells of visceral fat and Omentin1 is a major circulating isoform which was involved in pathogenesis of obesity and related diseases (Gerdes et al 2011)

Multiple factors like proatherogenic lipoprotein profile which includes hypertriglyceridemia, raised plasma concentrations of LDL C and a lowered HDL C concentration have been reported as associated with psoriasis (Shenoy et al 2015)

The aim of this work to estimate levels of visfatin, omentin1 and lipid profile in Egyptian patients with psoriasis as compared to healthy controls and evaluating their relation to disease severity to investigate their possible role in psoriasis pathogenesis

Materials & Methods

The present case control study included 30 patients with psoriasis vulgaris and 30 healthy controls. All participants were subjected to full history taking, general and dermatological examination, BMI and PASI scoring for patients. Blood samples were withdrawn from all participants after 12 hours fasting. Lipid profile (cholesterol, triglycerides HDL and LDL) was estimated immediately after collection of serum and visfatin and omentin1 were estimated by ELISA technique. Skin punch biopsies were obtained from psoriatic lesions and normal skin of controls for examination of tissue visfatin and omentin1

Results

We found a significant difference between patients and controls regarding serum and tissue visfatin (figure1) higher in psoriasis patients ($p<0.05$) and a significant positive correlation with PASI score as indicative of psoriasis severity and both of serum (r 0.53, p 0.003) and tissue visfatin (r 0.39, p 0.001). There was a significant difference ($p<0.05$) between both groups regarding serum omentin1 lower in psoriasis patients ($p<0.05$). There was a significant difference between groups regards HDL ($p<0.05$) lower among patients and LDL ($p<0.05$) higher among patients, and there was a significant positive relations between total cholesterol, LDL and PASI with severe

psoriasis (p<0.05), and between low HDL and PASI with severe psoriasis (p<0.05). Our data revealed no significant difference between both groups regarding total cholesterol, triglycerides, tissue omentin1. Also there was no significant correlations between each of serum and tissue omentin1and PASI score, BMI and lipid profile (p > 0.05). No significant correlations between serum and tissue visfatin and each of BMI and lipid profile (p > 0.05)

**

Visfatin level among study groups

5

4.1

4

3.42

3.5

3

2.49

2

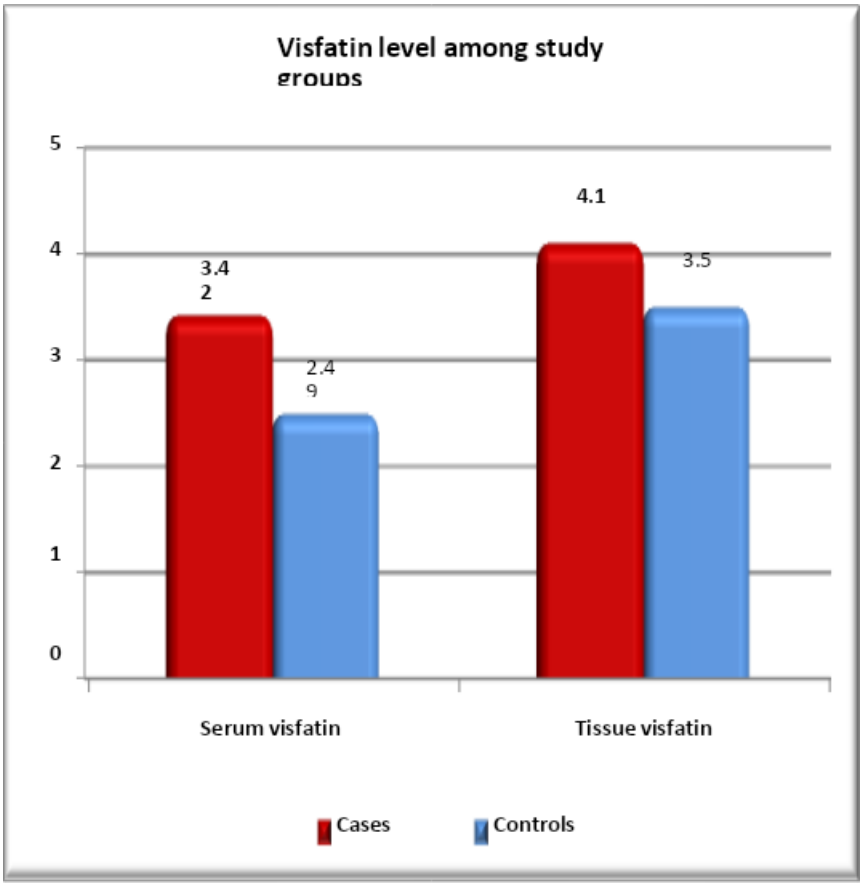
1

0

Serum visfatin

Tissue visfatin

Cases



Controls

Figure 1 Comparison of serum and tissue visfatin between groups

Conclusion

In conclusion psoriasis patients have high serum and tissue visfatin and low serum omentin1 levels and altered LDL and HDL levels in comparison to healthy controls and these differences were not correlated with BMI. High visfatin, high LDL and low HDL levels were positively correlated with PASI score and severity in psoriasis patients. Which indicates a possible role of visfatin and omentin1 in pathogenesis of psoriasis and potential cardiovascular comorbidity

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Abstract N°: 1683

A Multicenter, Randomized, Double-blind, Placebo-controlled Phase II Study to Evaluate the Efficacy and Safety of Individual Dose Regimens of HB0017 in Patients With Moderate to Severe Plaque Psoriasis

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Introduction & Objectives:

HB0017 is a recombinant humanized IgG1 monoclonal antibody that targets IL-17A. Phase Ia and Ib trials have demonstrated HB0017 safety and tolerability in both healthy subjects and patients with moderate to severe plaque psoriasis as well as encouraging signal of efficacy with a longer half-life and long-term effectiveness. This abstract analyzes the efficacy and safety results of a phase II study of different dose regimens of HB0017 in patients with moderate to severe plaque psoriasis.

Materials & Methods:

This is a Phase 2, multicenter, randomized, double-blind, placebo-control study evaluating the efficacy and safety of HB0017 for the treatment of moderate to severe plaque-type psoriasis. The study consisted of screening, initial, maintenance and follow-up periods. Patients (n=160) were randomized in a 1:1:1:1 ratio to one of four groups, with 40 patients in each group (Fig 1.). The co-primary end point was PASI 90 and sPGA 0/1 response rate at week 12. Considering Group1&2 had identical dose regimens in the initial treatment period, patients in these two groups were pooled into HB0017 150 mg dose group for analysis for the first 12 weeks.

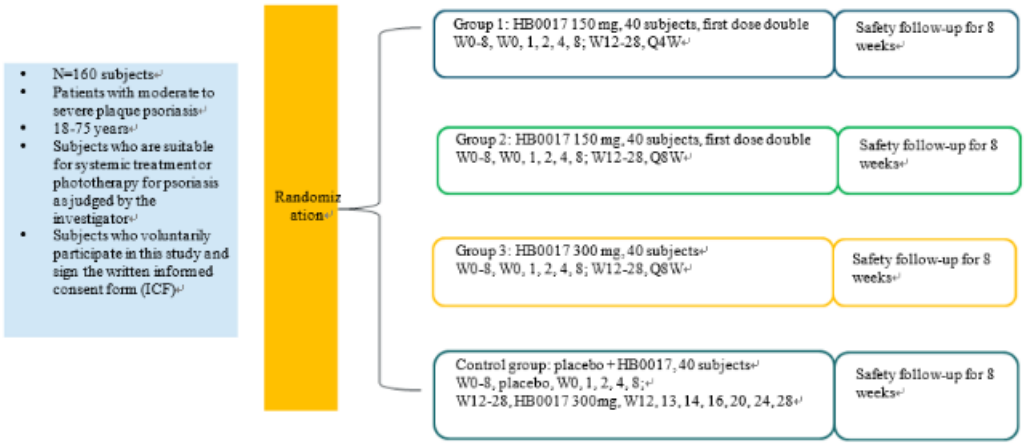

Fig 1. Study design and dosing regimens.

Results:

At week 12, the PASI 90 response rate in the control group (Weeks 0-12), HB0017 150 mg, and HB0017 300 mg

dose groups was 1.0%, 79.9%, and 69.4%, respectively. The sPGA 0/1 response rate was 1.1%, 77.1% and 78.2%, respectively（Fig 2.）. Both the sPGA 0/1 and PASI 90 response rates in each HB0017 group were all significantly higher than those in the control group (Weeks 0-12) ($p<0.001$). In the maintenance treatment period, at Week 36, the PASI 90 response rate was 94.3%, 92.3%, 94.6%, and 97.5% in the control group (Weeks 12-36), HB0017 150 mg Q4W, HB0017 150 mg Q8W, and HB0017 300 mg dose groups, respectively. The sPGA 0/1 response rate was 91.4%, 92.3%, 91.9%, and 97.5% respectively. The PASI90 and sPGA 0/1 response rate at Week 36 were both the highest in HB0017 300mg dose group.

HB0017 was safe and well tolerated at both dose levels. No significant correlation was shown between the incidence of TEAEs and the dose. During the initial treatment period, 80.0% (32/40) subjects in the control group (Weeks 0-12) experienced TEAEs, the incidences of TEAEs in HB0017 150 mg and HB0017 300 mg dose groups were 68.4% (54/79) and 68.3% (28/41), respectively. During the maintenance treatment period, a total of 135 (87.1%) subjects experienced TEAEs, and the incidences of TEAEs/ADRs were similar among HB0017 150 mg Q4W, HB0017 150 mg Q8W, HB0017 300 mg dose groups, and the control group (Weeks 12-36). The severity of TEAEs was mostly Grade 1 or 2. The overall safety profile of HB0017 was similar to those of similar drugs, and no new safety signals were identified.

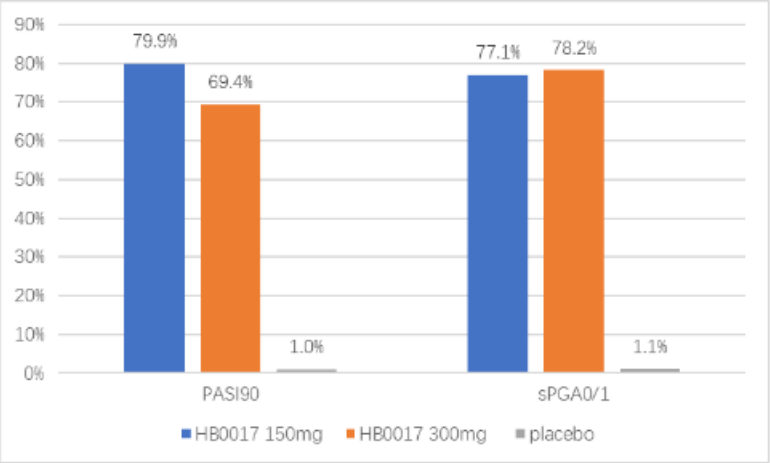

Figure2. Coprimary efficacy end points at week 12.

Conclusion: HB0017 showed promising efficacy for moderate-to-severe plaque psoriasis. HB0017 300 mg Q8W dose group maintained higher response rate in PASI 90. The overall safety profile of HB0017 was similar to those of similar drugs, and no new safety signals were identified.

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Abstract N°: 1744

Acceptable Clinical Trial Differences vs Placebo in Plaque Psoriasis

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Introduction & Objectives: In plaque psoriasis (PsO) dermatologists have a substantial number of advanced systemics in their armamentarium. Each biologic option increases the efficacy threshold resulting in a saturated biologic market. As such, the pipeline for psoriasis product is primarily comprised of oral options in a variety of mechanism of actions. This research sought to understand what dermatologists consider to be minimally acceptable and a significant advance for PASI-75 and PASI-90 among in-line and pipeline oral options in the US and EU5.

Materials & Methods: An independent market analytics firm collaborated with US & EU5 dermatologists (n=372) to conduct analysis of the PsO market. Data were collected via an online survey fielding at various time points from October 25, 2023, through February 26, 2024, including physician demographics, product usage, and attitudinal survey responses.

Results: With an expanding armamentarium, dermatologists across the US and EU5 report PsO has one of the lowest unmet needs for new treatment options compared to other dermatology conditions with most physicians reporting a low to moderate need. Despite having access to oral options such as apremilast and deucravacitinib, the desire for a highly efficacious, yet safe oral option is reported across geographies.

When reviewing placebo-controlled clinical trials for oral options in PsO, US dermatologists consider the minimally acceptable improvement (delta between study results vs placebo) for PASI-75 to be 38% and 32% for PASI-90. EU5 dermatologists report similar figures for PASI-75, though they report a higher delta for PASI-90 (39%). When compared to various clinical trial results for apremilast, deucravacitinib, JNJ-2113, orismilast, and ME3183, all molecules are at or nearly meeting dermatologists' minimally acceptable range, apart from apremilast.

When identifying what would be considered a significant advance over the standard of care, US dermatologists consider a delta of 62% for PASI-75 and 56% for PASI-90 as a significant advance. EU5 dermatologists report a similar delta of 63% for PASI-75 and report a higher delta of 61% for PASI-90. The deltas from various clinical trial results for apremilast, deucravacitinib, JNJ-2113, orismilast, and ME3183, suggest only JNJ-2113 at the 100mg dose meets physician's expectations.

Regarding perceptions of JNJ-2113, dermatologists across geographies are more interested in having the oral IL-23 inhibitor approved and a greater percentage of physicians anticipate prescribing the asset within the first three months of being available compared to other oral assets.

Conclusion: With a substantial armamentarium for biologics in psoriasis,** physicians express a need for efficacious and safe oral options for PsO. Current late-stage assets and deucravacitinib meet dermatologists' minimum threshold for improvement, however, only JNJ-2113 100mg meets the delta considered to be a significant advance over the standard of care. Data suggests JNJ-2113 would fill an unmet need if approved.

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Abstract N°: 1805

Interest of periungual capillaroscopy in psoriasis

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Introduction & Objectives:

Periungual capillaroscopy is a rapid, non-invasive examination that provides morphological and functional information on the periungual microcirculation.

We were interested in studying these parameters in psoriatic patients.

Materials & Methods:

We carried out a descriptive study of peri-ungual capillaroscopy, over a 13-month period.

Patients with comorbidities known to impair periungual capillaroscopy were excluded from this study: systemic lupus erythematosus, systemic scleroderma, dermatomyositis, diabetes, arterial hypertension, primary or secondary Raynaud's or other acrosyndrome.

The following capillaroscopic parameters were studied: density, size, shape, organization of capillaries, shape of capillary walls, background color, quality of capillary flow, diameters of afferent and efferent branches, top of loop, width and length, visibility of suprapapillary plexus, and presence of edema or hemorrhage.

Results:

We enrolled 31 patients with psoriasis vulgaris (PV).

Age ranged from 12 to 72 years, with 14 women (45%) and 17 men (54%) (sex ratio= 0.82), 3 children (9.6%) and 28 adults (90.3%),

8 patients had PASI<5(25.8%), 7 PASI 5-10 (22.5%) and 16 PASI>10(51.6%).

Nail involvement was noted in 21 patients (67.7%).

The duration of psoriasis ranged from 20 days to 68 years.

18 (58%) had received topical treatments, 12 (38.7%) methotrexate, 4 (12.9%) cyclosporine, 1 (3.22%) acitretin.

Mean capillaroscopic density was 16.4. Loop shape was found in 22 (70.9%), distortion in 9 (29%), inverted U-shape in 23 (74.1%), and branching in (19.3%). Capillary wall disorganization was noted in 4 (12.9%). Capillary disorganization was found in 2 (6.45%). Background color was pink in 27 (87%), pale in 3 (9.6%) and dark in 1 (3.2%). Capillary flow was discontinuous in 2 (6.45%). Mean diameters of afferent branches were 11.9, efferent branches 13.4, loop heights 16.8, loop widths 33 and loop lengths 105. The supra-papillary plexus was visible in 4 (12.9%). Edema was noted in 4 (12.9%). Haemorrhages were present in 3 (9.6%).

Discussion:

According to our PV capillaroscopy findings:

Density was normal (>9/mm), with a predominance of loop and invaginated U shapes, with some distortion and branching. Capillary walls were predominantly organized. Background color was predominantly pink. Afferent branches were more dilated compared to efferent branches (8-10um and 10-14um respectively). The top of the loop was also dilated (<10um). Capillary dilatation was noted (size<20um). Length was within limits (<100um).Visibility of supra-papillary plexuses, presence of edema and hemorrhage was rare.

Abnormalities such as dilated and tortuous efferent branches have been reported in PV patients, while in patients with psoriatic arthritis (PsA), a reduction in capillary density, a decrease in capillary length, a reduction in the diameter of afferent branches, sinuous capillaries with distortions and visibility of the suprapapillary plexus have been reported, although these abnormalities vary from one study to another.

Conclusion:

Given that cutaneous inflammation and keratinocyte differentiation abnormalities are parallel with microcirculation abnormalities in psoriasis, morphological and functional changes in capillaries can be considered early markers of psoriasis, or even of its severity (PsA), although the latter population requires particular attention.

Further studies are still needed to confirm or refute the data from existing studies.

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Abstract N°: 1821

Comparison of Severity Assessment Methods in Generalized Pustular Psoriasis

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Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a rare disease showing extensive erythema with multiple pustules and systemic inflammation, which largely affects patients' quality of life. Access to professional medical care may be a key to disease management. Japanese Dermatological Association severity score (JDA score) is described as a total score after rating skin symptoms (erythematous, pustular, and edematous) score and laboratory findings associated with systemic inflammation (pyrexia, white blood cell count, serum CRP level, and serum albumin level), and the severity of each patient is classified as mild, moderate, or severe based on the score. Whereas the JDS scoring takes into account systemic symptoms such as pyrexia, other severity assessment tools such as GPPGA (Generalized Pustular Psoriasis Physician Global Assessment), GPPASI (Generalized Pustular Psoriasis Area and Severity Index), and IGA (Investigator's Global Assessment) are based solely on the skin symptoms and may not accurately represent the patient's overall severity, especially in the acute stage of GPP. The aim of this study was to compare the usefulness of GPP severity assessment tolls in the acute phase of the disease.

Materials & Methods:

The medical records of the GPP patients from 2014 to 2024 were collected and used for the analysis. JDA score, GPPGA, GPPASI, and IGA score were used for the assessment of severities. Age, sex, body mass index (BMI), disease duration, treatment history, and laboratory data were also used for analysis. The data from each patient at the time of admission due to acute phase condition were statistically analyzed.

Results:

A total of 13 patients (10 male, 3 female, mean age 55.8 ± 22.4 years) were retrieved and analyzed. The total number of hospitalization was 23, with a mean ± standard deviation of 1.77 ± 1.12 times per patient. At the time of hospitalization, mean ± standard deviation of JDA score, GPPGA, GPPASI, and IGA score were 9.54 ± 3.18, 2.52 ± 0.71, 20.4 ± 10.3, and 3.78 ± 0.41, respectively. JDA score was positively correlated with GPPGA with coefficients 0.6061 ($p = 0.0028$), GPPASI with coefficients 0.6988 ($p = 0.0003$), and IGA score with coefficients 0.5954 ($p = 0.0035$), respectively. The duration of hospital stay and JDA score were positively correlated ($r = 0.4816$, $p = 0.0232$), but GPPGA, GPPASI, and IGA score were not [GPPGA ($r = 0.08495$, $p = 0.700$), GPPASI ($r = 0.2486$, $p = 0.2526$), IGA score ($r = 0.1354$, $p = 0.5379$)]. In addition, CRP and BMI were positively correlated with the duration of hospital stay [CRP ($r = 0.5164$, $p = 0.0139$), BMI ($r = 0.6122$, $p = 0.0019$)].

Conclusion:

Since the JDA score includes systemic inflammation in addition to skin symptoms for evaluation, it is superior to other severity assessment tools such as GPPGA, GPPASI, and IGA score based solely on skin symptoms for evaluating overall patient condition in the acute phase requiring hospitalization.

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Abstract N°: 1861

Correlation between the two questionnaires used to assess sexual function in psoriatic patients

Claudio Carneiro[1], Maria Alice Penetra[2], Marcia Ramos-e-Silva[2], Sueli Coelho Da Silva Carneiro*[2]

[1]Clementino Fraga Filho University Hospital, Rio de Janeiro, Brazil, [2]Clementino Fraga Filho University Hospital, Medical Clinics, Rio de Janeiro, Brazil

Introduction & Objectives: Psoriatic disease is prevalent (1-3% of the world population has psoriasis and of these, approximately 30% have arthritis). According to the WHO, sexual dysfunction affects 40.8% of psoriatic patients. Previous nacional work found that this prevalence can reach 68% in women. However, despite being very common, sexual difficulties in these patients are rarely described in the literature. The aime was to analyze the correlation between the Sexual Quotient questionnaires and the International Index of Erectile Function and Female Sexual Function Index questionnaires in psoriasis patients with or without arthritis.

Materials & Methods: 120 patients (60 men and 60 women) with psoriatic skin and/or joint disease were evaluated for sexual function using the male and female sexual quotient (SQ) (<62) and the female sexual function index (IFSF - dysfunction sexual function <26.5) and international index of erectile function (IIFE - erectile dysfunction <26). Data analysis was performed using the chi-square test and Pearson's correlation coefficient, to verify the degree of correlation between the variables. The significance criterion was 5%.

Results: There was a decrease in sexual function measured by SQ; IIFE and IFSF in individuals with skin disease (58.5 and 15.25) and/or joint disease (61 and 18.75) with lower values for females (46.50 and 16.55; 44.11 and 18 ,91). (Tables 1 and 2) However, no statistically significant relationship was found between the severity of the skin and/or joint disease and the decrease in sexual function ($p<0.05\%$). The correlation analysis was positive between IIFE and QS. (+0.77, r=0.592) and between IFSF and QS (+0.83, r=0.688).(Grph 1)

Conclusion: Reduced sexual function is very prevalent in psoriatic disease. This study demonstrated a strongly positive correlation (not yet published) between the QS and the more complex IIEF and IFSF scores. Considering the sensitivity of the subject for both patients and the care team, we suggest the use of the sexual quotient, as it is a quick, self-administered instrument, with accessible and easy-to-understand language, which covers functional and relational elements relevant to performance/satisfaction sexual relations of both sexes. Assessment of sexual function should be part of routine outpatient care, with the aim of discussing the causes and reducing sexual dysfunction

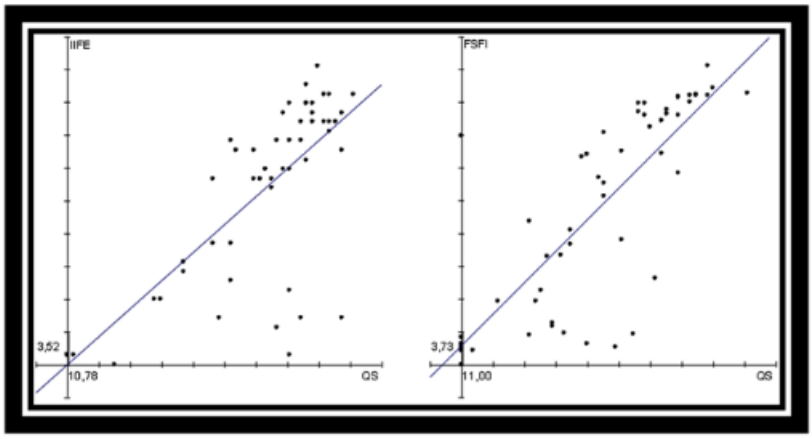
Table 1: Psoriasis and psoriatic arthritis and the means of sexual quotient

Psoriasis	QS- M	QS- F
Cutaneous	58.50	46.50
Articular	61.00	44.11

Table 2: Psoriasis and psoriatic arthritis and the means of International Erectile Function Index and Female Sexual Function Index

Psoriasis	IIFE	FSFI
Cutaneous	15.25	16.55
Articular	18.75	18.91

Graph 1: Correlation between Sexual Quotient and International Index of Erectile Function and between Sexua lQuotient and Female Sexual Function Index



QS: Sexual Quotient

IIFE : International Index of Erectile Function

FSFI: Female Sexual Function Index

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Abstract N°: 1882

Risk of cancer in patients with moderate-to-severe plaque psoriasis on TNF-alpha therapies: A systematic review and meta-analysis

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Introduction & Objectives

Psoriasis is a chronic inflammatory skin disease mediated by T lymphocytes and varies in prevalence among adults —from 0.91% in the US to 8.5% in Norway. Psoriasis involves a complex interplay of genetic predisposition, immune dysregulation, and environmental factors. Prior research suggests certain treatments for psoriasis, such as phototherapy and systemic immunosuppressants, may increase cancer risk. With ongoing concerns about the long-term effects of biologics, especially TNF-alpha inhibitors (TNFi), it is crucial to distinguish whether the increased cancer risk is due to psoriasis itself, its treatments, or if treatments could potentially mitigate both psoriasis severity and cancer risk. This understanding is essential for informed therapeutic decision-making. Recent large-scale studies and systematic reviews have examined cancer risks associated with biologic therapies, showing mixed results. Our study aims to clarify these aspects through a comprehensive systematic review and meta-analysis, comparing cancer risks in psoriasis patients treated with TNFi to those in the general population, focusing on both overall and specific cancer types.

Materials & Methods

This study adheres to the PRISMA guidelines. Data was collected from PubMed, Embase, the Cochrane Library, and databases containing Chinese-language articles, using a comprehensive search strategy involving terms related to psoriasis, cancer, and TNFi therapies. We included studies comparing cancer incidence in adults with psoriasis or psoriatic arthritis treated with TNFi to the general population, excluding reviews, case reports, and incomplete data studies. Study quality was assessed using the Quality in Prognostic Studies (QUIPS) tool, and any disagreements in data extraction or quality assessment were resolved through consensus with a third reviewer.

Results

Out of the 37 initially selected references, the final number of studies included in the systematic reviews was 7 papers. Our study uncovered a significant increase in the risk of squamous cell carcinoma among psoriasis patients treated with TNFi (Standardized Incidence Ratio (SIR), 4.18; 95% CI, 2.83-6.16). Furthermore, subgroup analysis indicated a heightened risk of non-melanoma skin cancer (NMSC) in patients with psoriatic arthritis (PsA) undergoing TNFi therapy compared to the general population (SIR, 1.84; 95% CI, 1.16-2.92). However, there was no increased risk of other cancers, such as melanoma, lymphoma, basal cell carcinoma, prostate cancer, and breast cancer, among individuals receiving long-term TNFi therapy for psoriasis or PsA.

Conclusion

Our findings confirm the necessity of personalized treatment strategies in psoriasis, taking into account individual risks and benefits. Although TNFi therapy in psoriasis patients showed an increased risk of NMSC compared to the general population, it did not significantly impact the overall cancer risk, indicating its safety for long-term psoriasis management. Additionally, we considered that the effect was contributed by psoriasis itself. These insights are crucial for clinicians to tailor treatments effectively for psoriasis management while minimizing

potential risks.

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Abstract N°: 1890

Inhibition of epidermal isoleucyl-tRNA synthetase ameliorates psoriasis-like skin lesions via JAK2/STAT3/CXCL16 signaling pathway

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Introduction & Objectives:

Aminoacyl-tRNA synthetases (ARSs) are a family of essential enzymes that participate in protein synthesis by ligating amino acids to their corresponding tRNAs. Isoleucyl-tRNA synthetase (IARS) is belongs to the class-I aminoacyl-tRNA synthetase family. Our previous study revealed that mupirocin blocked imiquimod (IMQ)-induced psoriasis-like skin lesions by inhibiting epidermal IARS, but the mechanisms by which IARS affects psoriatic local inflammation have remained unclear.

Materials & Methods:

RNAseq analysis and western blotting from silencing the IARS gene in normal human epidermal keratinocytes were performed to determine the mechanisms in vitro. In addition, imiquimod (IMQ)-induced mouse psoriasis-like model with subcutaneous injection of the anti-IARS antibody was used to mimic treatment in human psoriasis patients. Skin dorsal tissues were harvested for flow cytometry, western blotting, and histology analyses.

Results:

Here, we investigated that the mRNA and protein levels of IARS were increasing in the lesional skin of psoriatic patients. Importantly, we found that subcutaneous injection of a neutralizing IARS antibody markedly ameliorated epidermal hyperplasia and inflammatory infiltration in the IMQ-induced psoriasis-like mouse model. In vitro, silencing IARS in primary keratinocytes reduced the expression of related proinflammatory cytokines, chemokines, and antimicrobial peptides. Furthermore, we observed that silencing IARS inhibited cell proliferation and promoted apoptosis via the Janus kinase 2 (JAK2)/signal transducer and activator of transcription 3 (STAT3)/C-X-C motif chemokine ligand 16 (CXCL16) signaling pathway.

Conclusion:

This study identifies inhibition of epidermal isoleucyl-tRNA synthetase that can ameliorate psoriasis-like skin lesions via the JAK2/STAT3/CXCL16 signaling pathway and proposes IARS as a novel potential therapeutic intervention for psoriasis.

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Abstract N°: 1918

Image analysis, the correlation between color and roughness parameters and clinical evaluation of psoriatic lesions using a nomad camera (SkinCam)

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Introduction & Objectives:

Psoriasis is a common, chronic inflammatory disease affecting skin and joints, characterized by silvery thick scales on an underlying erythematous base. Its most common form, psoriasis vulgaris or chronic plaque leads to a substantial burden for individuals and society.

In previous studies, we reported the capacity of the SkinCam® (Nomad imaging system), to discriminate between a lesional and a non-lesional skin area by analyzing color and roughness parameters. The study suggested the possibility to use these techniques (photography and image analysis) for patient follow-up in clinical trials and in dermatology clinics. In line with these observations, a clinical study was postulated with the following aims:

\1. To objectively and remotely measure via image analysis the evolution of psoriatic lesions under treatment using SkinCam® in a clinical set up.

\2. To correlate clinical evaluation with color and roughness image analysis.

Materials & Methods:

Eleven volunteers with a confirmed clinical diagnosis of moderate to severe vulgar psoriasis were enrolled in the study. Patients received divers biologic and other dermatologic treatments. Psoriasis evolution was analyzed over time at three or four follow- up visits. Lesions were photographed by the dermatologist with the SkinCam® system and regions of interest in one psoriatic lesion were selected for each volunteer. Image analysis was performed in the region of interest to measure color, texture and roughness parameters with dedicated algorithms. The results were compared to clinical evaluations to determine a correlation with erythema, scaling and induration.

Results:

We were able to follow the evolution of lesions during treatment to detect minimal changes that may describe an improvement of the disease. A novel pattern of color parameters describing inflammation and scaling was revealed in psoriatic lesions.

The difference between erythema at the baseline and follow- up visits were described, and scaling was also evaluated by measuring skin homogeneity and roughness parameters.

Correlations were observed between colorimetric measurements, roughness parameters, and clinical evaluations. Our results confirmed that the nomadic camera was more sensitive in detecting minimal changes than visual evaluation.

Conclusion:

The study characterizes the visual evolution of psoriatic lesions under different biologic treatments.** Although visual evaluation by a dermatologist is the gold standard for assessment of various skin lesions, our high-resolution imaging can bring quantifiable precision to clinical evaluation, drug performance and comparison, even in the context of minimal changes. We believe that this methodology could also be applied to the evaluation of other inflammatory skin diseases such as eczema, acne or rosacea.

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Abstract N°: 1922

Oral administration of ruxolitinib in psoriasis vulgaris: A case report of plaque psoriasis accompanied by myelofibrosis secondary to polisitemia vera successfully treated with oral ruxolitinib

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease, chracaterized by keratinocyte hyperproliferation and immune cell infiltration. Various therapies have been discovered for psoriasis including topical treatments, phototherapy, convansional systemic agents and biologics.

Materials & Methods:

JAK/STAT pathway inhibitors targeting TNF-α, IL-23 and IL-17 can be effective in psoriasis. Ruxolitinib, FDA-approved first-generation Janus kinase inhibitor for polycythemia vera, myelofibrosis, and acute graft-versus-host disease. Ruxolitinib cream has been investigated in various dermatologic diseases including atopic dermatitis, vitiligo, psoriasis, and alopecia areata. Ruxolitinib 1% and 1.5% cream have been found effective in psoriasis lesions with few mild adverse effects. However, there is no data on the efficacy of oral ruxolitinib in patients with psoriasis vulgaris. Here in, we report a patient diagnosed with myelofibrosis coexisting with psoriasis vulgaris, successfully treated with oral ruxolitinib.

Results:

A 64-year-old male patient with diagnosis of psoriasis vulgaris for 14 years referred to our Dermatology outpatient clinic. He was treated with narrow band ultraviolet-B for 6 months, metotrexat (subcutaneous, 15 mg weekly) for one year and ustekinumab for two years. On dermatological examination, there were well-bordered, erythematous and scaly plaques on body, extremities and scalp (Figure 1). Nail and joint involvement were detected. PASI score was 15. Genetic tests showed positive BCR-ABL test. Ustekinumab was discontinued due to risk of hematological malignancy. He was diagnosed with myelofibrosis secondary to esential trombocytotosis by the Hematology Department. Oral Ruxolitinib (Jakavi®) was started for myelofibrosis by Hematology Department. We followed up patient with only topical treatments (Calcipotriol oinment, mometazone furoat cream and moisturizers). After oral administration of Ruxolitinib, PASI score was 5.4 at month 1, 1.2 at month 2 and 0 at month 3. (Figure 1-2-3). No significant side effects were observed except for a moderate decrease in platelets (88.000) that improved by reducing the oral ruxolitinib dose.

Oral janus kinase inhibitors (JAKi), ruxolitinib and fedratinib, are main treatment options in the management of myeofibrosis,however they may have some potancial side effects and lead decrease in leukocyte, hemoglobin, and platelet concentrations. Indications for the use of JAKi in dermatology are increasing day by day. Topical therapy with JAKi (INCB018424) can be an effective alternative therapeutic option in psoriasis. However, data on the use of JAKi in psoriasis are limited. On the other hand, topical ruxolitinib (Opzelura®) 1.5% is approved by the US Food and Drug Administration (FDA) based on clinical trials in patients 12 years of age or older for the treatment of non-segmental vitiligo. It has been reported topical ruxolitinib have minimally side effects in vitiligo.

Conclusion:

To the best of our knowledge, our case is the first case report in which ruxolitinib was used orally in psoriasis. It is clear that oral ruxolitinib is effective in psoriasis, but it is debatable how necessary its oral use is in patients with psoriasis due to the possible side effects of this drug. More studies are needed on the use of topical and systemic JAKi in psoriasis.

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Abstract N°: 1927

Effectiveness and effect on quality of life of risankizumab treatment in bio-naïve patients – 3-year real world data from the German cohort of the VALUE study

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Introduction & Objectives:

Risankizumab (RZB) is an IL-23 p19 inhibitor approved for the treatment of moderate-to-severe plaque psoriasis (PsO), active psoriasis arthritis and moderate-to-severe active Crohn's disease. Real world data of RZB on effectiveness and in patients' quality of life (QoL) in patients with PsO have been previously reported1-3 but are still limited. This 3-year analysis of the real-world VALUE study assesses the effectiveness and impact on QoL of Risankizumab (RZB) treatment in bio-naïve and bio-experienced patients.

Materials & Methods:

VALUE [NCT03982394] is an ongoing multi-country prospective post-marketing observational study of RZB and other biologics approved for the treatment of moderate-to-severe plaque psoriasis. Treatment decisions were made at the discretion of the patients' physician independently of study enrolment.

In this 3-year interim analysis the patients of the German cohort treated with RZB were divided into a bio-naïve (bio-n) and bio-experienced (bio-e) group. Analyzed parameters include e.g. PASI (Psoriasis Area and Severity Index), DLQI (Dermatological Quality of Life Index), and several relevant patient reported outcome (PRO) questionnaires like 6-Item Stigmatization Scale, Rosenberg self-esteem scale (RSES), Hospital anxiety and depression scale (HADS-A/-D), Perceived Stress Scale (PSS-10), The University of California, Los Angeles (UCLA) loneliness scale and Work productivity and activity impairment (WPAI), and itch.

Data cut-off for this VALUE interim analysis was December the 7th 2023. Data are presented as mean and percentage of patients with [95 % CI], where appropriate.

Results:

Baseline data for 452 patients (228 were bio-n and 224 bio-e) were available in this interim analysis. Absolute (a) PASI scores were higher in the bio-n compared to the bio-e group at baseline (mean: 18,7 and 15.0, respectively; $p<0.0001$). After 3 years of treatment mean aPASI was 1.1 [0.50-1.60] in the bio-n and 2.1 [1.46-2.64] in the bio-e group and lower compared to baseline ($p<0.0001$) with significant differences between groups ($p<0.05$). Achievement of DLQI 0/1 also revealed differences after 3 years of treatment between the bio-n and bio-e group (75.8 % [65.7-84.2] vs. 57.8 % [46.5-68.6], respectively; $p<0.05$).

Sustained effects could also be observed for PROs like stigmatization, RSES, HADS-A/-D, PSS-10, UCLA and WPAI with less patients being meaningful impaired after 1 and 3 years in the bio-n RZB group.

Conclusion:

Patients receiving RZB over the 3-year period showed sustained improvements in effectiveness and QoL. These favorable results were observed in the hard-to-treat group of bio-experienced patients. Especially bio-naïve patients benefitted the most from RZB treatment. These findings indicate the value of an effective treatment at an early timepoint in clinical practice to optimize treatment outcomes which might prevent cumulative life course impairment.

\1. Stavermann et al., presented at EADV Congress 2023, P2309.

\2. Staubach et al., presented at EADV Congress 2023, P2349.

\3. Stavermann et al., presented at AAD Annual Meeting 2024, P51362.

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Abstract N°: 1954

Prediction of the risk of discontinuation of Anti-TNF among patients with plaque psoriasis: A logistic regression model

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Introduction & Objectives:

Psoriasis is a complex immune-mediated skin disease. Nowadays, immunobiologics have proven themselves to be highly effective for its management. But there are some concomitant pathologies, which could impact biologic treatment response. The aim of this study is to investigate the significant risk factors predicting discontinuation of Anti-TNF (DoAnti-TNF) by logistic regression (LR) analysis and establish a risk prediction model.

Materials & Methods:

42 cases of moderate-to-severe plaque psoriasis were enrolled in this study. 11 risk factors were used for the univariate and multivariate analysis based on the literature and clinical experience: age, sex, BMI, disease duration, smoking, PASI, presence of diabetes, biologic naive status, blood levels of cholesterol, triglycerides, and creatinine. Several significant risk factors of DoAnti-TNF were found, and a predictive model was established using univariate and multivariate LR analyses. All statistical analyses were performed using R software.

Results:

DoAnti-TNF occurred in 28.6% (12/42) of cases. Univariate analysis showed an increase (p=0,024) of the risk of DoAnti-TNF for patients with concomitant diabetes, odds ratio (OR) =14.5 (95% CI 1.42 - 149) compared to patients without diabetes. An increase (p=0,005) of the risk of DoAnti-TNF was revealed with increasing BMI, OR=1.25 (95% CI 1.07-1.46) for each gradation. An increase (p=0,021) in the risk of DoAnti-TNF was established with an increase in the blood level of triglycerides, OR=2.85 (95% CI 1.17-6.94) for each gradation. In the second stage of the analysis, using the method of building multivariate LR models, the selection of factors significantly associated with the risk of DoAnti-TNF for patients with psoriasis was performed. The AIC criterion was used. Two significant risk factors were identified: the presence of diabetes and BMI. The multivariate LR analysis showed an increase (p=0.014) in the risk of DoAnti-TNF for patients with concomitant diabetes, OR=39 (95% CI 2.12-718) compared to patients without diabetes (when standardized by BMI). An increase (p=0.005) in the risk of DoAnti-TNF was revealed with an increase in BMI, OR=1.35 (95% CI 1.11-1.65) for each gradation (when standardized by the presence of diabetes).

The prediction of DoAnti-TNF was analyzed using the ROC curve (AUC =0.894 (95% BI 0.789-1). The Youden index was applied to identify the optimal cutoff point for the LR model (Ycrit ≥ 0.421), the sensitivity of the predictive model for DoAnti-TNF is 75.0% (95% BI 42.8% - 94.5%), the specificity of the model is 90.0% (95% CI 73.5% - 97.9%)

Conclusion:

The significant risk factors predicting DoAnti-TNF are increased BMI and concomitant diabetes. A 2-factor model for predicting the risk of DoAnti-TNF was built on the selected set of risk factors, the model is adequate (χ2-squared - 21.2 with 2 degrees of freedom, p<0.001).

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Abstract N°: 1963

A novel, rapid, and reliable measure of psoriasis severity for use in clinical practice; validating G2-PASE using registry data.

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Introduction & Objectives:

The Psoriasis Area and Severity Index (PASI) is a composite measure of psoriasis disease severity commonly used to determine treatment eligibility and response. It is, however, time consuming for every-day clinical use. The Gulliver-Gestalt-Psoriasis Area Severity Estimate (G2-PASE) measure (Figure 1) was developed to approximate PASI scores using Body Surface Area (BSA) and the Physician Global Assessment (PGA).

To determine the reliability and validity of G2-PASE compared to PASI using data from a multi-center, Canadian cohort of patients with psoriasis.

Materials & Methods:

Baseline disease severity data (PGA, BSA, and PASI) from 1,803 Canadian patients with moderate to severe psoriasis enrolled in the global, prospective, longitudinal, disease-based Psoriasis Longitudinal Assessment and Registry (PSOLAR) were leveraged to test the reliability and validity of the previously developed G2-PASE algorithm. The G2-PASE score for each patient was calculated by applying baseline BSA and PGA values available from PSOLAR patient data at enrollment. The correlation and reliability of G2-PASE compared to the collected PASI scores for each patient at enrolment were then assessed.

Results:

The average baseline PASI score for the Canadian PSOLAR cohort included in this study was 5.52 (SD 6.44, range 0.00-64.30). The mean calculated G2-PASE score was 8.37 (SD 7.51, range 0.00-45.00). Among the observations, the Pearson's correlation coefficient was 0.83 ($p<0.0001$), indicating very strong and significant correlation between PASI and G2-PASE scores (Figure 2). The standardized Cronbach coefficient alpha was 0.91.

Conclusion:

This study validates G2-PASE as a reliable measure of psoriasis severity when compared to PASI scores among a large cohort of patients with predominantly moderate to severe disease.

G2-PASE = PGA×3×BSAa score

a: BSA <10% = 1; BSA 10%–30% = 2; BSA >30% = 3

Figure 1. G2-PASE calculation.

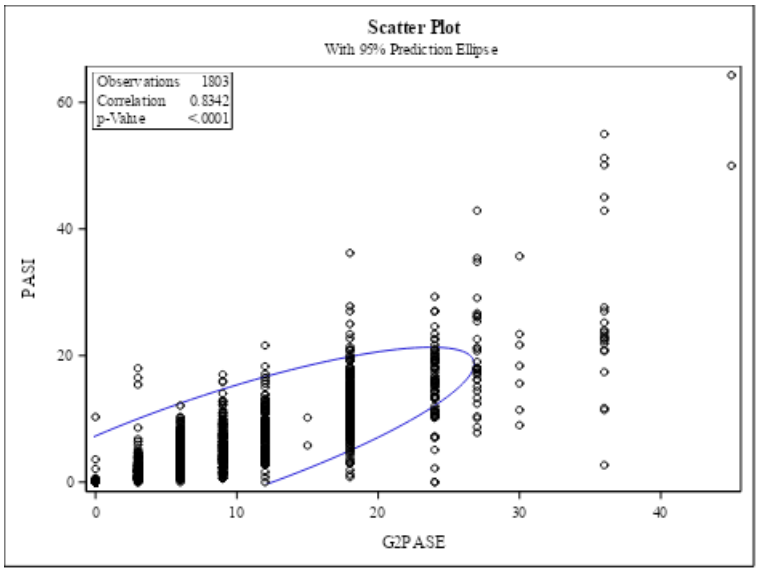

Figure 2. Scatter plot and prediction ellipse of correlation between PASI scores from Canadian patients enrolled in PSOLAR and calculated G2-PASE scores.

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Abstract N°: 2011

Fatigue Assessment in Patients with Psoriasis and Psoriatic Arthritis

Anber Tanaka[1], Carolina Sampaio[1], Fernanda Koga[1], Isabela Sampaio[1]

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Fatigue Assessment in Patients with Psoriasis and Psoriatic Arthritis

Introduction & Objectives:

Psoriasis is a chronic, multifactorial and immunomodulated disease. The prevalence increases with age, affects men and women equally and is associated with multiple comorbidities.

Fatigue is present in 17 to 50% of patients with psoriasis, and is defined as “extreme tiredness resulting from mental or physical exertion or illness”. Patients with psoriatic arthritis tend to have higher fatigue levels than patients with isolated psoriasis.

This study aims to analyze the presence and associations of fatigue in patients with diagnosis of psoriasis and psoriatic arthritis. Additionally, we seek to evaluate if fatigue severity is associated with arthritis, obesity, smoking, sedentarism, age, comorbidities, severity of cutaneal lesions, treatment and inflammatory laboratory tests.

Materials & Methods:

In this cross-sectional study, 90 patients were divided into three groups: patients diagnosed with psoriasis by a dermatologist (group 1); patients diagnosed with psoriasis by a dermatologist and with psoriatic arthritis by a rheumatologist (group 2); and patients without psoriasis or psoriatic arthritis (group 3). Epidemiologic data such as age, gender, BMI, comorbidities, physical activities practiced, current medications, previous treatments, time since onset of psoriasis and time until diagnosis was collected. The patients were evaluated through the Functional Assessment of Chronic Illness Therapy – Fatigue Scale (FACIT-F), Dermatology Life Quality Index (DLQI), fatigue Visual Analog Scale (VAS) and Psoriasis Area and Severity Index (PASI). In addition, erythrocyte sedimentation rate (ESR) and c-reactive protein (CRP) were analyzed in patients from groups 1 and 2.

Results:

In the epidemiological analysis, this study found that patients with psoriasis (groups 1 and 2) have higher weight and BMI than patients from the control group. Other epidemiological factors were statistically similar between all groups.

Patients with psoriatic arthritis had higher scores in all FACIT-F sections except Functional Well-Being. The scores of Physical Well-Being and Emotional Well-being were lower in patients with psoriasis than patients in the control group. There was no statistically significant difference in FACIT-F scores between groups 1 and 2. In all groups, FACIT-F scores were significantly lower in women and sedentary patients. There was no relevant difference between the groups in the evaluation of the VAS, DLQI, PASI, ESR or CRP. Current treatments did not impact the FACIT-F score.

Conclusion:

Threre was a positive correlation between psoriasis and presence of fatigue. Similarly to other studies, fatigue was not correlated to the severity of psoriasis – which may contribute to its undervaluation and undertreatment.

Higher levels of fatigue were reported in sedentary patients, which is corroborated in current literature and validates the need for multi-professional approaches. Other studies found correlation between fatigue and depression and chronic pain, which was not found in this analysis. Psoriatic arthritis was not associated with higher fatigue levels in this study, differing from recent articles.

This study establishes the need for a multi-professional assessment of patients with psoriasis. More studies are needed in order to understand fatigue’s causes and possible treatments.

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Abstract N°: 2018

Prevalence of Psychiatric Comorbidities in Patients with Psoriasis

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Prevalence of Psychiatric Comorbidities in Patients with Psoriasis

Introduction & Objectives:

Psoriasis is a highly prevalent cutaneous and articular disease that causes great quality of life and mental health impact. Due to the stigma associated with skin diseases, patients commonly show symptoms of depression, suicidal ideation and anxiety.

Several factors may contribute to the development of depression in patients with psoriasis, such as pain and pruritus of skin lesions, self-esteem issues, labor difficulties, isolation and emotional stress. Inflammatory interleukins also affect the metabolism of neurotransmitters. Patients with psoriasis have a higher prevalence of anxiety, with association between symptoms of anxiety and higher scores in the Dermatology Life Quality Index (DLQI).

This study aims to analyze the prevalence of psychiatric comorbidities in patients with psoriasis. Additionally, we seek to evaluate if the risk of depression and anxiety is associated with age, gender, body-mass index (BMI), treatment used and severity of psoriasis.

Materials & Methods:

In this cross-sectional study, 100 patients were divided into two groups: patients diagnosed with psoriasis by a dermatologist (group 1), and patients with other non-inflammatory skin diseases (group 2). Patients were evaluated with the Hospital Anxiety and Depression Scale (HADS), Dermatology Life Quality Index (DLQI) and Psoriasis Area and Severity Index (PASI). Epidemiological data such as age, gender, race, BMI, treatments in use, time since diagnosis, type of psoriasis, presence of psoriatic arthritis and presence of nail involvement were also analyzed.

Results:

A significant difference was observed between the groups regarding the DLQI score, showing a greater quality of life impact in psoriasis when compared to other non-inflammatory skin diseases. Other epidemiological variables did not significantly affect the DLQI score. Higher PASI scores were associated with nail involvement, BMI, higher DLQI scores and time since diagnosis.

There was no statistically significant difference between both groups in HADS scores. Female patients with psoriasis have higher HADS-A and HADS-D scores, indicating more intense anxious and depressive symptoms. Other variables did not affect depression and anxiety scores. There is a statistically relevant correlation between PASI scores and a higher diagnostic probability of depression.

Conclusion:

Despite being statistically similar, patients with psoriasis scored higher in the DLQI scale, indicating a large impact on quality of life. Female patients in the psoriasis group had higher depression and anxiety scores. The correlation

between severity of psoriasis and greater diagnostic probability of depression shows the importance of a thorough evaluation in these patients. The results of this research also demonstrated significant correlation between PASI scores and nail involvement, BMI and time of diagnosis in patients with psoriasis. This indicates that the severity of psoriasis is linked to these factors. The associations found in this study highlight the complexity of psoriasis as a dermatological and psychological condition, reinforcing the need for an integral approach. In future studies, we suggest long-term evaluation of patients, as well as the assessment of other psychiatric comorbidities such as suicidal ideation and sleep disorders.

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Abstract N°: 2027

Efficacy of Non-Ablative Bipolar Radiofrequency in The Treatment of Fingernail Psoriasis: A Novel Therapeutic Modality.

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Introduction & Objectives:

Psoriasis is a common chronic systemic disease affecting the skin, the nails as well as joints. Nails are commonly associated with a greater severity of the disease. Radiofrequency (RF) is a type of non-ionizing radiation that provides energy originating from electric current to generate heat inside the dermis with anti-inflammatory effects.

OBJECTIVE: To assess the efficacy of non-ablative bipolar radiofrequency in the treatment of fingernail psoriasis.

Materials & Methods:

Forty-three affected fingernails were treated with non-ablative bipolar RF. Sessions were performed every 2 weeks for 2 months with a maximum of 5 sessions. The 32-points target nail psoriasis severity index (tNAPSI), ultrasonography and the physicians' global assessment were used for assessment at baseline, 1 and 3 months from the last treatment session.

Results:

One month after last RF session, a significant reduction in median tNAPSI score from baseline was recorded ($p=0.002$), with a 58.33% reduction in pits count. The median thickness of subungual hyperkeratosis decreased significantly from baseline ($p=0.024$) and the median score of onycholysis was also significantly reduced ($p=0.005$). Ultrasonography revealed a significant reduction in median nail matrix, bed thickness and nail vascularity ($p=0.020$, $p<0.001$, $p=0.013$, respectively).

Conclusion:

Radiofrequency may offer a safe and effective treatment modality for fingernail psoriasis.

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Abstract N°: 2044

Elucidating cellular and molecular mechanisms during oral roflumilast treatment in moderate-to-severe psoriasis

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Introduction & Objectives:

Roflumilast is a phosphodiesterase-4 (PDE-4) inhibitor originally developed for the treatment of chronic obstructive pulmonary disease. A recent randomized clinical trial (EudraCT 2020-000711-76;** ClinicalTrials.gov NCT04549870) showed the efficacy and safety of oral roflumilast treatment in moderate-to-severe psoriasis. The underlying cellular and molecular mechanisms affected by oral roflumilast in psoriatic skin, however, have not previously been studied, and despite a wide array of treatment options, a need for more convenient and inexpensive oral medications for psoriasis patients persists. The objective of this study was to investigate the cellular and molecular effects of oral roflumilast treatment on psoriatic skin lesions.

Materials & Methods:

Patients with moderate-to-severe psoriasis were allocated 1:1 to monotherapy with oral roflumilast 500 µg once daily or placebo in the clinical trial. At baseline, week 4 and week 12, skin punch biopsies were collected from 12 patients in each treatment arm and analyzed in a mechanistic sub-study. Quantitative immunohistochemistry (IHC) and RNA-sequencing were performed.

Results:

Epidermal thickness was comparable between the roflumilast and the placebo groups at baseline (p = 0.5048). Throughout the study period, median epidermal thickness of psoriatic lesional skin was significantly lower in patients treated with roflumilast compared with placebo (p = 0.0059 at week 4 and p = 0.0286 at week 12). After 4 weeks, a median reduction in epidermal thickness from baseline of -23% was observed in the roflumilast group, while a 7% increase was observed in the placebo group (p= 0.0036). Corresponding percentage changes at week 12 were -33% and 5%, respectively (p = 0.1277). Keratinocyte proliferation, quantified through the Ki67-marker, was also reduced in the roflumilast group compared with placebo, with significant differences found at week 4 (p = 0.0151). Median CD4+ and CD8+ cellular infiltrates in the epidermis and dermis of lesional skin were both reduced (although non-significantly) in the roflumilast group compared with placebo.

Conclusion:

The histologic and cellular changes mediated by oral roflumilast treatment were consistent with the observed clinical response in the form of reduced epidermal thickness, keratinocyte proliferation, and CD4+ and CD8+ T-cell infiltration. RNA-sequencing results are currently underway and are being processed to uncover changes at the transcriptomic level.

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Abstract N°: 2050

Exploring survivin, as a new biomarker in psoriasis: a pilot study in 16 patients under brodalumab treatment

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Introduction & Objectives: Psoriasis is an autoimmune disease characterized by the overproduction and reduced apoptosis of keratinocytes. Survivin, an apoptosis inhibitor protein, is expressed in 70-80% of psoriatic plaques, which is much higher than in the normal skin of psoriatic patients as well as otherwise healthy individuals. The objective of this study is to evaluate the effect of anti-IL17RA (brodalumab) on survivin protein expression in the psoriatic skin of patients at weeks 0, 12, and 52, and its association with the clinical response of the disease.

Materials & Methods: A one-year single-center prospective observational case-control study was conducted at the Outpatient Dermatological Clinic in Tzaneio General Hospital in Greece. The study included 16 patients with moderate to severe psoriasis bionaive, who started therapy with brodalumab, and 16 healthy individuals as a control group. Demographic data, the duration and localization of psoriatic disease were also recorded. Before treatment, all patients underwent standard laboratory examinations, and survivin blood levels were measured at weeks 0, 12, and 52. Biopsies were taken from lesional and normal skin areas at week 0 to confirm the disease activity and to detect survivin tissue expression. Furthermore, the skin specimen at week 52 was examined, derived from the severely affected lesional skin area at the baseline visit. Clinical assessment of the disease included evaluation of PASI,BSA and DLQI scores.

The control group was selected randomly and underwent blood measurement of survivin and also skin expression of the protein with biopsy.

Results: The median PASI decreased from 12.5 at baseline to 0.0 at 12 months, and also DLQI from a mean of 15.2 (SD=2.4) at baseline to 0.1 (SD=0.3) at 12 months. Survivin serum levels at baseline in psoriasis group exhibited a lower mean serum level 24.3 (SD=9.5) compared to the control group 29.4 (SD=18.1). At 12 months, the psoriasis group showed a significant reduction in serum survivin levels, with mean serum levels 13.1 (SD=7.3) a statistically significant decrease from the control group's levels . In tissue samples, mean survivin level in healthy skin at baseline was higher in the psoriasis group 0.041 (SD=0.01) than in the control group 0.033 (SD=0.05) statistically significant. Psoriatic skin tissue at baseline exhibited significantly elevated mean survivin levels 0.072 (SD=0.02) compared to healthy skin from the control group 0.033 (SD=0.05). By 12 months, tissue survivin levels in psoriatic skin decreased significantly to a mean of 0.037 (SD=0.01), but still differed significantly from healthy skin in control group.

Conclusion: According to our knowledge, this is the first study that explores survivin levels in both the skin and serum of psoriatic patients, before and after treatment with an anti-IL17RA inhibitor, as compared to the control's. Our study found that survivin is present in higher concentrations in the skin biopsies of psoriatic patients compared to the control group. We also discovered that the levels of survivin in the skin are significantly reduced after treatment with anti-IL17RA, although they do not reach the levels of the control group. Further studies, with a larger psoriatic patient population, may shed light on the pathophysiology of psoriasis and the mechanism of action of survivin. Our study highlights the potential of survivin as a biomarker in the current era of psoriasis research.

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Abstract N°: 2062

Physician-Reported Outcomes and Patient-Reported Outcomes in Psoriatic Arthritis with Secukinumab: 36 Week Interim Analysis Results from the UNMASK 2 Study

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Introduction & Objectives:

Psoriatic arthritis (PsA) is a heterogeneous systemic inflammatory disease that requires a variety of outcome measures to describe the treatment effectiveness1-2. This interim analysis presents the 36-week effectiveness and

safety data of secukinumab in treating Chinese psoriasis (PsO) patients who have concomitant PsA at baseline.

Materials & Methods:

UNMASK2 is an ongoing, prospective, observational study conducted in 42 sites across China. Patients (≥18 years old) with moderate to severe plaque psoriasis treated with secukinumab for the first time between December 2021 and October 2022 were enrolled in the study. This analysis included a subgroup of UNMASK2 study population who 1) completed the visit at or quit the study prior to week 36 by June 9, 2023, and 2) had concomitant PsA at baseline.

The below physician- and patient-reported outcomes were assessed: Peripheral arthritis: Swollen joint count 28 (SJC28) and Tender joint count 28 (TJC28); Skin psoriasis: Psoriasis Area and Severity Index (PASI) and Body Surface Area Involvement Score (BSA); Nail psoriasis: modified Nail Psoriasis Severity Index (mNAPSI); Physician's Global Assessment (PGA): PGA Visual Analogue Scale score (VAS, scale 0-100 mm); Pain: Pain VAS (scale 0-100 mm); Patient's Global Assessment (PtGA): PtGA VAS (scale 0-100 mm); Physical function: Health Assessment Questionnaire Disability Index (HAQ-DI); Health-related Quality of Life: Physical Component Summary (PCS) and Mental Component Summary (MCS) of the Short Form-36 (SF-36) Health Survey.

Results:

Among 999 patients enrolled in UNMASK2, 723 (72.30%) completed 36-week visit or quit prior to week 36 as of June 9, 2023. Among these 112 (15.49%) with PsA at baseline were included in this subgroup interim analysis.

The patients had a mean age of 45.10 years. 66.96% were male. Compared with previous trials3, these patients had more severe skin psoriasis and less peripheral arthritis involvement at baseline (Table 1).

Physician-reported outcomes: the mean SJC28 and TJC28 decreased from 4.0 and 5.6 at baseline to 1.0 and 1.3 at week 36, respectively. 85.54% and 84.34% patients achieved PASI ≤3 and BSA ≤3%, respectively. The mean mNAPSI decreased from 24.3 at baseline to 8.8 at week 36. 96.30% patients achieved PGA VAS improvement ≥30% at week 36.

Patient-reported outcomes: 60.29%, 67.44% and 77.97% of patients achieved pain VAS improvement ≥30% at week 4, week 16 and week 36 respectively. 52.94%, 65.12% and 74.14% achieved PtGA VAS improvement ≥30%, respectively. The mean HAQ-DI score decreased from 0.6 at baseline to 0.2 at Week 36. The minimal clinically important difference (MCID) of ≥2.5 in SF-36 PCS and MCS were both observed in 72.58% patients at week 36 (Table 2).

From this interim analysis, there were 61 (54.46%) and 8 (7.14%) patients reporting adverse events and serious adverse events. No secukinumab discontinuation due to adverse events was reported. No death was reported. The most frequent AEs are reported in table 3.

Conclusion:

Due to the complexity and heterogeneity of PsA disease, a comprehensive assessment of disease is needed. The interim subgroup results suggested that secukinumab had improvement in both physician-reported outcomes and patient-reported outcomes in Chinese PsO concomitant PsA patients over a 36-week period. Safety data was consistent with previous trials4. These findings need to be confirmed by results from entire study population.

References

[1] Ogdie, A. et al. Arthritis Care Res (Hoboken). 2020;72 Suppl 10(Suppl 10):82-109.
[2] Ogdie, A, et al. J Rheumatol. 2017;44(5):697-700.
[3] Orbai AM, et al. J Rheumatol. 2020; 47(6):854-864.
[4] Rech J, et al. Lancet Rheumatol. 2020;2(4):e227-e235.

Table 1 Baseline Clinical Characteristics of PsO with Concomitant PsA Patients

Variables	Mean (SD)
Physician-reported outcomes	
SJC 28	4.0 (6.09)
TJC 28	5.6 (7.07)
PASI	16.6 (13.34)
BSA	24.9 (24.22)
mNAPSI	24.3 (25.38)
PGA VAS	51.2 (23.20)
Patient-reported outcomes	
Pain VAS	43.5 (28.91)
PtGA VAS	47.1 (29.46)
HAQ-DI	0.6 (0.63)
SF-36 PCS	41.6 (8.91)
SF-36 MCS	38.5 (12.39)

Note: PASI and BSA are summarized based on patients who have psoriatic skin symptom (N=112); mNAPSI are summarized based on patients who have nail psoriasis (N=60); SJC, TJC, PGA VAS, pain VAS, PtGA VAS, HAD-DI and SF-36 are summarized based on patients who have joint symptom (N=85). are SD: standard deviation.

Table 2 Physician- and Patient-Reported Outcomes at Week 4, 12, 16, 24 and 36

	Week 4	Week 12	Week 16	Week 24	Week 36
Physician-reported outcomes					
SJC 28, Mean (SD)	2.2 (4.68)	1.4 (2.80)	1.2 (2.70)	1.1 (2.88)	1.0 (3.16)
TJC 28, Mean (SD)	3.2 (5.07)	1.8 (2.99)	1.6 (3.01)	1.1 (2.38)	1.3 (2.57)
PASI ≤3	41/93 (44.09)	57/70 (81.43)	52/59 (88.14)	68/75 (90.67)	71/83 (85.54)
BSA ≤3%	25/92 (27.17)	53/69 (76.81)	49/58 (84.48)	60/72 (83.33)	70/83 (84.34)
mNAPSI, Mean (SD)	22.1 (25.85)	21.0 (28.80)	13.0 (21.55)	10.6 (16.25)	8.8 (14.13)
PGA VAS improvement ≥30%	42/69 (60.87)	40/45 (88.89)	34/41 (82.93)	45/50 (90.00)	52/54 (96.30)
Patient-reported outcomes					
Pain VAS improvement ≥30%	41/68 (60.29)	36/48 (75.00)	29/43 (67.44)	39/52 (75.00)	46/59 (77.97)
PtGA VAS improvement ≥30%	36/68 (52.94)	33/48 (68.75)	28/43 (65.12)	41/52 (78.85)	43/58 (74.14)
HAQ-DI, Mean (SD)	0.4 (0.51)	0.2 (0.39)	0.2 (0.31)	0.2 (0.37)	0.2 (0.35)
SF-36 PCS improvement ≥2.5	45/69 (65.22)	39/49 (79.59)	32/44 (72.73)	38/51 (74.51)	45/62 (72.58)
SF-36 MCS improvement ≥2.5	39/69 (56.52)	35/49 (71.43)	33/44 (75.00)	34/51 (66.67)	45/62 (72.58)

Note: PASI and BSA are summarized based on patients who have psoriatic skin symptom (At week 4, 12, 24, and 36, there were 103, 88, 81, 95, and 103 patients with follow-up visits respectively); mNAPSI are summarized based on patients who have nail psoriasis (At week 4, 12, 24, and 36, there were 56, 50, 50, 50, and 58 patients with follow-up visits respectively); SJC, TJC, PGA VAS, pain VAS, PtGA VAS, HAD-DI and SF-36 are summarized based on patients who have joint symptom (At week 4, 12, 24, and 36, there were 81, 66, 63, 71, and 79 patients with follow-up visits respectively). Unless otherwise specified, reported in the table are n/N (%). N: Number of patients with non-missing data; n: Number of patients achieving the specified endpoint; SD: standard deviation.

Table 3. The most frequent adverse events by MedDRA PT

Adverse event (by PT, >1%)	N (%)
COVID-19	17 (15.18)
Pyrexia	6 (5.36)
Cough	5 (4.46)
Upper respiratory tract infection	4 (3.57)
Tinea pedis	4 (3.57)
Psoriasis	4 (3.57)
Dermatitis	3 (2.68)
Eczema	3 (2.68)
SARS-CoV-2 test positive	2 (1.79)
Oropharyngeal pain	2 (1.79)
Productive cough	2 (1.79)
Fatigue	2 (1.79)
Rhinitis	2 (1.79)
Pruritus	2 (1.79)

Note: Adverse events were coded by MedDRA PT. Listed are the most frequent adverse events incidence of which is greater than 1%. MedDRA, medical dictionary for regulatory activities; PT, preferred term.

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Abstract N°: 2063

Effectiveness and Safety of Secukinumab Among Chinese Adults with Psoriasis: Interim Results from the UNMASK2 Study

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Introduction & Objectives:

Psoriasis (PsO) is a chronic immune-mediated, inflammatory, systemic disease. Secukinumab has shown sustained

effectiveness and a favorable safety profile, yet there is limited evidence in a real-world setting in China. This abstract reports the interim analysis results from the UNMASK2 study: the 36-week effectiveness and safety data of secukinumab treating moderate-to-severe psoriasis in China.

Materials & Methods:

UNMASK2 is a large, ongoing, prospective, observational study conducted at 42 sites in China. Adult patients with moderate-to-severe plaque psoriasis and initiating secukinumab treatment between December 2021 and October 2022 were enrolled in the study. This interim analysis included patients by the criteria of having completed the week 36 visit or having achieved the end of study prior to week 36 by Jun 9th 2023. The effectiveness endpoints included psoriasis area and severity index (PASI), investigator's global assessment (IGA), body surface area (BSA) and dermatology life quality index (DLQI). Safety was evaluated by analyzing incidence of adverse event (AE), serious adverse event (SAE), treatment discontinuation due to AE and all-cause mortality.

Results:

As of June 9th, 2023, 999 moderate-to-severe plaque psoriasis patients were enrolled in the UNMASK2 study. Among this 723 (72.37%) patients were included in this interim analysis. Patients had a mean age of 40.28 years at baseline, with over half of them being male (68.19%). The mean PsO duration was 11.70 years. Compared with China Phase 3 trial, patients in this analysis had less severe skin manifestations (table 1).

PASI 75, PASI 90 and PASI 100 was achieved in 93.35%, 81.15% and 59.42% of patients at week 16, respectively, reaching 94.55%, 85.12% and 64.15% at week 24 and maintained to week 36 (94.23%, 86.15% and 63.85%). The proportions of patients achieving IGA0/1 were 82.49% at week 16 and maintained to week 36 (83.03%). The mean changes of BSA from baseline (mean±SD) demonstrated sustained reductions, with -21.7 ±18.35 at week 16 ($P<0.0001$) and -23.3 ± 19.85 at week 36 ($P<0.0001$). Furthermore, a total of 63.67% of patients achieved a DLQI 0/1 response at week 16 and maintained it until week 36 (68.71%).

In this interim analysis, there were 364 (50.35%) and 28 (3.87%) patients reporting AE and SAE, respectively. Six patients (0.83%) discontinued secukinumab due to AE. No all-cause death was reported. The most frequent AE are reported in table 3.

Conclusion:

This interim analysis results suggest good and sustained effectiveness of secukinumab treatment moderate to severe plaque psoriasis patients over a 36-week period in real world setting. The most frequent AE were COVID-19 and pyrexia, probably due to the pandemic during the study period. The remaining common AE were known risks with relatively low incidence, aligning with the safety profile in previous study2. As this is an interim analysis with a subgroup patients included, complete results are needed to further confirm above conclusion.

Reference

[1] Cai, L. et al. Chin Med J (Engl). 2020. 133(22):2665-2673.

[2] Gottlieb, AB. et al. Acta Derm Venereol. 2022. 102:adv00698.

Table 1. Baseline characteristics

	Mean (SD)
Age, years	40.3 (13.14)
Gender, male, n (%)	493 (68.19)
Time from first PsO diagnosis, years	11.7 (9.07)
Previous treatment	
Traditional systemic therapy, n (%)	122 (16.87)
Biologics, n (%)	25 (3.46)
PASI	17.5 (11.47)
BSA	24.2 (20.40)
DLQI	13.0 (6.88)

Note: Otherwise specified, mean (SD) is reported. SD: standard deviation.

Table 2. Clinical Outcomes of PASI, IGA, BSA and DLQI over 36-week period

	Week 4	Week 12	Week 16	Week 24	Week 36
PASI 75	284 (47.89)	470 (90.73)	421 (93.35)	451 (94.55)	490 (94.23)
PASI 90	131 (22.09)	394 (76.06)	366 (81.15)	406 (85.12)	448 (86.15)
PASI 100	54 (9.11)	234 (45.17)	268 (59.42)	306 (64.15)	332 (63.85)
BSA reduction, mean (SD)	11.4(13.83)	20.5(18.41)	21.7(18.35)	22.9(19.83)	23.3(19.85)
IGA 0/1	218 (34.94)	423 (77.61)	391 (82.49)	422 (84.23)	460 (83.03)
DLQI 0/1	160 (25.68)	306 (56.98)	305 (63.67)	372 (70.99)	382 (68.71)

Note: Otherwise specified, n (%) is reported. SD: standard deviation.

Table 3. The most frequent adverse events by MedDRA PT

Adverse event (by PT, >1%)	
COVID-19	94 (13.00)
Pyrexia	43 (5.95)
Upper respiratory tract infection	24 (3.32)
Eczema	24 (3.32)
SARS-CoV-2 test positive	21 (2.90)
Cough	13 (1.80)
Pruritus	12 (1.66)
Pharyngitis	10 (1.38)
Psoriasis	10 (1.38)
Folliculitis	9 (1.24)
Arthralgia	8 (1.11)
Acne	8 (1.11)
Dermatitis*	8 (1.11)
Dermatitis allergic	8 (1.11)

Note: Adverse events were coded by MedDRA PT. Listed are the most frequent adverse events incidence of which is greater than 1%. MedDRA, medical dictionary for regulatory activities; PT, preferred term.

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Abstract N°: 2073

Application of NLP AI Tools in Dermatology: A cross sectional comparative study on Psoriasis Patient Data

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Introduction & Objectives:

Psoriasis, a chronic immune mediated disorder affecting the skin and joints, presents myriad challenges in diagnosis and management due to its diverse manifestations and complex etiology. Its association with comorbidities, such as psoriatic arthritis, complicates patient care and necessitates accurate classification methods for effective treatment decisions. Patient data in electronic medical records (EMR) supports treatment efficiency, disease classification, and quality of life evaluations. The challenge lies in the unstructured nature of clinical data, making its gathering and organization time-consuming. Recent integration of natural language processing (NLP) with EMR data has enhanced disease classification and research, providing valuable insights for improving patient care. Our study evaluates ChatGPT-4's ability to structure unstructured data, focusing on disease distribution and specific nail and joint involvement

Materials & Methods:

Data from the EMR of 94 patients at Sheba Medical Center's Dermatology department or Psoriasis Outpatient Clinic were analyzed. These included randomly selected visits with detailed anamneses, physical examinations, and treatment plans. The data, originally in Hebrew, was input into a ChatGPT-4 interface to analyze and report in English the affected body areas by psoriasis, especially noting nails and joints. A senior dermatologist also analyzed the EMR data similarly. The accuracy of ChatGPT-4's analysis was compared with the dermatologist's findings. Statistical significance was determined using Mann-Whitney and Chi-square tests for continuance and categorical variables, respectively, with $P<0.05$.

Results:

Of the 94 medical records reviewed, 55 were from female patients (58.5%) and 39 from male patients (41.5%). The age range was 18.9 to 86.7 years, with an average word count of 278 ± 154.1 in visit notes. Nail involvement was observed in 32 cases (34.0%), with ChatGPT-4 correctly identifying 29 cases (90.6% sensitivity, 100% specificity). Joint involvement was noted in 25 cases (26.6%), with 24 correctly identified (96.0% sensitivity, 98.6% specificity). In total, 479 body areas were involved across all visits; ChatGPT-4 accurately identified 445 (92.9%) but missed 34 (7.1%). Additionally, it mistakenly identified 30 of 475 body areas as involved. ChatGPT-4 accurately identified all affected body areas in 54 cases (57.4%) without any errors, but inaccuracies occurred in 40 cases (42.6%). Significant differences were observed between the two ChatGPT-4 accuracy groups regarding the number of characters ($p=0.005$), number of words ($p=0.008$), and number of body areas ($p=0.003$).

Conclusion:

ChatGPT-4 demonstrated a high level of performance in analyzing detailed and complex unstructured data from psoriasis patients, effectively identifying involved body areas, including nails and joints. NLP AI tools can be considered valuable aids in analyzing complex medical data for both follow-up and research purposes.

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Abstract N°: 2094

Genetic polymorphisms in psoriasis: investigating variations for precise responseprofiling to brodalumab in real-life clinical practice.

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Introduction & Objectives: Brodalumab, a monoclonal antibody inhibitor of IL-17RA, is approved for treating moderate to severe psoriasis. Despite its high success rates, a subset of patients fails to respond to treatment. Presently, no published studies explore the potential of polymorphisms in predicting response to this drug. This study aims to investigate the association of 180 polymorphisms with brodalumab effectiveness in real-world clinical practice, using absolute PASI ≤1 to identify super-responders.

Materials & Methods: A cohort of 119 plaque psoriasis patients from 10 Spanish hospitals, receiving brodalumab for at least 24 weeks, underwent genotyping for 180 polymorphisms associated with psoriasis immunopathogenesis. Optimal response was assessed by absolute PASI ≤1 at 6 and 12 months. Statistical analysis employed the last observation carried forward method for handling discontinuations due to efficacy issues. Multivariate analysis incorporated polymorphisms and clinical demographic variables with a False Discovery Rate ≤0.25.

Results: Of 119 included patients (52% male, mean age 51.1 ± 13 years, mean weight 84.5 ± 20.4 kg), 22% were biological treatment-naïve, and 24% had psoriatic arthritis. At 6 months, 87% achieved PASI≤3, 76% PASI ≤2, and 68% PASI ≤1; at 12 months, these percentages were 87%, 77%, and 62%, respectively. Five patients were excluded due to genotyping errors. Previous use of disease-modifying anti-rheumatic drugs and biologicals, psoriatic arthritis diagnosis, and patient weight significantly influenced brodalumab response. Univariate analysis found no polymorphism associated with achieving PASI ≤1 at 6 months. However, at 12 months, polymorphisms rs495337 (SPATA2), rs6311 (HTR2A), and rs4085613 (LCE3D) were associated with achieving PASI ≤1 independently of previous biologic and DMARD usage, psoriatic arthritis, or weight. Genotypes CT-TT for rs6311 (HTR2A) and GT for rs4085613 (LCE3D) were identified as risk factors for not achieving PASI≤1, while AG-AA for rs495337 (SPATA2) were protective. The model's area under the curve was 0.83 (95% CI: 0.75-0.91), with sensitivity of 0.69 and specificity of 0.91.

Conclusion: This study reveals genetic variations linked to optimal response to brodalumab, offering potential insights into its efficacy in treating plaque psoriasis.

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Efficacy and safety of treatment with biological drugs in psoriasis patients with a history of cancer: a single-centre observational study

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Introduction & Objectives:

Psoriasis is a multifactorial, chronical, systemic disease mainly involving skin and articulations. In severe or refractory psoriasis, treatment guidelines advocate for the use of biological therapies targeting TNF-alpha or the IL-23/17 axis. Clinical trials and real-world evidence have extensively documented the efficacy and safety of these biological agents. However, the safety of biologic treatments in psoriasis patients with a history or ongoing malignancy remains uncertain, and there's ongoing debate about their use in patients with a prior or concomitant malignancy. National and international guidelines generally advise against using biologic drugs in patients with a history of malignancy within the past 5 years. Recently released European guidelines propose a more nuanced approach, taking into account factors such as the risk of neoplastic disease progression and recurrence, as well as the burden of psoriasis itself, when making treatment decisions. These guidelines recommend individualized discussions with an oncologist before initiating biological therapy to weigh the potential risks and benefits for each patient.

Materials & Methods:

We have conducted a retrospective observational study of a group of oncology patients with moderate-to-severe psoriasis treated with biologic therapy who belonged to the Dermatology Clinic of the polyclinic of Bari during the period from 2016 to 2024. We included 15 adult patients (12 men and 3 women); in 8 of them the diagnosis of neoplasm preceded the start of treatment biologic, while seven of these patients had been diagnosed with cancer during the course of therapy biologics. The most represented neoplasms in our population were gastrointestinal tract carcinoma, bladder carcinoma, chronic myeloid leukaemia and lung carcinoma.

Results:

The patients in our study exhibited diverse cancer types and locations. In our patient group, the mean duration from cancer diagnosis to the initiation of biological therapy is 38 months. In our group, all individuals had achieved remission at the initiation of biologic therapy. The time elapsed between tumor diagnosis and the commencement of biological therapy ranged from 12 to 144 months. In our group, nine patients (60%) received anti-IL-17 biologics, six patients (40%) were treated with anti-IL-23 agents.

In all patients treatment was prescribed after a favourable opinion of the oncologist. The average follow-up time from the start of biological therapy is 26 months, with a range of 12 to 60. Among the 15 patients included in our study, the median PASI value at biologic initiation was 12. All patients in this group exhibited a significant amelioration in psoriasis following biologic initiation.

No adverse events that caused interruption or modifications of the therapy have been reported in the presented series. In both groups, no recurrence of primary tumour was observed during biotechnological therapy.

Conclusion:

This real-life study conducted at our hospital on patients with psoriasis vulgaris and a history of tumours firstly

demonstrates the efficacy of interleukin inhibitor drugs on complex patients; furthermore, no recurrence of the primary tumour was detected during our follow-up. Currently, patients undergo oncological and dermatological follow-up every 6 months and maintain a good response to therapy. However, further experience is needed to establish the true safety of biological therapies in patients with previous tumours.

EADV CONGRESS
AMSTERDAM 25-28 SEPTEMBER 2024
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Abstract N°: 2159

Treatment patterns, unmet medical needs, and preferences regarding systemic treatments for moderate to severe psoriasis from the perspectives of patients and dermatologists in China: a cross-sectional survey study

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Introduction & Objectives: Although biologic therapies have revolutionized the treatment of psoriasis in China and have become an important part of the therapeutic landscape, little is known about the unmet needs of patients with moderate to severe psoriasis (PsO) or the treatment preferences of dermatologists and patients with moderate to severe PsO. This study assessed the unmet needs and preferences regarding systemic treatments for moderate to severe PsO from the perspective of patients and dermatologists in China.

Materials & Methods: Fifty dermatologists and 300 patients with moderate to severe PsO (41% with severe PsO) from 5 Chinese tertiary hospitals were surveyed using a choice-based conjoint questionnaire to assess their unmet needs related to effectiveness, safety, and convenience of systemic treatments and their treatment preferences. Descriptive statistics and conjoint simulation analyses were employed to summarize survey information and assess treatment preferences.

Results: Surveyed patients reported that, among previous systemic treatments, acitretin was the most used oral treatment (46%) while adalimumab was the most-used biologic (17%). Both patients and dermatologists reported shorter treatment durations for oral drugs (2.7 to 6.2 months) than for biologics (9.5 to 17.0 months). The primary reasons for treatment discontinuation were unsatisfactory effectiveness for oral drugs and loss of efficacy over time for biologics. Common treatment inconveniences included regular lab tests for traditional oral drugs and administration assistance for biologics. Other treatment challenges with biologics included injection site reactions and needle fear. Both the patients and the dermatologists preferred oral drugs over subcutaneous injection drugs when the two had comparable attributes (preference shares in patients: 63% vs 37%, respectively; in dermatologists: 77% vs 23%, respectively).

Conclusion: In China, unmet needs for systemic treatments for patients with moderate to severe PsO remain. Oral treatments are preferred over injections to treat moderate to severe PsO when treatment attributes are comparable.

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Abstract N°: 2160

Safety and Treatment Persistence of Brodalumab in Patients with Plaque Psoriasis in the Canadian Real-World Setting: 6-Month Follow-up Interim Results from the CARE Study

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin condition affecting 2-3% of the Canadian population, and plaque psoriasis (PsO) is the most common subtype.1-3 Brodalumab is an interleukin 17 receptor A antagonist (IL-17RA) approved in Canada for the treatment of moderate-to-severe PsO in adult patients who are candidates for systemic therapy or phototherapy.4

The CARE study aims to evaluate the real-world outcomes of brodalumab amongst adult patients with PsO in Canada. In this interim analysis, we aim to describe brodalumab safety and treatment persistence (i.e., patients who remained on treatment) up to 6 months post-initiation.

Materials & Methods:

CARE is an ongoing multi-center, 12-month prospective, observational study in adult PsO patients who initiated brodalumab between October 2021 and February 2024 as part of routine care in Canada. Study visits are conducted at baseline, and then at 3, 6, and 12 months post-brodalumab initiation. Patient demographics are collected from patient medical charts or provided by the patient, while clinical characteristics and outcome measures are obtained from patient medical charts, physician assessments and patient reported outcomes.

This interim analysis reports on the safety profile and treatment persistence of brodalumab for patients who completed the baseline and 6-month follow-up visit (M6). The safety profile of brodalumab was evaluated based on rates of adverse events (AEs) and serious adverse events (SAEs) over the 6-month follow-up period. All study data was evaluated descriptively.

Results:

A total of 278 patients (57.2% male; 75.9% Caucasian) with verified data at baseline visit and M6 were included in this interim analysis. The average age of patients was 51.0 years (SD: 13.8) with a mean BMI of 29.93 (SD: 6.89) (**Table 1**). Over half of patients (55.0%, 148/269) experienced a PsO disease duration ≥10 years. Of the 278 patients, 88.8% had received treatments for PsO, and 84.9% had not previously been treated with biologics (bio-naïve). Most (68.3%) reported at least one comorbidity of interest including hypertension (25.5%), psoriatic arthritis (16.5%), type 2 diabetes mellitus (14.7%), or depression (13.7%).

Most patients received one or more concomitant medications (CMs) of interest at the time of brodalumab initiation (74.5%, 207/278) and at M6 (73.4%, 204/278). The most prevalent CMs of interest at M6 included topical corticosteroids (26.3%, 73/278), anti-psoriatics for topical use including vitamin D analogues and retinoids either alone or in combination with topical corticosteroids (23.7%, 66/278), ace inhibitors and angiotensin II receptor blockers (+/- diuretics) (18.0%, 50/278), and metformin (11.5%, 32/278).

A total of 223 AEs were reported in 44.2% (123/278) of patients from baseline to M6 (**Table 2**). Of the AEs, 58.3% were mild (130/223), 40.4% were moderate (90/223), and 1.3% were severe (3/223). Most AEs were assessed as unrelated to brodalumab (60.5%, 135/223).

At M6, almost all patients (96.8%, 269/278) persisted with brodalumab treatment. Of the 9 patients who discontinued, 4 were due to adverse events, 4 were due to lack of efficacy, and 1 was due to patient decision.

Conclusion:

Treatment persistence was high with brodalumab and well tolerated with few serious AEs reported during the 6-month follow-up period.

Table 1. Baseline Demographics and Clinical Characteristics

Baseline Demographics and Clinical Characteristics	All Patients
Number of Patients	278
Age in years, mean (SD)	51.0 (13.8)
Sex – male, n (%)	159 (57.2)
Race – Caucasian, n (%)	211 (75.9)
BMI (kg/m^2), mean (SD)	29.93 (6. 9)
Disease Duration[a]	
N	269
0 to <10 years, n (%)	121 (45.0)
10 to <20 years, n (%)	58 (21.6)
20 years or more, n (%)	90 (33.5)
Number of Comorbidities of Interest[b]	
N	278
None, n (%)	88 (31.7)
1, n (%)	75 (27.0)
2 – 4, n (%)	96 (34.5)
5 or more, n (%)	19 (6.8)
Comorbidities of Interest[c]	
Hypertension, n (%)	71 (25.5)
Psoriatic arthritis, n (%)	46 (16.5)
Type 2 diabetes mellitus, n (%)	41 (14.7)
Depression, n (%)	38 (13.7)
Anxiety, n (%)	28 (10.1)
Obesity, n (%)	27 (9.7)

BMI: Body Mass Index, SD: Standard Deviation

[a]Percentages are calculated using non-missing values as denominator.

[b]Comorbidities of interest include the following: Psoriatic arthritis, other autoimmune disease, other inflammatory disease, other dermatological conditions, cardiovascular disease, diabetes, obesity, depression, and other mental health conditions.

[c]More than one comorbidity could be selected for each patient.

Note: Due to rounding, percentage totals may not sum to 100.

Table 2. Adverse events (AEs) and Serious Adverse Events (SAEs) Reported Over 6 Months

Adverse Events	All Patients
Number of Patients	278
Any AE, n (%)	123 (44.2)
Any SAE, n (%)	4 (1.4)
AE Severity	
Number of Events	223
Mild, n (%)	130 (58.3)
Moderate, n (%)	90 (40.4)
Severe, n (%)	3 (1.3)
Assessment of relationship to brodalumab	
Number of Events	223
Related, n (%)	15 (6.7)
Probable, n (%)	8 (3.6)
Possible, n (%)	29 (13.0)
Unlikely, n (%)	36 (16.1)
Not Related, n (%)	135 (60.5)

AE: Adverse Event; SAE: Serious Adverse Event

References:

1. Armstrong AW, Read C. Pathophysiology, Clinical Presentation, and Treatment of Psoriasis: A Review. JAMA 2020;323(19):1945-1960. DOI: 10.1001/jama.2020.4006.
2. Eder L, Widdifield J, Rosen CF, et al. Trends in the Prevalence and Incidence of Psoriasis and Psoriatic Arthritis in Ontario, Canada: A Population-Based Study. Arthritis Care Res (Hoboken) 2019;71(8):1084-1091. DOI: 10.1002/acr.23743.
3. Papp KA, Gniadecki R, Beecker J, et al. Psoriasis Prevalence and Severity by Expert Elicitation. Dermatol Ther (Heidelb) 2021;11(3):1053-1064. DOI: 10.1007/s13555-021-00518-8.
4. Monograph SP. SILIQ™ Product Monograph. 2019.

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Abstract N°: 2196

Limited Self-Resolution of GPP Flare with Moderate-to-Severe Intensity: An Analysis from the HB0034 Phase Ib Study

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Limited Self-Resolution of GPP Flare with Moderate-to-Severe Intensity: An Analysis from the HB0034 Phase Ib Study

Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a rare, life-threatening, neutrophilic skin disease. The natural history of the disease is not well understood. The historical belief that GPP flares may exhibit some degree of self-limitation, implying that they could resolve without any specific treatment, raises an important question: do all patients with GPP experience spontaneous resolution?

The study aimed to describe the natural progression of GPP flares using prospective data from screening to baseline in the HB0034 Ib trial（NCT05512598).

Materials & Methods:

9 patients experiencing an acute GPP flare of moderate-to-severe intensity were enrolled in the HB0034 Ib study. Investigators collected retrospective medical data characterizing the natural history of GPP. Clinical severity was assessed mainly using Generalized Pustular Psoriasis Physician Global Assessment (GPPGA), Generalized Pustular Psoriasis Area and Severity Index (GPPASI), Body Surface Area (BSA) of erythema with pustules, Psoriasis Severity Score (PSS), and Dermatology Life Quality Index (DLQI). These assessments were conducted during screening, on Day 1, and after treatment with HB0034.

Results:

The mean (SD) onset age was 38.29 (15.39) years, with 6 patients (66.67%) having IL36RN mutation. Four patients (44.44%) experienced flare-ups more than twice a year. The characteristics and natural history of GPP are described in **Table 1**. No treatments were administered during the screening period, which lasted between 1 to 14 days (median= 3 days). A slight increase in body temperature was observed in over half of the patients from screening to Day 1 **(Figure 1(A))**. Other clinical measures such as GPPASI, BSA of erythema with pustules, PSS, and DLQI remained stable or increased slightly from screening to Day 1 but showed significant improvement by Day 3 and at week 1 following a single dose of HB0034 treatment **(Table 2 and Figure 1 (B, C))**.

Conclusion:

The study suggests that spontaneous resolution of moderate-to-severe GPP flares is limited, which highlights the necessity of therapeutic intervention in managing GPP. This observation aligns with the findings from the placebo group in two other GPP trials (Effisayil™ 1 and the GEMINI-1 study). However, the small sample size necessitates

further research to confirm these results.

Table 1. Characteristics and Natural history of 9 patients

Characteristics	Results
Sex	
Male, n%	4 (44.44)
Female, n%	5 (55.56)
IL36RN, n%	6 (66.67)
Age，Mean (SD), years	48.0 (9.63)
Onset Age of GPP	38.29 (15.39)
Number of flares per year	
>2, n%	4 (44.44)
<=1, n%	5 (55.56)
Clinical features of past GPP flares	
Fever, n%	7 (33.33)
Nail psoriasis, n%	3 (33.33)
Arthritis, n%	3 (33.33)
residual pustules after flare, n%	3 (33.33)

Table 2. The natural progression of GPP at Screening, Baseline, and post-HB0034 treatment

	Screening	Baseline	Post-HB0034 treatment
			D 3
GPPASI	33.26 (15.26，	37.54，15.23，	22.26 (13.94)
BSA of erythema with pustules	33.28 (21.42，	34.28，18.67，	15.83 (11.64)
PSS	11.0 (3.43)	11.0 (2.74)	8.0 (3.91)
DLQI	18.33 (9.04)	20.2 (7.85)	——

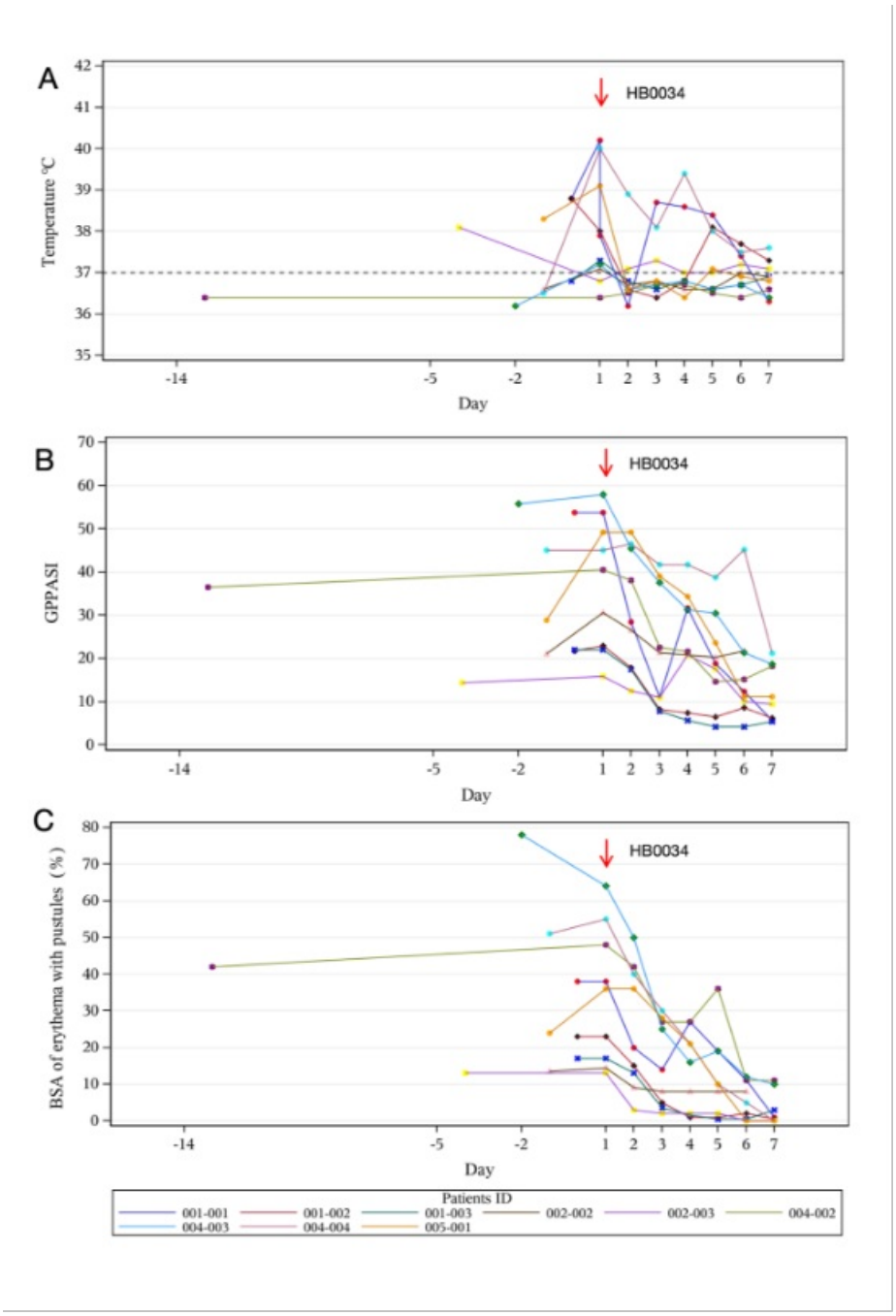

Figure 1. Temperature(B), GPPASI(A), and BSA of erythema with pustules (C) of 9 patients from screening to baseline (Day 1), and post-HB0034 treatment

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Abstract N°: 2230

Impact of calcipotriene and betamethasone dipropionate cream with PAD technology (CAL/BPD PAD cream) on scalp-PGA success, S-mPASI and clinician satisfaction among patients with mild-to-moderate scalp psoriasis in routine clinical practices in Europe. An interim analysis of the PRO-SCALP study

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Introduction & Objectives: In phase 3 trials, the fixed-dose combination of calcipotriene and betamethasone dipropionate cream with PAD technology (CAL/BDP PAD cream) demonstrated a high efficacy, measured with the physician global assessment (PGA) treatment success, but also satisfaction in patients with scalp psoriasis [1], but no data of this new formulation is available in real-world settings. The objective of this analyses was to evaluate scalp-PGA success, patient S-mPASI (Scalp-modified Psoriasis Area and Severity Index) and clinician satisfaction with treatment at week 8 (w8), among patients with scalp psoriasis treated with CAL/BDP PAD cream in real-world practices in Europe.

Materials & Methods: This single-arm, prospective cohort study (PRO-SCALP) was conducted in adults with mild-to-moderate scalp psoriasis who were newly initiated on CAL/BDP PAD cream as part of usual care in Germany, Spain and the United Kingdom. Both patients and clinicians completed surveys and clinical assessments at baseline and w8. Clinicians assessed treatment response using scalp-PGA on a 5-point adjectival response scale of 0 (clear), 1 (almost clear), 2 (mild), 3 (moderate) and 4 (severe). Scalp-PGA success was defined as PGA score of 0/1 and with >=2-point improvement from baseline at w8. Clinicians also assessed S-mPASI score for efficacy and reported their personal satisfaction with CAL/BDP PAD cream using a 9-item questionnaire (adapted from patient-version of TSQM-9 questionnaire), with 3 questions each related to treatment effectiveness, convenience of use, and global satisfaction with treatment; each domain score range was 0 (least satisfaction) to 100 (most satisfaction). This interim analysis was performed when at least 50% of planned study population completed the end-of-study assessments at w8.

Results: A total of 152 patients were included in the analyses (mean age: 48.78 years; female: 67.11), and 131 patients had evaluable clinician-reported outcomes data. At w8, a statistically significant ($p<0.0001$) rate of 77.86% of patients with a scalp-PGA score of 0/1 was observed; 70.99% achieved scalp-PGA success. At w8, a statistically significant ($p<0.0001$) decrease in mean (SD) S-mPASI scores from baseline of -1.34 (1.15) was observed (baseline: 1.65 (1.11); w8: 0.31 (0.46)). At w8, mean (SD) clinician satisfaction scores were - effectiveness: 82.31 (18.56), convenience of use: 76.40 (17.80), global satisfaction: 81.36 (19.83).

Conclusion: In real-world clinical practice settings in Europe, a majority of patients with mild-to-moderate scalp psoriasis using CAL/BPD PAD cream experienced scalp-PGA success at w8, accompanied by a statistically significant decrease in S-mPASI score. Mean clinician satisfaction scores associated with CAL/BPD PAD cream were high, in the range of 76 to 82.

[1] Pinter A, et al. JEADV. 2022;36(2):228-36.

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Abstract N°: 2254

Disease burden, patient needs and family planning in women of childbearing age with moderate to severe psoriasis

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Introduction & Objectives:

About 28.9% of patients with psoriasis are in their reproductive years. Women of childbearing age (WoCBA) with psoriasis who wish to conceive face additional challenges related to the limited pregnancy-compatible systemic treatments and to the physical and psychosocial impact of psoriasis on their social/ intimate relationships. This study aimed (1) to compare patient-reported outcomes (PROs) of disease burden and specific patient needs between WoCBA with and without current wish to conceive; and (2) to test the links between patients' sociodemographic, sexual/ reproductive and clinical characteristics and PROs of disease burden, and their childbearing preferences.

Materials & Methods:

This observational cross-sectional study included female patients aged 18-45 years with moderate to severe psoriasis vulgaris, recruited consecutively during routine consultations at a German university hospital. The physicians assessed clinical variables (e.g., psoriasis severity, current treatment) and the patients reported on sociodemographic and sexual/ reproductive characteristics, quality of life outcomes, patient-defined treatment needs and benefits, symptoms of depression, anxiety and body dysmorphic disorder, perceived stigmatization, and sexual function.

Results:

After excluding nine patients who did not meet the inclusion criteria or had missing data on core variables, the sample included 145 WoCBA: 73 were pregnant or planning to conceive (group CB+) and 72 reported no wish to have (more) children (group CB-). Women with childbearing wishes were younger, more often with no previous children, and more often prescribed with TNF alpha inhibitors; in contrast, the group CB- were more often prescribed with non-biologic systemic drugs (Table 1). Comparative analyses of PROs revealed more depression symptoms and higher levels of perceived stigmatization among women with no childbearing wishes (Table 2). For all patients, the most important needs were to be free of itching, to be healed of all skin defects and to get better skin quickly. In addition, the group CB- rated the needs of being able to lead a normal everyday and working life, having no fear that the disease will become worse, having confidence in the therapy and regaining control of the disease as more important (Figure 1). Finally, multivariable logistic regression analysis (model summary: $\chi 2(16) = 67.33$, $p < 0.001$; Cox & Snell R2 = 0.52; Nagelkerke R2 = 0.69) showed that the likelihood of conception wishes was associated with younger age, no previous children, comorbidities, and less perceived stigmatization (Table 3).

Conclusion:

The wish of having (more) children in WoCBA with psoriasis was mostly related to individual factors, such as age and previous children, while psoriasis-related variables did not play an important (direct) role in the patients' family planning. Nevertheless, disease characteristics (e.g., visibility) might be related to higher levels of perceived stigmatization, which in turn were associated with a lesser likelihood of childbearing wishes. The availability of

pregnancy-compatible systemic drugs makes it possible for every woman to realize their motherhood desires without compromising an effective psoriasis treatment. An enhanced people-centered routine health care for WoCBA with psoriasis must involve a sex-sensitive approach by considering specific patient needs and family planning preferences in the clinical decision.

Table 1 | Sociodemographic, sexual/ reproductive and clinical characteristics of women of childbearing age with and without current wish to have (more) children (group CB- vs. group CB+).

	No childbearing wish (group CB-)	Childbearing wish (group CB+)	t/ χ^2	p
Age (years), M±SD	36.44 ± 6.60	29.88 ± 5.69	6.43	< 0.001
Marital status, n (%)				
Unmarried (single, separated, divorced)	26 (36.1%)	25 (34.2%)	0.09	0.77
Married/ Partnership	45 (62.5%)	48 (65.8%)		
Job situation, n (%)				
Employed	52 (72.2%)	56 (76.7%)	0.39	0.54
Not currently working	20 (27.8%)	17 (23.3%)		
Regular sexual intercourse (yes), n (%)	53 (73.6%)	58 (79.5%)	0.72	0.40
Previous children (yes), n (%)	43 (59.7%)	11 (15.1%)	31.79	<0.001
Disease duration (years), M±SD	16.43 ± 10.24	13.44 ± 8.26	1.91	0.06
PASI, M±SD	1.97 ± 3.29	1.46 ± 3.31	0.94	0.35
Comorbidities (yes), n (%)	33 (45.8%)	31 (42.5%)	0.17	0.68
Current treatment				
TNF alpha inhibitors	12 (16.7%)	23 (31.5%)	4.36	0.04
IL12/23 or IL23 inhibitors	28 (38.9%)	27 (37.0%)	0.06	0.81
IL17 inhibitors	19 (26.4%)	13 (17.8%)	1.55	0.21
Januskinase (JAK) inhibitors	0 (0.0%)	1 (1.4%)	0.99	0.32
Other non-biologic systemic treatment	13 (18.1%)	5 (6.8%)	4.19	0.04
No systemic treatment	3 (4.2%)	5 (6.8%)	0.50	0.48

PASI – Psoriasis Area and Severity Index, score ranging from 0 = minimum severity to 72 = maximal severity; TNF alpha inhibitors included Adalimumab, Certolizumab and Infliximab; IL12/23 or IL23 inhibitors included Guselkumab, Risankizumab, Tildrakizumab and Ustekinumab; IL17 inhibitors included Bimekizumab, Brodalumab, Ixekizumab and Secukinumab; Januskinase (JAK) inhibitors included Upadacitinib; Other non-biologic systemic treatment included Apremilast, Fumaric acid esters and Methotrexate.

n – number of patients; M – Mean; SD – Standard-deviation; χ^2 – chi-squared test (for categorical variables); t – independent-samples t-test (for continuous variables); p – significance (2-sided).

Table 2 | Patient-reported outcomes of disease burden in women of childbearing age with and without current wish to have (more) children (group CB- vs. group CB+).

	No childbearing wish (group CB-)	Childbearing wish (group CB+)		
	M ± SD	M ± SD	F	p
General health (EQ-VAS)	72.89 ± 23.19	74.84 ± 18.52	0.38	0.54
Quality of life impairments (DLQI)	5.03 ± 6.52	3.52 ± 4.79	2.23	0.14
Depression (PHQ-2)	1.70 ± 1.83	1.23 ± 1.29	7.70	0.01
Anxiety (GAD-2)	1.41 ± 1.79	1.25 ± 1.42	2.64	0.12
Body dysmorphic concerns (DCQ)	7.37 ± 5.18	8.13 ± 4.73	0.09	0.77
Patient benefits (PBI)	2.85 ± 1.30	2.91 ± 1.12	0.03	0.86
Stigmatization (PSQ)	0.58 ± 0.75	0.43 ± 0.63	3.85	0.05
Sexual quality of life (QSQ)	8.10 ± 9.47	7.29 ± 7.78	0.14	0.71
Sexual function (FSFI-6)	20.96 ± 6.37	21.69 ± 5.94	0.03	0.87

EQ-VAS – Visual Analogue Scale, score ranging from 0 = worst imaginable health state to 100 = best imaginable health state; DLQI – Dermatology Life Quality Index, score ranging from 0 = no impairment to 30 = very large impairment; PHQ – Patient Health Questionnaire, score ranging from 0 to 6 = more symptoms of depression; GAD – General Anxiety Disorder, score ranging from 0 to 6 = more symptoms of anxiety; DCQ – Dysmorphic Concerns Questionnaire, score ranging from 0 to 21 = more symptoms of body dysmorphic disorder; PBI – Patient Benefit Index, score ranging from 0 = no benefit to 4 = maximal benefit; PSQ – Perceived Stigmatization Questionnaire, score ranging from 0 to 4 = higher levels of perceived stigmatization; QSQ – QualiPsoSex Questionnaire, score ranging from 0 = no impact to 40 = maximum impact; FSFI – Female Sexual Function Index, score ranging from 2 = worse sexual functioning to 30 = best sexual functioning.

M – Mean; SD – Standard-deviation; F – Univariate analysis of covariance, controlling for age and previous children; p – significance (2-sided).

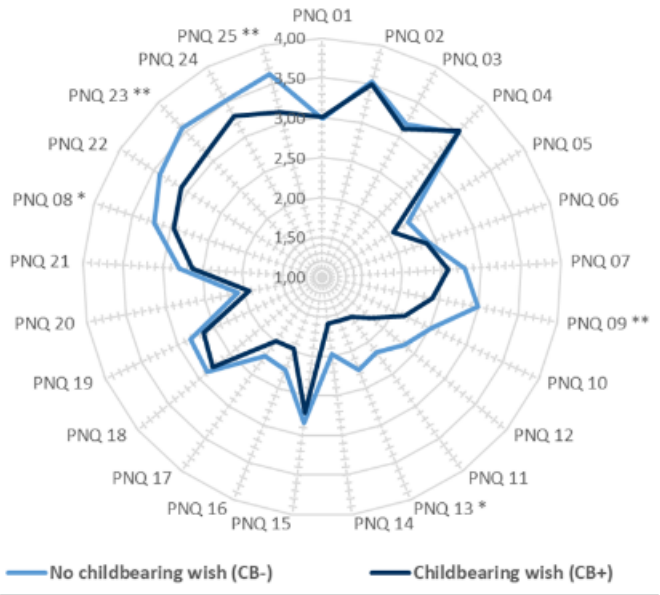

Figure 1 | Comparison of specific patient needs between women of childbearing age with and without current wish to have (more) children (group CB- vs. group CB+).

PNQ – Patient Needs Questionnaire, score ranging from 0 = not at all/ does not apply to me to 4 = very. M – Mean; SD – Standard-deviation; Z – Non-parametric Mann-Whitney U-test for independent samples; p – significance (2-sided).

As a result of therapy, how important is it for you...	CB- M ± SD	CB+ M ± SD	Z	p
Reducing physical impairments				
PNQ 01 ... be free of pain	2.99 ± 1.57	3.01 ± 1.48	-0.23	0.82
PNQ 02 ... be free of itching	3.53 ± 0.99	3.49 ± 0.96	-0.49	0.62
PNQ 03 ... no longer have burning sensations on your skin	3.19 ± 1.49	3.12 ± 1.34	-1.34	0.18
PNQ 04 ... be healed of all skin defects	3.49 ± 0.97	3.52 ± 0.88	-0.29	0.98
PNQ 05 ... be able to sleep better	2.28 ± 1.85	2.05 ± 1.67	-1.28	0.20
Reducing psychological impairments				
PNQ 06 ... feel less depressed	2.41 ± 1.78	2.38 ± 1.56	-0.51	0.61
PNQ 07 ... experience a greater enjoyment of life	2.79 ± 1.67	2.58 ± 1.51	-1.55	0.12
PNQ 09 ... be able to lead a normal everyday life	2.99 ± 1.61	2.41 ± 1.63	-2.79	0.01
PNQ 10 ... be more productive in everyday life	2.51 ± 1.69	2.14 ± 1.64	-1.56	0.12
PNQ 12 ... be able to engage in normal leisure activities	2.34 ± 1.67	1.81 ± 1.73	-1.79	0.07
Reducing social impairments				
PNQ 11 ... be less of a burden to relatives and friends	2.16 ± 1.72	1.62 ± 1.66	-1.82	0.07
PNQ 13 ... be able to lead a normal working life	2.25 ± 1.75	1.59 ± 1.70	-2.30	0.02
PNQ 14 ... be able to have more contact with other people	1.97 ± 1.76	1.58 ± 1.60	-1.33	0.18
PNQ 15 ... be comfortable showing yourself more in public	2.84 ± 1.55	2.71 ± 1.47	-0.96	0.34
PNQ 16 ... be less burdened in your partnership	2.25 ± 1.80	1.96 ± 1.71	-1.14	0.26
PNQ 17 ... be able to have a normal sex life	2.22 ± 1.80	1.99 ± 1.71	-0.89	0.38
Reducing impairments due to therapy				
PNQ 18 ... be less dependent on doctor and clinic visits	2.87 ± 1.38	2.78 ± 1.30	-0.70	0.48
PNQ 19 ... need less time for daily treatment	2.83 ± 1.43	2.64 ± 1.46	-0.87	0.39
PNQ 20 ... have fewer out-of-pocket treatment expenses	2.07 ± 1.85	1.93 ± 1.63	-0.48	0.63
PNQ 21 ... have fewer side effects	2.79 ± 1.59	2.63 ± 1.60	-0.83	0.41
Having confidence in healing				
PNQ 08 ... have no fear that the disease will become worse	3.21 ± 1.41	2.96 ± 1.33	-2.08	0.04
PNQ 22 ... find a clear diagnosis and therapy	3.41 ± 1.22	3.10 ± 1.35	-1.90	0.06
PNQ 23 ... have confidence in the therapy	3.56 ± 1.06	3.13 ± 1.32	-2.60	0.01
Not assigned to any subscale				
PNQ 24 ... get better skin quickly	3.52 ± 1.04	3.30 ± 1.20	-1.39	0.16
PNQ 25 ... regain control of the disease	3.63 ± 1.00	3.14 ± 1.36	-2.70	0.01

Table 3 | Associations between socio-demographic, sexual/ reproductive and clinical variables and patient-reported outcomes, and the likelihood of current childbearing wishes.

	B (SE)	Wald	p	OR (95% CI)	VIF
Age (years)	-0.18 (0.07)	7.39	0.01	0.83 (0.73/ 0.95)	1.74
Regular sexual intercourse [a]	1.16 (1.07)	1.17	0.28	3.18 (0.39/ 26.02)	1.56
Previous children [a]	-4.36 (1.26)	12.05	<0.001	0.01 (0.001/ 0.15)	1.77
Disease duration (years)	0.05 (0.05)	1.40	0.24	1.06 (0.97/ 1.15)	1.44
Disease severity (PASI)	-0.38 (0.23)	2.59	0.11	0.69 (0.44/ 1.09)	1.51
Comorbidities [a]	1.87 (0.82)	5.28	0.02	6.52 (1.32/ 32.26)	1.23
Treatment with TNF alpha inhibitors [a]	1.79 (1.01)	3.17	0.08	5.98 (0.83/ 42.89)	1.14
General health (EQ-VAS)	0.01 (0.02)	0.14	0.71	1.01 (0.96/ 1.06)	1.65
Quality of life impairments (DLQI)	0.01 (0.13)	0.01	0.93	1.01 (0.78/ 1.31)	2.08
Depression (PHQ-2)	-0.38 (0.32)	1.41	0.23	0.69 (0.37/ 1.28)	2.33
Anxiety (GAD-2)	0.17 (0.32)	0.27	0.60	1.18 (0.64/ 2.19)	2.34
Body dysmorphic concerns (DCQ)	-0.04 (0.09)	0.23	0.63	0.96 (0.81/ 1.14)	1.48
Patient benefits (PBI)	-0.95 (0.52)	3.33	0.07	0.39 (0.14/ 1.07)	1.86
Stigmatization (PSQ)	-2.77 (1.02)	7.32	0.01	0.06 (0.01/ 0.47)	1.56
Sexual quality of life (QSQ)	0.03 (0.06)	0.17	0.68	1.03 (0.91/ 1.16)	1.97
Sexual function (FSFI-6)	0.00 (0.08)	0.00	1.00	1.00 (0.86/ 1.17)	1.92
Constant	8.52 (4.06)	4.40	0.04	5009.49	-

[a] 0 = no, 1 = yes. PASI – Psoriasis Area and Severity Index; EQ-VAS – Visual Analogue Scale; DLQI – Dermatology Life Quality Index; PHQ – Patient Health Questionnaire; GAD – General Anxiety Disorder; DCQ – Dysmorphic Concerns Questionnaire; PBI – Patient Benefit Index; PSQ – Perceived Stigmatization Questionnaire; QSQ – QualiPsoSex Questionnaire; FSFI – Female Sexual Function Index.

B – Unstandardized coefficient; SE – Standard Error; p – significance; OR – Odd Ratio; CI – Confidence Interval; VIF – Variance Inflation Factor.

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Abstract N°: 2261

Epidemiological registry-based studies of patients with generalized pustular psoriasis in Denmark

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Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a rare and severe variant of psoriasis characterized by episodic painful skin eruptions with systemic symptoms. This study aimed to investigate the incidence, prevalence, and hospitalization characteristics of GPP in Denmark to enhance our understanding of disease burden and management.

Materials & Methods:

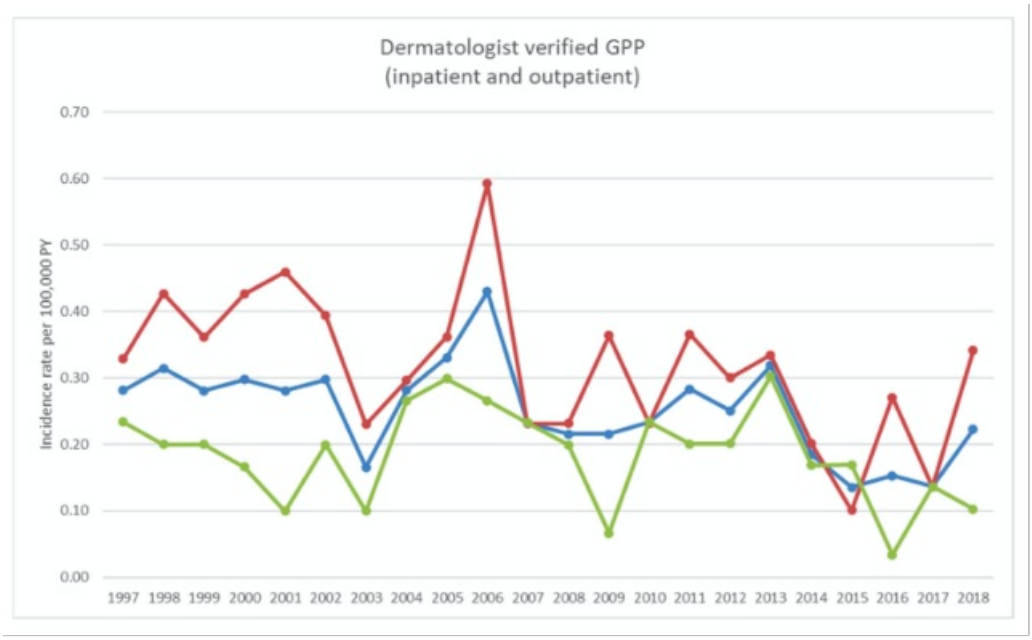
Two retrospective studies were conducted using Danish nationwide administrative registries. The first study assessed GPP incidence and prevalence over a 22-year period (1997-2018), identifying patients with incident GPP based on diagnostic codes. The second study focused on hospitalization characteristics over a 10-year period (2008-2017), using registries to identify patients hospitalized for GPP and assess comorbidities, mortality, and treatment patterns.

Results:

The incidence of GPP ranged from 0.14 to 0.43 per 100,000 person-years over 22 years, with a lifetime prevalence estimated at 0.0111% (11.1 per 100,000 Danish residents). There was a notable female predominance among diagnosed patients, and the mean age at diagnosis ranged from 47 to 64 years. Among hospitalized patients, the median duration of hospitalization was 9 days (interquartile range 6-15). No inpatient mortality was recorded, but 7% of patients died within the first 12 months post-discharge. The most common comorbidity was hypertension (21%), followed by dyslipidemia (9%) and diabetes (12%). Pharmacotherapy administered during hospitalization primarily involved acitretin (16%) and methotrexate (7%), with subsequent prescriptions continued post-discharge.

Conclusion:

This study offers important epidemiological insights into generalized pustular psoriasis (GPP) in Denmark, revealing stable incidence rates over a 22-year period. Hospitalization characteristics of GPP patients highlight low in-hospital mortality but increased mortality within the first year post-discharge. The study underscores the necessity for ongoing research and effective management strategies to improve outcomes and alleviate the burden of this severe dermatological condition.


Dermatologist verified GPP
(inpatient and outpatient)
Incidence rate per 100,000 PY
0.70
0.60
0.50
0.40
0.30
0.20
0.10
0.00
1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018

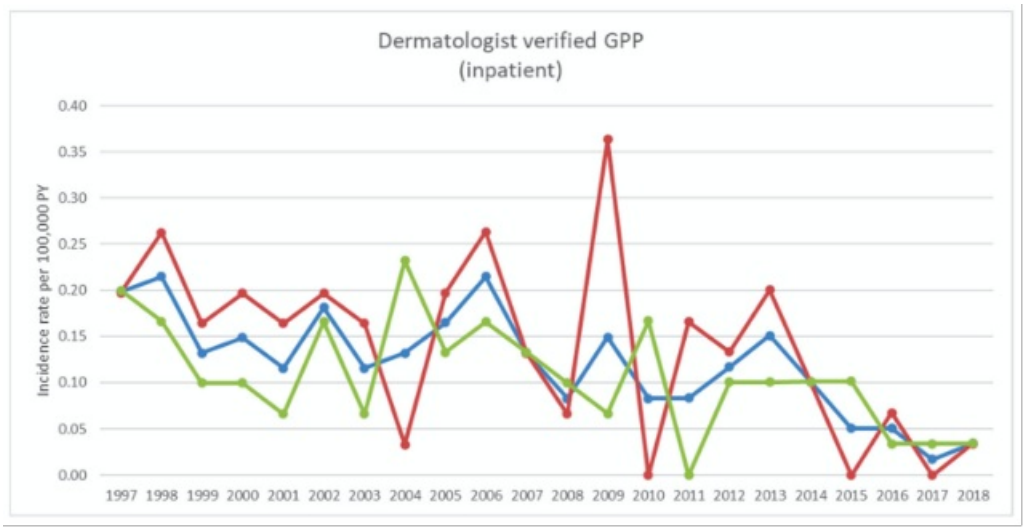

Dermatologist verified GPP
(inpatient)
Incidence rate per 100,000 PY
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018

TABLE 1 Incidence of dermatologist-verified generalized pustular psoriasis (inpatient and outpatients) during the study period from 1997 to 2018 including mean age at the time of diagnosis, grouping in age-groups and systemic treatment.

Incidence of dermatologist-verified GPP (inpatient and outpatients)																						
	1997		1998		1999		2000		2001		2002		2003		2004		2005		2006		2007	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	n	%	n	%	n	%	n	%	n	%
Population	6,046,508		6,054,971		6,060,238		6,063,710		6,065,131		6,063,199		6059626		6058713		6056810		6054616		6049387	
Women	3,045,261	50.4	3,048,696	50.4	3,050,223	50.3	3,050,832	50.3	3,050,222	50.3	3,047,790	50.3	3044799	50.2	3043329	50.2	3041227	50.2	3039147	50.2	3035515	50.2
Men	3,001,247	49.6	3,006,275	49.6	3,010,015	49.7	3,012,878	49.7	3,014,909	49.7	3,015,409	49.7	3014827	49.8	3015384	49.8	3015583	49.8	3015469	49.8	3013872	49.8
Generalized pustular psoriasis																						
Mean age, year	50.6		52.9		56.4		63.7		54.4		49.7		50.8		53.7		50.5		54.9		61.3	
Any	17	0.00	19	0.00	17	0.00	18	0.00	17	0.00	18	0.00	10	0.00	17	0.00	20	0.00	26	0.00	14	0.00
Women	10	58.8	13	68.4	11	64.7	13	72.2	14	82.4	12	66.7	7	70.0	9	52.9	11	55.0	18	69.2	7	50.0
Men	7	41.2	6	31.6	6	35.3	5	27.8	3	17.6	6	33.3	3	30.0	8	47.1	9	45.0	8	30.8	7	50.0
Age groups																						
0–19	<3	NS	<3	NS	0	0.0	0	0.0	<3	NS	<3	NS	<3	NS	<3	NS	<3	NS	<3	NS	0	0.0
20–29	0	0.0	0	0.0	<3	NS	0	0.0	0	0.0	<3	NS	<3	NS	<3	NS	<3	NS	<3	NS	0	0.0
30–39	3	17.6	<3	NS	<3	NS	0	0.0	3	17.6	<3	NS	<3	NS	<3	NS	5	25.0	3	11.5	0	0.0
40–49	<3	NS	3	15.8	3	17.6	<3	NS	<3	NS	4	22.2	<3	NS	4	23.5	4	20.0	<2	NS	≤3	NS
50–59	3	17.6	6	31.6	4	23.5	5	27.8	4	23.5	<3	NS	<3	NS	<3	NS	3	15.0	6	23.1	≤3	NS
60–69	3	17.6	4	21.1	6	35.3	<5	NS	4	23.5	3	16.7	<3	NS	4	23.5	<3	NS	7	26.9	6	42.9
≥70	4	23.5	3	15.8	<3	NS	7	38.9	4	23.5	4	22.2	3	30.0	3	17.6	4	20.0	5	19.2	3	21.4
Systemic Tx[a]																						
Any	8	47.1	12	63.2	10	58.8	13	72.2	9	52.9	11	61.1	7	70.0	10	58.8	11	55.0	17	65.4	6	42.9
Nonbiologic	8	47.1	12	63.2	10	58.8	13	72.2	9	52.9	11	61.1	7	70.0	10	58.8	11	55.0	17	65.4	6	42.9
Biologic	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0.0	0.0	0	0.0	<3	NS	0	0.0

	2008		2009		2010		2011		2012		2013		2014		2015		2016		2017		2018	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Population	6,043,358		6,033,787		6,022,623		6,007,868		5,990,402		5,969,780		5,949,441		5,925,714		5,901,104		5,873,017		5,847,699	
Women	3,031,893	50.2	3,026,733	50.2	3,020,818	50.2	3,013,090	50.2	3,003,522	50.1	2,992,705	50.1	2,982,404	50.1	2,970,605	50.1	2,958,377	50.1	2,945,086	50.1	2,933,347	50.2
Men	3,011,465	49.8	3,007,054	49.8	3,001,805	49.8	2,994,778	49.8	2,986,880	49.9	2,977,075	49.9	2,967,037	49.9	2,955,109	49.9	2,942,727	49.9	2,927,931	49.9	2,914,352	49.8
Generalized pustular psoriasis																						
Mean age, year	50.8		56.3		47.2		54.3		47.1		57.6		49.0		49.5		54.3		55.8		57.2	
Any	13	0.00	13	0.00	14	0.00	17	0.00	15	0.00	19	0.00	11	0.00	8	0.00	9	0.00	8	0.00	13	0.00

(Continues)

TABLE 1 (Continued)

	2008		2009		2010		2011		2012		2013		2014		2015		2016		2017		2018	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Women	7	53.8	<13	NS	7	50.0	11	64.7	9	60.0	10	52.6	6	54.5	3	37.5	<9	NS	4	50.0	10	76.9
Men	6	46.2	<3	NS	7	50.0	6	35.3	6	40.0	9	47.4	5	45.5	5	62.5	<3	NS	4	50.0	3	23.1
Age groups																						
0–19	<3	NS	<3	NS	<3	NS	<3	NS	0	0.0	0	0.0	<3	NS	0	0.0	0	0.0	0	0.0	<3	NS
20–29	<3	NS	<3	NS	<3	NS	<3	NS	3	20.0	0	0.0	0	0.0	<3	NS	<3	NS	<3	NS	<3	NS
30–39	0	0.0	0	0.0	3	21.4	<3	NS	3	20.0	≤3	NS	<3	NS	<3	NS	<3	NS	<3	NS	<3	NS
40–49	3	23.1	<3	NS	<3	NS	3	17.6	3	20.0	≤3	NS	<3	NS	<3	NS	0	0.0	0	0.0	0	0.0
50–59	<3	NS	4	30.8	3	21.4	3	17.6	<3	NS	6	31.6	4	36.4	0	0.0	3	33.3	<3	NS	<3	NS
60–69	4	30.8	4	30.8	<3	NS	3	17.6	3	20.0	6	31.6	<3	NS	0	0.0	<3	NS	3	37.5	0	0.0
≥70	<3	NS	<3	NS	3	21.4	4	23.5	<3	NS	3	15.8	<3	NS	3	37.5	<3	NS	<3	NS	7	53.8
Systemic Tx[a]																						
Any	7	53.8	12	92.3	9	64.3	9	52.9	10	66.7	12	63.2	8	72.7	5	62.5	9	100.0	<3	NS	9	69.2
Nonbiologic	7	53.8	12	92.3	8	57.1	9	52.9	9	60.0	12	63.2	8	72.7	5	62.5	6	66.7	<3	NS	7	53.8
Biologic	0	0.0	4	30.8	<3	NS	3	17.6	<3	NS	<3	NS	<3	NS	<3	NS	4	44.4	<3	NS	3	23.1

Abbreviation: NS, not shown due to data security requirements.

[a]Systemic Tx = Methotrexate, acitretin, fumarates, cyclosporine, biologics.

TABLE 2 Prevalence of generalized pustular psoriasis.

	Total population ($n = 5{,}834{,}465$)	
	N	**%**
Ever GPP	645	0.0111
Ever GPP diagnosis by a dermatologist	358	0.0061
Ever GPP hospitalization in dermatology department	202	0.0035
Ever GPP by age groups *(age on 31/12/2018)*		
0–19	61	0.0047
20–29	62	0.0079
30–39	58	0.0084
40–49	55	0.0072
50–59	104	0.0130
60–69	129	0.0194
≥70	176	0.0215

Abbreviation: GPP, generalized pustular psoriasis.

Table 1 Characteristics of 57 patients hospitalized for generalized pustular psoriasis in Denmark, 2008–2017

Age (years), mean (SD)	56.2 (18.1)
Sex	
Female	32 (56)
Male	25 (44)
Ethnicity[a]	
Danish	54 (95)
European/Asian/African	3 (5)
BMI (kg m^{-2})	
Mean (SD)	29.2 (7.9)
Median (IQR)	26.9 (24.5–33.7)
CCI	
0	43 (75)
1	8 (14)
2	3 (5)
≥ 3	3 (5)
Specific comorbidity of interest	
Hypertension	12 (21)
Dyslipidaemia	5 (9)
Diabetes	7 (12)
Medication use in the 6 months prehospitalization	
Oral glucocorticoids	6 (10)
Methotrexate	< 3[b]
Acitretin	3 (5)
Dimethyl fumarate	0 (0)
Ciclosporin	< 3[b]
Infliximab	0 (0)
Etanercept	0 (0)
Adalimumab	< 3[b]
Certolizumab pegol	< 3[b]
Ustekinumab	< 3[b]
Secukinumab	0 (0)
Ixekizumab	0 (0)
Brodalumab	0 (0)

Data are presented as *n* (%) unless otherwise indicated. BMI, body mass index; CCI, Charlson Comorbidity Index; IQR, interquartile range. [a]Fewer than three patients were immigrants (i.e. without complete data from birth); however, migration happened > 26 years from the study date, thus providing a minimum of 26 years of medical history. [b]Owing to data security requirements, data on very small groups (1–2 individuals) are reported as < 3.

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Abstract N°: 2320

Efficacy and safety of tildrakizumab through Week 28 in patients with early vs late-onset moderate-to-severe plaque psoriasis: A post hoc analysis of reSURFACE 1 and reSURFACE 2

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Introduction & Objectives: Psoriasis characteristics and response to treatment can vary by age of onset. We are not aware of any registered clinical trials or post hoc or subgroup analyses that have examined the efficacy and safety of anti-interleukin (IL)-23 p19 therapies for the treatment of psoriasis based on age of onset. Here, the efficacy and safety of tildrakizumab, an anti–IL-23 p19 antibody approved for the treatment of adults with moderate-to-severe plaque psoriasis, are reported in patients with early vs late-onset psoriasis.

Materials & Methods: This was a post hoc analysis from the Phase 3 reSURFACE 1 (NCT01722331) and reSURFACE 2 (NCT01729754) trials based on age of psoriasis onset: <40 (early) vs ≥40 (late) years; only patients ≥40 years of age at enrollment were included to limit the potential confounding effect of age. Patients who received tildrakizumab 100 mg (Week 0, Week 4, and every 12 weeks thereafter) or placebo were included. Efficacy was assessed through Week 28 using absolute Psoriasis Area and Severity Index (PASI), proportions of patients who achieved ≥75%/90%/100% reductions from baseline in PASI (PASI 75/90/100 responses), a Physician Global Assessment (PGA) score of clear or almost clear (PGA 0/1), and Dermatology Life Quality Index (DLQI) (absolute and proportion of patients who achieved scores of 0 or 1 [DLQI 0/1]). Estimates and *P*-values were obtained from a logistic regression model. Missing data were handled using non-responder imputation for absolute PASI, relative PASI, PGA, and DLQI responses. Mean DLQI was analysed as observed. Safety was assessed from treatment-emergent adverse events (TEAEs) through Week 28.

Results: Among patients treated with tildrakizumab 100 mg, 225/248 (90.7%) with early-onset psoriasis and 141/153 (92.2%) with late-onset psoriasis completed Week 28. Mean ± standard deviation age of patients randomised to tildrakizumab 100 mg vs placebo was 50.0 ± 8.2 years vs 50.6 ± 7.8 in patients with psoriasis onset at <40 years of age and 58.4 ± 8.7 vs 58.3 ± 9.0 in patients with psoriasis onset at ≥40 years of age. At Week 28, significantly more late-onset vs early-onset patients achieved PASI 90 responses (81 [52.9%] vs 111 [44.8%]; $P = 0.0040$), PASI 100 responses (36 [23.5%] vs 42 [16.9%]; $P = 0.0015$), and PASI <1 (61 [39.9%] vs 80 [32.3%];$P = 0.0016$), whereas significantly more early-onset vs late-onset patients achieved DLQI 0/1 (125 [50.4%]) vs 71 [46.4%]; $P = 0.0270$). There were no significant differences by age of onset in PASI 75 response, PGA 0/1, or PASI <3 rates (**Table**). Age at enrollment was a significant factor for achievement of PASI 90 ($P = 0.0040$), PASI 100 ($P = 0.0002$), and PASI <1 ($P = 0.0030$). In patients treated with tildrakizumab 100 mg, TEAEs were recorded in 160 (64.5%) early-onset and 97 (63.4%) late-onset patients. Of these, 7 (2.8%) patients in the early-onset group and 10 (6.5%) in the late-onset group had TEAEs considered severe.

Conclusion: Tildrakizumab was equally or more effective in patients with late-onset vs early-onset psoriasis, whereas early-onset patients were more likely to report minimal impact of psoriasis on quality of life. The safety profile of tildrakizumab was comparable in patients with early vs late-onset psoriasis.

Table. Efficacy at Week 28 in patients originally randomised to tildrakizumab

	Age of psoriasis onset		
Responders, n (%)	<40 years TIL 100 mg (n = 248)	≥40 years TIL 100 mg (n = 153)	*P*-value
PASI 75	171 (69.0)	114 (74.5)	0.5989
PASI 90	111 (44.8)	81 (52.9)	**0.0040**
PASI 100	42 (16.9)	36 (23.5)	**0.0015**
PGA 0/1	144 (58.1)	96 (62.7)	0.7276
DLQI 0/1	125 (50.4)	71 (46.4)	**0.0270**
PASI <3	140 (56.5)	96 (62.7)	0.6383
PASI <1	80 (32.3)	61 (39.9)	**0.0016**

Estimates and *P*-values were obtained from a logistic regression model with the following: treatment group, psoriasis onset group, prior biologic use (yes/no), baseline weight group (≤90 kg vs >90 kg), and week as fixed effects; age at enrollment and baseline score as covariates; and subject as a random effect.

DLQI, Dermatology Life Quality Index; DLQI 0/1, DLQI of 0 or 1; PASI, Psoriasis Area Severity Index; PASI 70/90/100, ≥75%/90%/100% reduction in PASI from baseline; PGA, Physician Global Assessment; PGA 0/1, PGA score of 0 or 1; TIL, tildrakizumab.

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AMSTERDAM 25-28 SEPTEMBER 2024
EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 2420

Improvements in patient-reported outcomes with oral roflumilast for psoriasis - results from a randomised controlled trial (PSORRO)

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Improvements in patient-reported outcomes with oral roflumilast for psoriasis – results from a randomised controlled trial (PSORRO)

Introduction & Objectives:

Psoriasis is associated with physical and psychological discomfort. Recent data find that oral roflumilast, a phosphodiesterase (PDE)-4 inhibitor approved for chronic obstructive pulmonary disease, is efficacious and safe in psoriasis. The aim of the current study was to investigate patient-reported outcomes (PROs) with oral roflumilast therapy in patients with plaque-type psoriasis.

Materials & Methods:

Post-hoc analyses from the Psoriasis Treatment with Oral Roflumilast (PSORRO) study, an investigator-initiated, randomised, placebo-controlled trial (EudraCT 2020-000711-76;** ClinicalTrials.gov (NCT04549870)). Adult patients with moderate-to-severe plaque-type psoriasis were randomised to oral roflumilast 500 µg or placebo once-daily monotherapy for 12 weeks, followed by open-label, active treatment until week 24 in both groups. Predefined study outcomes were changes in dermatology life quality index (DLQI), Beck depression inventory (BDI) II, and numeric rating scale (NRS) for itch and skin pain. In addition, overall NRS treatment satisfaction was registered.

Results:

A total of 46 patients were randomized, with baseline characteristics being comparable between the two arms. Median age was 38.5 years; 74% were men, and median psoriasis area and severity index (PASI) was 10.8. At week 12, significant differences were noted in the roflumilast group compared to placebo: DLQI (1.0 vs. 5.5, $p<0.001$), NRS itch (1.0 vs. 5.0, $p<0.001$), NRS skin pain (0.0 vs. 3.0, $p<0.001$), and NRS treatment satisfaction (9.0 vs. 2.0, $p<0.001$). In the active group, results were maintained through week 24, when a corresponding catch-up was seen in patients initially allocated to placebo. In both treatment arms, median BDI II was low within the normal range at baseline (4.0 vs. 3.0) and decreased further during the study period, however not statistically significantly.

Conclusion:

Twelve weeks monotherapy with oral roflumilast provided high levels of treatment satisfaction and significant improvements in life quality, itch, and skin pain. The findings support oral roflumilast as an off-label treatment for patients with psoriasis.

EADV CONGRESS
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Abstract N°: 2427

Generalized pustular psoriasis effectively treated with spesolimab – a case report.

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Introduction & Objectives:

This report presents the case of a 39-year-old woman experiencing her third flare-up of Generalized Pustular Psoriasis (GPP), affecting her groins, skin folds, and submammary region. The affected body surface area was 12%, and the PGA-Score for GPP was 8, with a GP-PASI of 7.

Materials & Methods:

Spesolimab is currently unavailable in German pharmacies, but was successfully procured from international pharmacies. To address the issue, we administered brodalumab to the patient, resulting in a rapid improvement and healing of the sterile pustules within a few days. The fast-acting nature of brodalumab is well-known, with effects typically seen after just two weeks. However, the patient's response was so positive that it suggests an even faster onset of effect.

Results:

The joint pains persisted, but we were able to promptly improve the skin condition with 900 mg spesolimab after the reoccurrence of pustules one week after the second dose of brodalumab. A second dose was not required.

Conclusion:

This case highlights the significance and efficacy of spesolimab in a specific patient population, demonstrating the effectiveness of this treatment.

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Abstract N°: 2455

Association of dermoscopic NPASI with joint involvement in psoriasis

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Introduction & Objectives:

The prevalence of nail involvement in psoriasis is 50%, rising to 80% in cases of associated psoriatic arthritis. Diagnosis is based on histology, and since nail biopsy is an invasive procedure, dermoscopic evaluation is used to detect matrix and nail bed lesions. The dNAPSI(dermoscopic nail psoriasis severity index) score groups together the various characteristics of this type of damage. The aim of this study is to establish the sensitivity of the correlation between dermoscopic nail and rheumatic damage.

Materials & Methods:

This was a monocentric cross-sectional study conducted from February to May 2023 in the dermatology department of the Ibn Sina University Hospital, including patients treated for clinically or histologically confirmed psoriasis and dividing them into those with joint involvement and those without. The study focused on the fingernails of patients undergoing local treatment or naïve to any therapy. Nail lesions were examined using a DermLit4 dermoscope. The NAPSI score was calculated for each nail, the non-dominant hand was taken as reference and the various dermoscopic aspects were studied.

Results:

Of 55 patients, 42 presented with nail lesions. The average age was 44. Plaque psoriasis predominated (87% of cases). The average duration of disease was 11 years. The most common dermoscopic finding was dilated capillaries in 22 cases (47%). The mean dNAPSI in our cohort was 15.1 ± 10.4 in the dominant hand and 16.4±10.4 in the non-dominant hand. The median dNAPSI in the non-dominant hand was 26 in patients with joint involvement and 16 in patients without joint involvement (p = 0.022).

Conclusion:

Nail involvement is often a neglected aspect of psoriatic disease. Over the last decade, it has been the subject of elaborate characterization and recognized quantification methods. Our study is the1st large Moroccan cohort to address this issue. The NAPSI score was used because of its simplicity and reproducibility. Its value was correlated with the duration of disease progression. A high NAPSI score was closely associated with joint involvement, in line with several studies in the literature. Contrary to our expectations, the non-dominant hand was more strongly correlated than the dominant hand. Severe nail involvement in the non-dominant hand could be an early sign of joint involvement in psoriatic disease. These results remain to be validated in a larger study.

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Abstract N°: 2494

High Induction Dosing of Risankizumab in Patients with Moderate-to-Severe Plaque Psoriasis: 52-Week Results from the Phase 2 KNOCKOUT Study

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Encore Abstract (AAD 2024)

Introduction & Objectives:

Risankizumab, an IL-23 inhibitor, is approved to treat moderate-to-severe plaque psoriasis. The Ph2, double-blinded, single-center KNOCKOUT (NCT05283135) study is evaluating higher-than-approved risankizumab induction doses for modulation of lesional resident memory T cells (Trm), cells responsible for psoriasis recurrences, as well as achieving and sustaining clearance of psoriasis. To evaluate changes in resident memory T cell populations after high induction/initial doses of risankizumab (300 mg or 600 mg) for the treatment of moderate-to-severe plaque psoriasis at Week 52 and to evaluate efficacy and safety of high induction/initial doses of risankizumab (300 mg or 600 mg) for the treatment of moderate-to-severe plaque psoriasis at Week 52.

Materials & Methods:

Patients were randomized 1:1 to subcutaneous risankizumab 300 or 600 mg at Weeks 0, 4, and 16, with no further dosing, and monitored through Week 52. RNAseq was performed on lesional and non-lesional skin to assess Trm levels. Efficacy was assessed as Psoriasis Area and Severity Index (PASI) improvement, reported by modified non-responder imputation. Safety was assessed as treatment-emergent adverse events.

Results:

20 patients enrolled and 16 completed Week 52 (2 lost to follow-up, 2 withdrawn). Lesional inflammatory cells at Week 52 returned to levels observed in baseline non-lesional skin, with significant reductions in Trm. At Week 52, PASI 75/90/100 responses were achieved by 77.8%, 66.7%, and 44.4% of patients treated with 300 mg and by 77.8%, 55.6%, and 44.4% of patients treated with 600 mg risankizumab, respectively. No new safety signals were detected with higher risankizumab doses.

Conclusion:

At Week 52 (36 weeks after the last dose), patients receiving three high doses of risankizumab achieved high levels of skin clearance and prolonged disease remission, with corresponding marked reductions in Trm. “Knockout therapy,” or high induction dosing with risankizumab, an IL-23 inhibitor, may be a promising new way to induce high levels of both short- and long-term efficacy in psoriasis patients.

EADV CONGRESS
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Abstract N°: 2536

Epidermal feed-forward inflammatory loop in psoriasis plays a dominant role in psoriasis development

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Introduction & Objectives:

Skin is the outmost barrier that separates the human body from the external environment. In psoriasis, immune cells are resident and/or infiltrated into the epidermis in order to form the epidermal immunological microenvironment (EIME) and constitute a complex interaction with keratinocytes, together with nerve and microbiota influence.

Materials & Methods:

In this study, we mapped psoriatic skin immune cells from paired lesional, perilesional, and nonlesional skin

samples using mass cytometry.

Results:

Our results have shown that psoriasis is mainly mediated by specific inflammatory environment composed by keratinocyte-neuro-immune cell units (KNICUs), which is the interaction of activated epidermal immune cells, keratinocytes and peripheral nerves fibers, which are increased in psoriatic lesions and are closely innervated around immune cells and keratinocytes. Phenotypical dendritic cells (DCs) were found in the psoriatic epidermis and dermis. Psoriatic dermal CD1c+CD11b+ cDC2s migrated to the epidermis in the perilesional skin, positioned in preinitiation. CD1c+CD11b+ cDC2s rapidly replaced EpCAM+CD11clowLC cells and initiated inflammation. Simultaneously, CD207+CD11chiLC and CD5+ T cells occurred in the psoriatic epidermis and orchestrated epidermal inflammation in psoriasis.

Conclusion:

Multiple units gathering to complete circulatory and amplified loop, both an epidermal feed-forward inflammatory loop constituted with epidermal dendritic cells pDC, cDC, Langerhans cells and CD8+T cells. The epidermal loop was more significant and coincided with the inflammation of psoriasis.

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Abstract N°: 2541

VISIBLE: Clearance and symptom improvement with guselkumab at week 16 in skin of color participants with moderate-to-severe plaque psoriasis

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Introduction & Objectives: VISIBLE is an ongoing, first-of-its kind, large-scale, prospective, phase 3b, randomized, double-blind, placebo-controlled study to examine the efficacy and safety of guselkumab in skin of color participants with moderate-to-severe plaque psoriasis.

Materials & Methods: VISIBLE Cohort A comprised 103 participants with moderate-to-severe plaque psoriasis who self-identified as non-white, across all skin tones. Participants were randomized (3:1) to receive guselkumab 100 mg or placebo at Weeks 0, 4, and then every 8 weeks. Psoriasis Area and Severity Index (PASI), Investigator Global Assessment (IGA), and body surface area (BSA), along with participant health-related quality of life improvements as assessed by the Psoriasis Symptoms and Signs Diary (PSSD) were evaluated at Week 16.

Results: At Week 16, the co-primary endpoints of IGA 0 (clear)/1 (almost clear) and ≥90% improvement from baseline in the PASI score (PASI 90) were achieved by significantly higher proportions of participants treated with guselkumab compared with placebo (IGA 0/1, 74.0% vs 0%; PASI 90, 57.1% vs 3.8%; both $p<0.001$), as were IGA 0 (32.5% vs 0%; $p<0.001$) and PASI 100 (complete skin clearance: 29.9% vs 0%;$p<0.01$). The proportions of guselkumab-treated participants achieving improvements in each PASI component (erythema, induration, scaling) were similar over time. In the guselkumab vs placebo groups, respectively, mean percent improvements from baseline were: 77.9% vs 0.9% for BSA, 84.5% vs 8.3% for PASI (both $p<0.001$). Mean changes from baseline in the PSSD symptom score were: guselkumab -49.4 vs placebo -8.2 ($p<0.001$), with a change of ≥40 considered clinically meaningful. Mean changes from baseline in the individual PSSD symptom scores for guselkumab vs placebo were: -6.2 vs -1.4 for redness, -4.9 vs -0.9 for dryness, -6.2 vs -1.2 for scaling (all $p<0.001$). Overall safety was consistent with the established guselkumab safety profile, and no new safety signals were identified.

Conclusion: After 3 doses of guselkumab, the majority of skin of color participants with moderate-to-severe plaque psoriasis achieved significantly clearer skin and reported clinically meaningful improvement in psoriasis symptoms.

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Abstract N°: 2545

Secukinumab for the Treatment of Psoriatic Lesions in Difficult-to-Treat Areas in Chinese Adult Patients with Moderate-to-Severe Plaque Psoriasis

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Introduction & Objectives:

Scalp, nails and palmoplantar area are considered as difficult-to-treat areas among plaque psoriasis patients.

Secukinumab has shown long-lasting efficacy in plaque psoriasis, but there is still a paucity of evidence in Chinese patients with lesions in special area. The UNMASK2 study aims to evaluate the effectiveness and safety of secukinumab in the treatment of psoriatic lesions on scalp, nails and palmoplantar area.

Materials & Methods:

UNMASK2 is a large, ongoing, prospective, observational study conducted at 42 sites across China. Adult patients with moderate-to-severe plaque psoriasis initiated secukinumab treatment from December 2021 to October 2022 were enrolled in this study. The baseline characteristics are shown in Table 1. Patients who completed the week 36 visit or achieved end of study prior to week 36 by June 9th, 2023, were included in this analysis. The effectiveness was measured by Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI), Psoriasis Scalp Severity Index (PSSI), Palmoplantar Psoriasis Area and Severity Index (ppPASI) and modified Nail Psoriasis Severity Index (mNAPSI) [Table 2]. Safety was evaluated by adverse event (AE), serious adverse event (SAE), drug discontinuation due to AE and deaths [Table 3].

Results:

A total of 723 psoriasis patients were included in this interim analysis, among which 236 (32.64%), 61(8.44%), and 531(73.44%) patients had nail, palmoplantar, and scalp psoriasis [Figure 1].

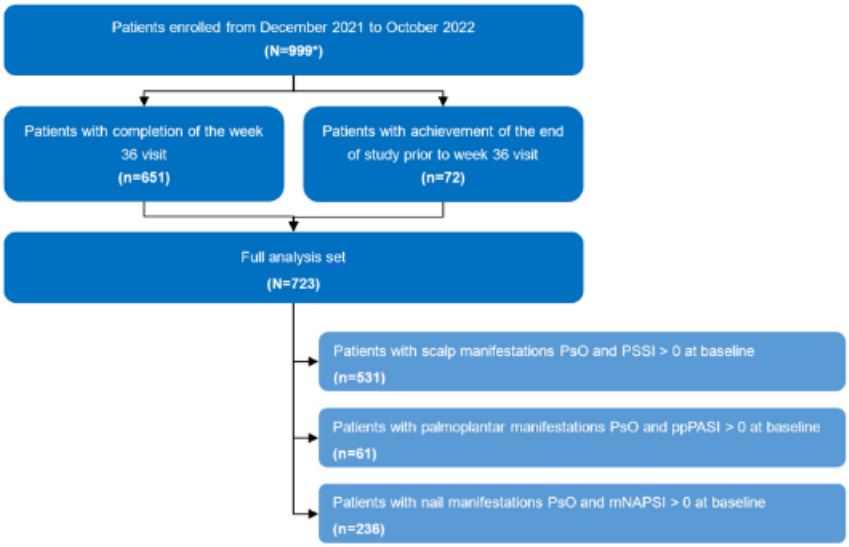
For patients who had scalp lesions, PASI 90 and DLQI 0/1 response were achieved in 86.27% and 68.72% patients at week 36, respectively. The PSSI 100 was achieved by 39.28%, 80.73% and 81.91% patients at week 4, week 16 and week 36. The proportion of patients with at least one AE and SAE were 46.52% and 3.95%, respectively.

For patients with palmoplantar psoriasis, PASI 90 and DLQI 0/1 response were achieved in 80.95% and 64.29% patients at week 36, respectively. The ppPASI 100 were achieved by 41.86%, 88.24% and 92.50% patients at week 4, week 16 and week 36. For safety data, 40.98% and 8.20% patients reported at least one AE and SAE, respectively.

For patients who had nail psoriasis, PASI 90 and DLQI 0/1 response were achieved in 86.27% and 68.72% patients at week 36, respectively. As for mNAPSI, 67.63% and 54.91% patients achieved mNAPSI 75 and mNAPSI 100 at week 36. Significant mNAPSI changes in relation to baseline (mean ± SD) were observed at both week 16 (-5.9 ± 13.00) and week 36 (-12.1 ± 18.07). The proportion of patients who reported at least one AE and SAE were 45.76% and 5.51%, respectively.

Conclusion:

Secukinumab showed rapid improvement as early as week 4 and sustained effectiveness over a 36-week period in palmoplantar and scalp psoriasis. For nail psoriasis, secukinumab also showed a long-term improvement up to week 36. The results also demonstrated a favorable safety profile of secukinumab, consistent with clinical trials[1,2,3]. However, the results should be interpreted with caution considering limited sample size for sub-populations.



*Among the 999 patients enrolled from December 2021 to October 2022, two patients were excluded from the analysis because of invalid baseline data.
Abbreviations: **PsO:** Psoriasis, **PPSI:** Psoriasis Scalp Severity Index, **mNAPSI:** modified Nail Psoriasis Severity Index, **ppPASI:** Palmoplantar Psoriasis Area and Severity Index

Figure 1. Patients flow diagram

Table 1. Baseline characteristics

Baseline characteristics	Nail psoriasis (N=236)	Palmoplantar psoriasis (N=61)	Scalp psoriasis (N=531)
Age (years), mean (SD)	41.58 (13.23)	45.62 (13.56)	40.14 (12.77)
Male, n (%)	171 (72.46)	53 (86.89)	368 (69.30)
Psoriasis duration (years), mean (SD)	11.63 (8.29)	12.45 (10.22)	12.09 (9.20)
Patients with baseline PsA, n (%)	60 (25.42)	20 (32.79)	87 (16.38)
PsA duration (years), mean (SD)	3.54 (6.85)	4.07 (9.61)	3.91 (7.90)
Patients with prior biologics treatment, n (%)	13 (5.51)	3 (4.92)	17 (3.20)
Patients with prior topical treatment, n (%)	85 (36.02)	15 (24.59)	182 (34.27)
Patients with prior TCM treatment, n (%)	72 (30.51)	13 (21.31)	158 (29.76)
PASI score, mean (SD)	19.50 (12.39)	25.30 (16.03)	18.00 (11.63)
DLQI score, mean (SD)	13.10 (7.10)	15.20 (7.82)	13.10 (6.84)
mNAPSI score, mean (SD)	16.60 (21.25)	/	/
ppPASI score, mean (SD)	/	8.89 (13.96)	/
PSSI score, mean (SD)	/	/	16.30 (13.92)

SD, standard deviation; PsA, psoriatic arthritis; TCM, traditional Chinese medicine

Table 2. Clinical outcomes from week 4 to week 36

	Week 4	Week 12	Week 16	Week 24	Week 36
Patient with nail psoriasis					
PASI 90, n/N (%)	34/205 (16.59)	132/176 (75.00)	128/156 (82.05)	144/169 (85.21)	157/182 (86.26)
DLQI 0/1 response, n/N (%)	56/203 (27.59)	101/170 (59.41)	99/154 (64.29)	124/174 (71.26)	126/182 (69.23)
mNAPSI change from baseline, mean (SD)	-2.10 (10.17) ****	-3.80 (15.46) ****	-5.90 (13.00) ****	-11.00 (17.56) ****	-12.10 (18.07) ****
mNAPSI 75, n/N (%)	23/197 (11.68)	59/168 (35.12)	71/152 (46.71)	105/164 (64.02)	117/173 (67.63)
mNAPSI 90, n/N (%)	19/197 (9.64)	47/168 (27.98)	57/152 (37.50)	85/164 (51.83)	99/173 (57.23)
mNAPSI 100, n/N (%)	18/197 (9.14)	41/168 (24.40)	54/152 (35.53)	79/164 (48.17)	95/173 (54.91)
Patients with palmoplantar psoriasis					
PASI 90, n/N (%)	6/48 (12.50)	20/37 (54.05)	27/37 (72.97)	34/42 (80.95)	34/42 (80.95)
DLQI 0/1 response, n/N (%)	11/47 (23.40)	18/34 (52.94)	19/37 (51.35)	28/48 (58.33)	27/42 (64.29)
ppPASI change from baseline, mean (SD)	-6.44 (9.96) ****	-8.27 (14.28) ****	-10.14 (16.08) ****	-10.45 (15.71) ****	-10.55 (15.76) ****
ppPASI 75, n/N (%)	23/43 (53.49)	31/34 (91.18)	33/34 (97.06)	39/39 (100.00)	40/40 (100.00)
ppPASI 90, n/N (%)	19/43 (44.19)	30/34 (88.24)	31/34 (91.18)	36/39 (92.31)	39/40 (97.50)
ppPASI 100, n/N (%)	18/43 (41.86)	28/34 (82.35)	30/34 (88.24)	35/39 (89.74)	37/40 (92.50)
Patient with scalp psoriasis					
PASI 90, n/N (%)	87/459 (18.95)	301/394 (76.40)	284/351 (80.91)	323/375 (86.13)	352/408 (86.27)
DLQI 0/1 response, n/N (%)	132/459 (28.76)	231/385 (60.00)	233/352 (66.19)	281/389 (72.24)	279/406 (68.72)
PSSI change from baseline, mean (SD)	-13.10 (12.59) ****	-15.30 (12.90) ****	-15.50 (13.36) ****	-15.80 (14.38) ****	-15.00 (14.07) ****
PSSI 75, n/N (%)	308/443 (69.53)	342/372 (91.94)	311/327 (95.11)	337/354 (95.20)	350/376 (93.09)
PSSI 90, n/N (%)	233/443 (50.34)	307/372 (82.53)	287/327 (87.77)	310/354 (87.57)	327/376 (86.97)
PSSI 100, n/N (%)	174/443 (39.28)	264/372 (70.97)	264/327 (80.73)	301/354 (85.03)	308/376 (81.91)

N, the number of patients with non-missing data; n, the number of patients achieving specific endpoint; SD, standard deviation; ****, P<0.0001

Table 3. Safety outcomes

Safety outcomes	Nail psoriasis (N=236)	Palmoplantar psoriasis (N=61)	Scalp psoriasis (N=531)
Adverse event			
AE, n (%)	108 (45.76)	25 (40.98)	247 (46.52)
SAE, n (%)	13 (5.51)	5 (8.20)	21 (3.95)
Treatment-related adverse event			
Treatment-related AE, n (%)	37 (15.68)	8 (13.11)	79 (14.88)
Treatment-related SAE, n (%)	0 (0.00)	0 (0.00)	3 (0.56)
Treatment discontinuation due to AE, n (%)	3 (1.27)	0 (0.00)	4 (0.75)
Death, n (%)	0 (0.00)	0 (0.00)	0 (0.00)

AE, adverse events; SAE, serious adverse events

1. Gottlieb A et al. *J Am Acad Dermatol*. 2017;76(1):70-80.↩

2. Bagel J et al. *J Am Acad Dermatol*. 2017;77(4):667-674.↩

3. Armstrong AW et al. *J Clin Aesthet Dermatol*. 2016;9(6 Suppl 1):S12-S16.↩

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Abstract N°: 2555

GUIDE trial (part 3): Following guselkumab withdrawal and a long treatment-free period, disease control is rapidly regained upon re-treatment in psoriasis super-responders

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Introduction & Objectives: The ongoing Phase IIIb GUIDE trial assesses the impact of guselkumab withdrawal in super responders (Psoriasis Area and Severity Index [PASI]=0 at both Weeks 20+28), and the subsequent response to re-treatment if disease control was not maintained.1

Materials & Methods: In GUIDE part 3 (Week 68 to Week 220), super responders with PASI<3 at Week 68 were withdrawn from guselkumab. Upon reaching PASI >5, patients received guselkumab at re-treatment Weeks 0/8/16 (R0/R8/R16). In this interim analysis up to Week 116, we report PASI outcomes following re-treatment (intent-to-treat [ITT]; non-responder imputation).

Results: Overall, 273 super responders entered the withdrawal phase at Week 68.2 Through Week 116, 74 (27.1%) super responders remained re-treatment-free and 186 super responders were re-treated after a median therapy-free period of 259 days. Among the latter, 28% were female, 43.5% had disease duration ≤2 years, 91.4% were biologic-naïve; baseline mean values were: age 39.2 years, weight 83.9 kg, PASI 19.0. At the R0 visit, the mean PASI score triggering re-treatment was 7.3. After re-administration of guselkumab, 75.8% of patients regained disease control (PASI <3) at R8, with higher proportions at subsequent visits (R16/R24=87.1%/92.5%). Similarly, rates of achieving higher responses increased by visit (PASI ≤1: R8/R16/R24=41.4%/66.1%/78.5%; PASI=0: R8/R16/R24=21.0%/46.2%/58.1%). The mean PASI score upon re-treatment was 1.8/0.8/0.5 at R8/R16/R24 (n=184/n=172/n=180), respectively. No significant differences were observed for regaining disease control based on prior guselkumab dosing interval (every 8 weeks/every 16 weeks), disease duration (≤2 years/>2 years), or weight (≤90 kg/>90 kg). Rates of achieving PASI=0 after re-treatment were higher for those with PASI=0 at Week 68 (yes/no): R8=24.5%/9.5%; R16=53.8%/21.4%; R24=66.4%/31.0% (nominal p<0.001).

Conclusion: Following guselkumab withdrawal, super responders generally had a long treatment-free period. Those who subsequently lost response regained disease control quickly, mostly within 8 weeks after just one guselkumab dose, with no differences between subgroups.

References:

\1. Eyerich K *et al*. *BMJ Open* 2021;11:e049822

\2. Schäkel K *et al*. Abstract accepted at EADV congress 2023, abstract ID 2042

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Abstract N°: 2565

Examining Differences in the Psoriasis Treatment Pathway Based on Patients' Fitzpatrick Scale Classification

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Introduction & Objectives:

Psoriasis (PsO) is a chronic autoimmune condition which affects people of all skin tones. It is postulated that people of colour are underdiagnosed in PsO, with many social and medical barriers preventing them from receiving an effective diagnosis and treatment for their condition1. This study aims to highlight discrepancies in treatment between patients based on their classification on the Fitzpatrick scale.

Materials & Methods:

A multi-centre online medical chart review study of PsO patients treated with advanced therapies (AT) was conducted in Q4 2023 among dermatologists from UK, FR, DE, IT & IT. Recruited physicians were screened for practice duration, patient volume and ability to prescribe AT. Patients were grouped into three categories based on Fitzpatrick scale: group 1 (pale/fair type I&II), group 2 (olive/moderate brown type III&IV) and group 3 (dark brown/black type V&VI).

Results:

248 dermatologists reported 1306 PsO AT patients across EU4+UK; 616 patients were reported as group 1, 654 as group 2, and 36 as group 3. Group 3 patients were significantly more likely to be currently severe than those in groups 1 and 2 (3: 22.2%; 1: 11.5%, 2: 6.3%, $p<0.01$), although reported rates of severe patients at diagnosis were similar across all groups (1: 43.8%; 2: 41.8%; 3: 40.6%, $p<0.01$). Rates of uncontrolled disease were significantly higher amongst group 1 and 3 patients (1: 22.7%; 2: 12.8%; 3: 36.1%, $p<0.05$). On average, group 3 patients diagnosed in the last 5 years waited a directionally longer amount of time to be initiated on their first AT (3: 25.4 months; 1: 14.4 months; 2: 16.1 months). Group 3 patients also experienced a higher average number of lines of AT (3: 1.5; 1: 1.3; 2: 1.3). Group 3 patients were currently prescribed TNFis at a directionally higher rate (3: 41.7%; 1: 27.8%; 2: 29.1%); when asked what the next suitable product was for these patients, TNFis were also mentioned at a significantly higher rate for group 3 patients than other groups (3: 41.7%; 1: 9.9%; 2: 11.4%, $p<0.01$).

Conclusion:

Within this study cohort, a higher proportion of group 3 patients experienced a severe form of PsO, a higher average number of lines of therapy, and a longer average time to wait for AT initiation; this suggests unmet needs for this patient type, reflected in the significantly higher levels of uncontrolled disease in this patient group. While TNFis are prescribed at the highest rate amongst group 3 patients, TNFis were also most frequently selected as the next most suitable product for this group; current and potential use of other MOA therapies were much more prevalent in group 1 and 2 patients, suggesting physicians were unsure how to proceed with treatment in the case of a group 3 patient. Ensuring equity in care across all patient types is paramount; further investigation is warranted.

[1] https://www.webmd.com/skin-problems-and-treatments/psoriasis/racial-disparities-psoriasis-treatment

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Abstract N°: 2567

Results from a prospective study on the psychosocial and quality of life implications of switching biologics in patients with chronic plaque psoriasis.

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Introduction & Objectives:

Patients with psoriasis face impaired health-related quality of life (HRQoL). Treatment with biologic agents can improve HRQoL, dermatologic symptoms and overall well-being, but 'biologic treatment failure' is common. The primary objective of this longitudinal study was to investigate the effect of biologic treatment failure on depression (Hospital Anxiety and Depression Scale [HADS-D]) in patients in United Kingdom (UK) hospital clinics. Key patient-reported outcome (PRO) measures (DLQI, Anxiety [HADS-A], patient health questionnaire depression module [PHQ-9]) and Psoriasis Area and Severity Index [PASI] were also assessed.

Materials & Methods:

Demographic and clinical data were retrospectively collected from medical records of patients ≥18 years of age with moderate-to-severe plaque psoriasis and treated with biologic therapy from 3 UK sites (March 2020–October 2023). Data on clinical response to treatment, including PRO measures, were collected prospectively. Treatment failure was defined according to NICE criteria (primary failure), or due to adverse events/lack of efficacy at any point thereafter (secondary failure). For the primary objective, HADS-D scores in patients who experienced versus did not experience biologic treatment failure during follow-up were compared using a multivariate generalized linear model (GLM; tweedie family-log link).

Results:

Table 1. Demographic and clinical characteristics

Baseline demographic and clinical characteristics	
Patient groups	**N=274**
Failure	48
Responder	196
Missing status (no follow-up)	30
Age at recruitment (years), median (range) N=274	49 (21-89)
Age at diagnosis (years), median (range) N=118	27 (2-69)
Male sex, N (%)	154 (56%)

The treatment failure group had a higher mean [SD] HADS-D score (6.2 [+/-4.3]) compared to the responder group (4.7 [+/-4.3]); a GLM demonstrated a 15% mean difference in scores between responders and failures, which was not significant [p=0.50]. The treatment failure group also had a higher mean [SD] HADS-A score (8.0 [+/-4.5]) compared to the responder group (5.5 [+/-4.7]). A GLM showed a 28% mean difference in HADS-A score, on average, between responders vs. failures, but this was not significant [p=0.20]. The failure group had a significantly higher mean [SD] DLQI score (13.6 [+/-8.2]) compared to the responder group (2.8 [+/-4.2]) [p<0.001], and a significantly higher mean [SD] PHQ-9 score (9.7 [+/-6.5]) compared to the responder group (6.6 [+/-6.3]) (p=0.02), using a GLM.

Repeated measure correlations demonstrated a moderate positive correlation between DLQI and PASI scores (0.69, p<0.001); a low, significantly positive correlation (0.32, p<0.001) was found between PASI and the HADS (A+D) scores. Biologic treatment persistence was assessed by the number of previous treatment lines (Figure 1).

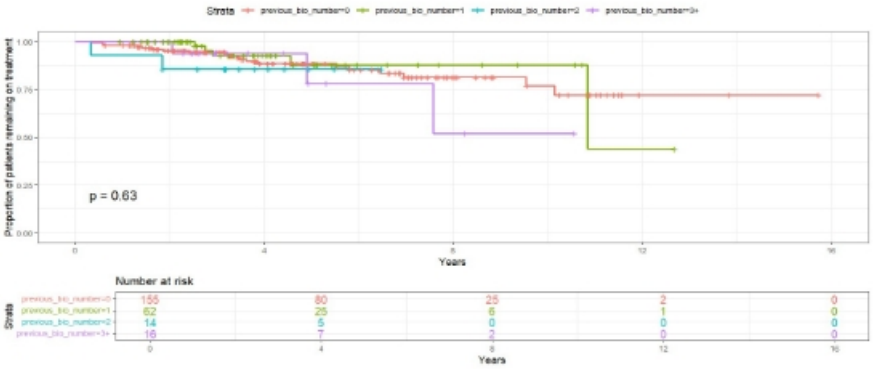

Figure 1. Biologic treatment persistence by number of prior lines. Fewer prior treatment lines trends with longer duration of treatment, this association was not significant (p=0.63 [for log rank test]).

Conclusion:

As with clinical trials, we show a direct relationship between PASI and PRO scores (including the HADS and DLQI). We show a correlation between psoriasis severity measured by PASI, with QoL and severity of anxiety and depression. We see a trend of worsening depression and anxiety in patients who failed their biologic treatment, compared to those who responded to treatment. Further, patients who failed treatment had higher disease burden, QoL impairment and greater psychosocial burden (HADS).

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Abstract N°: 2609

Patient-reported well-being using tildrakizumab for psoriasis in a real-world setting: 52-week interim data of the phase IV POSITIVE study

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Introduction & Objectives: Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being.1 Tildrakizumab (TIL) is an interleukin-23p19 inhibitor indicated for moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.2,3** The objective of this analysis was to assess the effect of TIL on the overall well-being of patients with moderate-to-severe psoriasis treated with TIL in routine care.

Materials & Methods: POSITIVE is a 24-month, phase IV observational study in adults with moderate-to-severe plaque psoriasis treated with TIL.4 Well-being was assessed through the 5-item WHO Well-being Index (WHO-5; range 0-100, where 0=absence of well-being and 100=maximal well-being).5 As a reference, the mean WHO-5 score in the general population of the countries participating in the POSITIVE study was calculated to be 64.9,6 and was 52.2 in women with breast cancer or 51.4 in patients with diabetes with distress.7,8 The threshold for a clinically relevant change is 10 points.5 When WHO-5 is used for the screening of depressive symptoms, a cut-off score of ≤50 is used (≤28: possible presence of moderate-to-severe depressive symptoms). 5 Here, we report 52-week (W) interim data using an observed cases approach.

Results: 400 patients were included (63.3% male, mean±95%CI age 46.5±1.5 years). Mean±95%CI WHO-5 score significantly increased from 53.8±2.2 at baseline to 65.2±2.2 at W16 ($p<0.0001$; mean change from baseline: 11.3), to 66.0±2.3 at W28 ($p<0.0001$; mean change from baseline: 11.5), and to 65.7±2.7 at W52 ($p<0.0001$; mean change from baseline: 11.1). At baseline, 41.0% of patients had a WHO-5 score ≤50 (17.0% ≤28). The percentages decreased to 20.5% (6.0% ≤28) and 20.6% (6.0% ≤28) at W16 and W52. WHO-5 scores by baseline characteristics are shown in **Table 1**: females and patients aged >30-<60 years showed lower WHO-5 scores at baseline. The mean±95%CI individual WHO-5 item scores at baseline, W16, and W52 were 11.6±0.5, 14.2±0.5, and 14.3±0.5 for "I have felt cheerful and in good spirits", 10.7±0.5, 13.4±0.5, and 13.4±0.6 for "I have felt calmed and relaxed", 10.4±0.6, 12.7±0.5, and 12.6±0.6 for "I have felt active and vigorous", 9.5±0.6, 11.6±0.6, and 12.0±0.7 for "I woke up feeling fresh and rested", and 11.8±0.5, 13.3±0.5, and 13.3±0.6 for "My daily life has been filled with

things that interest me" ($p<0.0001$ for all comparisons vs baseline). At W52, a significant correlation between WHO-5 and Psoriasis Area and Severity Index scores was observed ($r=-0.18$, $p<0.05$).

Conclusion: Patients with moderate-to-severe plaque psoriasis showed an impaired well-being score, comparable to other impacting diseases, such as breast cancer or diabetes with distress, which highlights the unmet needs in the management of psoriatic patients, especially females. TIL significantly improved patients' well-being in patients with moderate-to-severe plaque psoriasis, achieving a well-being status similar to the general population after 16 weeks, which was maintained up to W52.

References: 1Armstrong AW, et al. PLoS One 2012;7:e52935. 2Thaçi D, et al. BJD 2021;185:323–34. 3Tsianakas A, et al. JEADV 2023;37:85–92. 4Augustin M, et al. BMJ Open 2023;13:e060536. 5Topp CW, et al. PP 2015;84:167–76. 6https://www.eurofound.europa.eu/data/european-quality-of-life-survey; 7Hoffman, CJ, et al. JCO 2012;30:1335–42. 8Pintaudi B, et al. JPR 2015;79:348–54.

Table 1. Baseline WHO-5 score by baseline characteristics (N=400)

		WHO-5 score*			
		Mean (SD)	**0-≤28**, n (%)	**>28-≤50**, n (%)	**>50-100**, n (%)
	N (%)	53.8 (21.7)	61 (17.0)	86 (24.0)	212 (59.1)
Gender					
Male	253 (63.3)	56.3 (21.9)	34 (14.8)	48 (20.9)	148 (64.3)
Female	147 (36.8)	49.4 (20.9)	27 (20.9)	38 (29.5)	64 (49.6)
Age (years)					
18-<30	56 (14.0)	57.7 (19.3)	5 (10.0)	12 (24.0)	33 (66.0)
≥30-<60	266 (66.5)	51.4 (22.7)	50 (21.1)	59 (24.9)	128 (54.0)
≥60	78 (19.5)	59.1 (18.9)	6 (8.3)	15 (20.8)	51 (70.8)
BMI (kg/m^2)					
<25	120 (30.0)	55.1 (21.2)	17 (15.5)	23 (20.9)	70 (63.6)
≥25	271 (67.8)	53.1 (22.0)	43 (17.9)	62 (25.8)	135 (56.3)
PASI					
0-10	153 (38.3)	55.6 (22.2)	21 (15.0)	35 (25.0)	84 (60.0)
>10-72	239 (59.8)	52.6 (21.5)	39 (18.3)	51 (23.9)	123 (57.7)
Time since diagnosis (years)**					
1st quartile	99 (24.8)	52.3 (20.9)	14 (16.9)	24 (28.9)	45 (54.2)
2nd quartile	99 (24.8)	53.7 (20.2)	13 (14.3)	21 (23.1)	57 (62.6)
3rd quartile	99 (24.8)	57.9 (22.6)	13 (14.3)	17 (18.7)	61 (67.0)
4th quartile	98 (24.5)	51.3 (22.8)	20 (22.2)	24 (26.7)	46 (51.1)

*N=359. **Q1: 0-4.7; Q2: >4.7-12.1; Q3: >12.1-22.5; Q4: >22.5-55.2. BMI, body mass index; PASI, Psoriasis Area and Severity Index; SD, standard deviation; WHO-5, 5-item WHO Well-being Index.

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Abstract N°: 2618

Incremental improvements in QOL, Psoriasis Symptoms, and treatment satisfaction by clearance targets in moderate plaque psoriasis

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Introduction & Objectives: Patients with psoriasis frequently report impacts on their health-related quality of life (HRQoL). In previous studies, patients have reported that improvements in skin clearance have been associated with improvements in HRQoL. The objective of this analysis was to evaluate the impact of incremental improvements in skin clearance on patient reported outcomes in moderate PsO from the week 16 results of the IMMpulse trial.

Materials & Methods: IMMpulse (NCT04908475) is a phase IV, multicenter, randomized, open-label study which enrolled patients with moderate, chronic plaque psoriasis. Patients were randomized 1:2 to receive either 150 mg subcutaneous risankizumab at weeks 0, 4 and 16, or oral apremilast (30mg twice daily). For this analysis, patients were stratified by their week 16 Psoriasis Area and Severity Index (PASI) response (50 to <75, 75 to <90, and 90 percent improvement) and week 16 achievement of National Psoriasis Foundation treat to target responses (affected body surface area target [<1%], acceptable [<3% or at least 75% improvement from baseline], and neither target nor acceptable). Dermatology Life Quality Index 0/1 (DLQI, no impact on quality of life), Psoriasis Symptom Score 0/1 (PSS, psoriasis symptom free or having mild problems for no more than 1 type of symptom), and achievement of satisfied, very satisfied, and extremely satisfied for questions 1 or 2 of the treatment satisfaction questionnaire (TSQM-9) are reported at week 16 for each skin clearance subgroup.

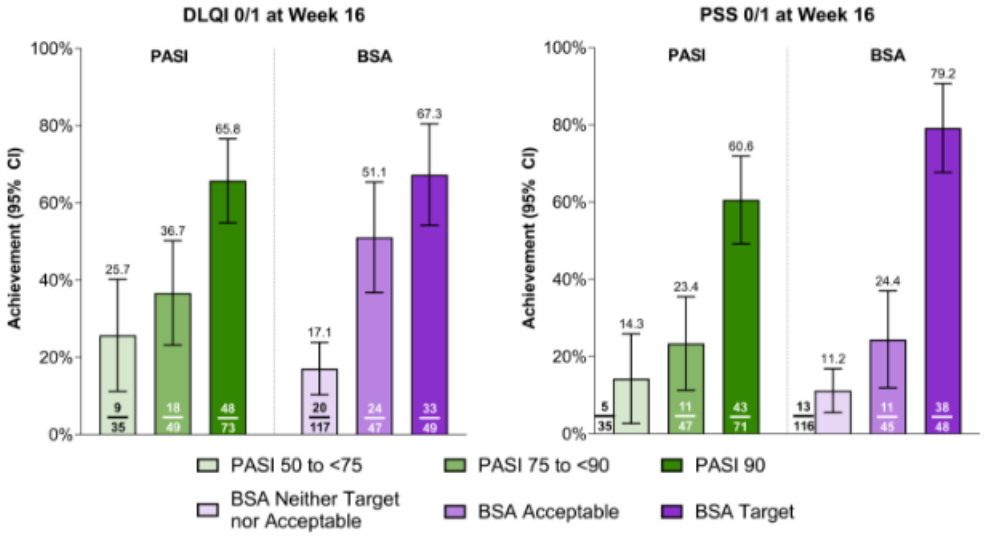
Results: Patients who achieved higher levels of skin clearance were more likely to report achievement of DLQI 0/1 and PSS 0/1 (Figure 1). For patients achieving PASI 50 to <75 at week 16, 25.7% of patients achieved DLQI 0/1, compared to 65.8% in patients achieving PASI 90 (Figure 1). Similarly, for patients not meeting an NPF acceptable/target goal, 17.1% achieved DLQI 0/1, compared to 67.3% of patients that met the NFP target response (Figure 1). These results were similar to those for achievement of PSS 0/1 (Figure 1). For patients achieving PASI 50 to <75 at week 16, 14.3% achieved PSS 0/1 versus 60.6% in patients achieving PASI 90 (Figure 1). For patients failing to reach an NPF treatment acceptable/target response, 11.2%, vs 79.2% of patients achieving NPF target clearance also achieved PSS 0/1 (Figure 1).

Patient satisfaction (measured TSQM-9 questionnaire) was higher among patients who achieved greater skin clearance (Figure 2). Patients achieving PASI 50 to <75 reported 62.9% satisfaction with the ability of their medication to treat or prevent their condition and 60.0% for symptom relief, compared to 93.0% in patients achieving PASI 90 for ability of the medication to treat or prevent your condition and 95.8% for the way medication relieves your symptoms (Figure 2). Similarly, for patients failing to meet an NFP acceptable/target response, 38.8% of patients responded they were satisfied with their medication, compared to 97.9% in patients

achieving the NPF target response for ability of the medication to prevent or treat your condition and 95.8% for the way the medication relieves your symptoms (Figure 2).

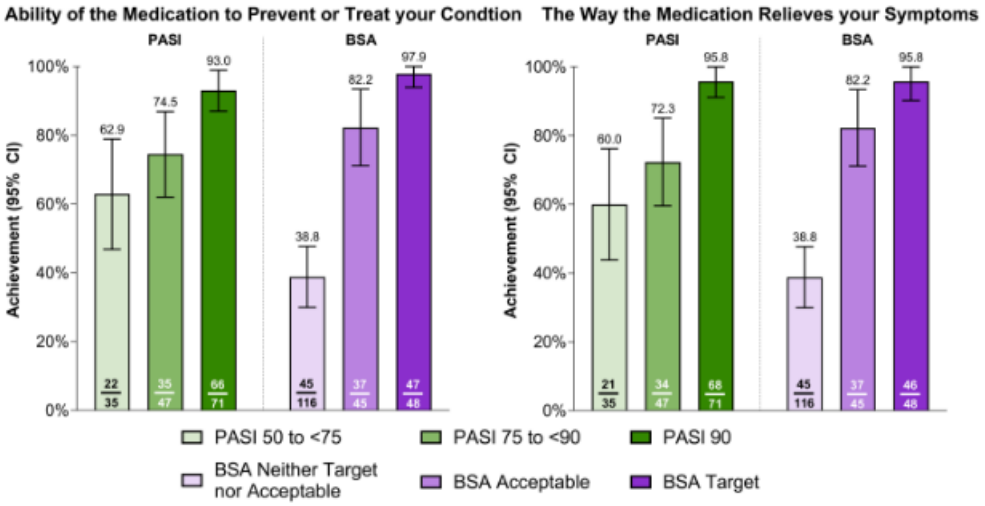
Conclusion: Patients who achieved higher levels of skin clearance at week 16, as measured by PASI and BSA, were more likely to achieve significant improvements in their psoriasis symptoms, health-related quality of life, and report higher satisfaction rates with their medication to prevent or treat their condition and relieve symptoms.

Figure 1. Proportion of Patients Achieveing DLQI or PSS 0/1



BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; PSS, Psoriasis Symptom Score

Figure 2. Proportion of Patients Achieving Satisfied, Very Satisfied, and Extremely Satisfied for Questions 1 and 2 of TSQM-9



BSA, body surface area; PASI, Psoriasis Area and Severity Index; TSQM-9, treatment satisfaction questionnaire

EADV CONGRESS
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Abstract N°: 2638

Identification of ADAM23 as a potential signature for psoriasis integrative machine learning and experimental verification

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Introduction & Objectives:

Psoriasis is a frequently encountered, persistent, relapsing, and inflammatory skin condition. Presently, there exists no standardized definition for diagnosing the criteria of psoriasis. Traditional diagnosis primarily relies on visual inspection by experienced clinicians, along with invasive skin biopsies and analysis. However, given that diagnosis requires trained medical professionals, obtaining such diagnostic methods can be challenging in many healthcare institutions, often leading to delayed or inappropriate treatment for patients. Therefore, identifying novel potential biomarkers holds significant importance for the diagnosis and treatment of psoriasis. The aim of this study is to explore potential key biomarkers associated with psoriasis and validate their relevance to the disease.

Materials & Methods:

We downloaded psoriasis-related datasets from the Gene Expression Omnibus and screened for differential expressed genes. We conducted GO functional and KEGG pathway enrichment analysis on the selected DEGs. Utilizing four machine learning algorithms—Random Forest, Least Absolute Shrinkage and Selection Operator, logistic regression, Weighted Gene Co- expression Network Analysis, and Support Vector Machine - Recursive Feature Elimination—we screened for psoriasis-related candidate biomarkers from the GSE30999 and GSE6710 datasets. To further investigate, we constructed a psoriasis mouse model using imiquimod and detected the expression levels of ADAM23 in psoriatic lesions and healthy skin tissues using immunoprecipitation techniques. Immunohistochemical analysis compared he expression of ADAM23 in psoriatic mouse models and healthy mice. Additionally, we established a HaCaT cell line with knocked-down ADAM23 expression and verified the knock down efficiency through immunoprecipitation experiments. After knocking down ADAM23, we explored its impact on the migration of HaCaT cells using scratch tests and its influence on cell proliferation through CCK-8 experiments.

Results:

1. We identified 709 differentially expressed genes from GSE30999 and GSE6710. GO and KEGG pathway enrichment analysis suggested that these genes are associated with immune cell participation and inflammatory signaling. (2) Using four machine learning strategies and single-cell RNA-seq sequencing analysis, we found that ADAM23, may serve as a biomarker for psoriasis with high diagnostic value. (3) We detected ADAM23 expression levels in psoriatic lesions and healthy skin using immunoprecipitation. Results showed that ADAM23 is overexpressed in psoriatic lesions. Immunohistochemical analysis confirmed the upregulation of ADAM23 in the psoriatic mouse model. (4) Scratch tests demonstrated reduced migration ability in HaCaT cells following ADAM23 knockdown.

Conclusion: ADAM23 may serve as a potential biomarker for the diagnosis of psoriasis and may influence the pathogenesis of the disease by regulating immune cells in psoriatic lesions.

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Abstract N°: 2672

Incidence of Major Adverse Cardiovascular Events in Patients With Dermatologist-Diagnosed Psoriasis

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Introduction & Objectives:

Several studies have linked psoriasis with major adverse cardiovascular events (MACE) in a range of data sources with mixed conclusions (varying from no to moderate associations).

The objective was to examine the incidence of MACE in patients with psoriasis vs. patients without psoriasis or other chronic inflammatory skin diseases (CISD) including atopic dermatitis, hidradenitis suppurativa, vitiligo, and alopecia areata.

Materials & Methods:

A cohort study of patients aged 40 or more years using commercial insurance claims data from a nationwide US health care database from Jan 1, 2004 through Aug 31, 2023 was conducted. The exposure was psoriasis (excluding psoriatic arthritis), defined as two dermatologist-based ICD codes for psoriasis within one year. Risk-set sampling identified comparator patients who were also seen by a dermatologist twice within one year but were not diagnosed with psoriasis or other CISDs at any time. The outcome was MACE, defined as a composite of myocardial infarction and ischemic stroke, which was identified with validated algorithms. Patient follow-up lasted until the first of the following occurred: MACE event, death, disenrollment, or end of data stream. Incidence rates were computed, and hazard ratios were estimated using a multivariable Cox proportional hazards model to compare the incidence of MACE in the cohort with psoriasis vs. the cohort without psoriasis or other CISDs. Covariates included demographics, markers of healthcare utilization, comorbidities, and medications.

Results:

A total of 2,048,699 patients were identified, including 85,370 (4.2%) patients with psoriasis and 1,963,329 (95.8%) patients without psoriasis or other CISDs. The median follow-up time was 2.1 years (interquartile range, 0.9-4.2 years) in patients with psoriasis. The crude incidence rate (per 1000 person-years) of MACE was 6.5 in patients with psoriasis, compared with 6.8 in those without psoriasis or other CISDs. The multivariable-adjusted Cox regression yielded a hazard ratio of 1.15 (95%CI, 1.10-1.21) for MACE.

Conclusion:

In this large-scale cohort study of a representative dermatology patient population in the United States, the incidence of MACE was increased in patients with psoriasis compared to those without in adjusted analysis.

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Abstract N°: 2673

VISIBLE: Guselkumab demonstrated significant scalp psoriasis clearance and scalp itch improvements at week 16 in skin of color participants with moderate-to-severe plaque psoriasis

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Introduction & Objectives: The** scalp is the most commonly involved special site among patients with moderate-to-severe plaque psoriasis and may be challenging to treat in skin of color patients due to greater visibility of scales and styling/hair types. Here, we report the efficacy of guselkumab on scalp psoriasis in the Phase 3b VISIBLE study, which exclusively enrolled skin of color participants with moderate-to-severe plaque psoriasis.

Materials & Methods: Participants in VISIBLE Cohort A (N=103) were randomized 3:1 to receive guselkumab 100 mg or placebo at Weeks 0, 4, and then every 8 weeks. Scalp psoriasis outcomes (scalp-specific Investigator Global Assessment [ss-IGA] score, Psoriasis Scalp Severity Index [PSSI], scalp surface area [SSA], and scalp itch numeric rating scale score) were evaluated at Week 16 among participants with at least mild scalp psoriasis (ss-IGA score ≥2) at baseline.

Results: At baseline, 77 participants had at least mild scalp psoriasis (ss-IGA score of 2-mild [22.1%], 3-moderate [63.6%], 4-severe [14.3%]; mean SSA 33.4%). Significantly greater improvements in scalp itch numeric rating scale were observed in guselkumab versus placebo groups, with mean change from baseline -4.3 versus -1.3, respectively* (p<0.001). Significantly greater proportions of participants in guselkumab versus placebo groups achieved ss-IGA score of 0/1 with ≥2-grade improvement from baseline (guselkumab versus placebo: 80.7% versus 15.0%, p<0.001) and ss-IGA score of 0 (guselkumab versus placebo: 71.9% versus 10.0%,p<0.001). At Week 16, mean percent change from baseline in SSA was -87.6% (improved) for guselkumab versus +167.1% (worsened) for placebo (p<0.01); and mean percent improvement from baseline in PSSI was 81.0% for guselkumab versus 12.1% for placebo (p<0.001).

Conclusion: After 3 doses, 80% of participants with at least mild scalp psoriasis achieved clear or almost clear scalp psoriasis with guselkumab and reported significant improvements in scalp itch.

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Abstract N°: 2676

Longitudinal evaluation of neutrophil-to-lymphocyte ratio in guselkumab-treated patients with psoriatic disease and levels of systemic inflammation associated with elevated cardiovascular risk: post hoc analysis of 4 phase 3, randomized, controlled studies

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Introduction & Objectives:

Psoriatic disease (PsD) is associated with increased risk of cardiovascular (CV) disease, likely due to common co-occurrence of traditional CV risk factors. Neutrophil-to-lymphocyte ratio (NLR) is a biomarker of systemic inflammation; NLR 2.5–<3.5 (elevated) or ≥3.5 (high) are independently associated with CV risk vs NLR <2.5. Guselkumab (GUS), a human IL-23p19-subunit inhibitor, demonstrated significant efficacy in treating multiple psoriatic arthritis (PsA) domains in the phase 3 DISCOVER-1 (D1) and -2 (D2) studies and psoriasis (PsO) in the phase 3 VOYAGE-1 (V1) and -2 (V2) studies. GUS had a favorable safety profile during the placebo (PBO)-controlled period, and low rates of major adverse CV events through up to 2 years (Y) and 5Y of the PsA and PsO trials, respectively. We evaluated the effect of GUS on NLR levels in adults with PsD and NLR levels indicative of elevated/high CV risk.

Materials & Methods:

D1/2 patients (pts; ~90% biologic-naïve [BN]) with active PsA were randomized 1:1:1 to GUS 100 mg Q4W (N=373); GUS 100 mg at W0, W4, then Q8W (N=375); or PBO (N=372). V1/2 pts (~80% BN) with moderate-to-severe PsO were randomized 2:1 to GUS 100 mg at W0, W4, then Q8W (N=825) or PBO (N=422). This analysis included GUS Q8W- and PBO-randomized pts with baseline (BL) NLR ≥2.5; subgroup analyses in pts with NLR levels associated with elevated (2.5–<3.5) and high (≥3.5) CV risk were performed. Least square mean (LSM) changes in NLR from W0-W100 were assessed with mixed models for repeated measures. In pts with elevated/high CV risk per BL NLR level, attainment of NLR <2.5 (associated with no increased risk) through W16 (PBO-controlled period common to all trials) was compared between GUS and PBO with logistic regression (**Figure**). Changes from W0-W100 in traditional CV risk factors were described.

Results:

Among 1061 total pts with elevated/high (57.4%/42.6%) risk based on NLR level, 877 (82.7%) were BN. BL characteristics (other than NLR) were generally similar between Total and BN cohorts. Despite different randomization ratios, higher proportions of pts in GUS vs PBO group were enrolled in PsO vs PsA trials. GUS-

randomized pts were more likely to be male; less likely to be treated with csDMARDs, corticosteroids, and/or NSAIDs at BL; and had higher PASI scores at BL **(Table)**. Upon adjusting for potential confounders, and regardless of BL NLR-defined CV risk category, GUS-treated Total and BN pts had significantly greater reductions in NLR vs PBO at first timepoint assessed (W4) and through W16; LSM reductions were sustained through 1Y (Total) and 2Y (BN) of GUS (data not shown). In Total and BN pts with BL elevated/high CV risk, significantly greater proportions of GUS- vs PBO-randomized pts achieved NLR <2.5 as of W4/W8 and continuing through W16 (**Figure**). In GUS-treated BN pts with elevated/high CV risk at BL who were followed through 2Y, rates of achieving NLR level <2.5 increased from W16 (41.9%/27.5%) to W100 (48.8%/40.0%). Also in pts with elevated/high CV risk, mean BMI/systolic/diastolic blood pressure (SBP/DBP) were stable through up to 2Y of GUS (data not shown).

Conclusion:

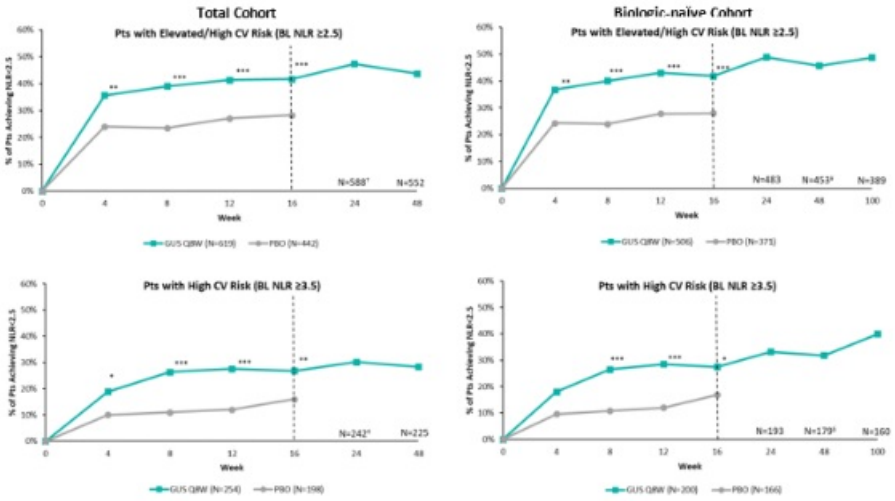
In PsD pts with elevated/high CV risk defined by BL NLR, GUS led to rapid, significant, and sustained reductions in NLR, resulting in substantial proportions of pts exhibiting NLR levels that have in other analyses been associated with no increased CV risk at follow-up. Together with stable BMI/SBP/DBP for up to 2Y, findings are consistent with the GUS safety profile established through 5Y.

Table. BL Characteristics by Treatment Group of Patients in the Total and Biologic-naïve Cohorts with Baseline NLR ≥2.5

	Total		Biologic-naïve	
Parameter	**GUS Q8W (N=619)**	**PBO (N=442)**	**GUS Q8W (N=506)**	**PBO (N=371)**
D1/D2, %	35.1%	51.4%	37.9%	54.2%
V1/V2, %	64.9%	48.6%	62.1%	45.8%
Self-reported PsA*	20.4%	18.6%	17.5%	15.3%
Age (years)	44.7 (12.3)	45.3 (12.8)	44.0 (12.4)	44.5 (12.6)
Male sex, %	67.9%	59.7%	67.2%	58.8%
BMI (kg/m^2)	29.1 (6.3)	29.1 (6.5)	28.7 (6.1)	29.0 (6.6)
PsD duration (years)	13.6 (11.9)	12.3 (11.5)	12.3 (11.2)	10.7 (10.4)
PASI score [0-72]	18.5 (12.5)	15.7 (11.6)	18.0 (12.4)	15.2 (11.4)
IGA [0-4]	2.9 (0.8)	2.8 (0.9)	2.9 (0.8)	2.7 (0.9)
NLR	3.7 (1.4)	3.9 (1.7)	3.7 (1.5)	3.9 (1.8)
≥3.5 (high), %	41.0%	44.8%	39.5%	44.7%
SBP (mmHg)	128.7 (13.4)	128.2 (12.3)	128.6 (13.7)	127.9 (11.8)
DBP (mmHg)	79.8 (8.8)	80.3 (8.3)	79.8 (8.8)	80.3 (8.1)
Use at BL, %				
csDMARD	23.4%	36.0%	25.3%	37.2%
Corticosteroid	6.8%	11.8%	7.1%	12.4%
NSAID	27.3%	36.9%	28.3%	38.5%

Data are mean (SD) unless noted otherwise.
*Proportions based on the number of patients enrolled in V1/V2.
BL, baseline; BMI, body mass index; csDMARD, conventional synthetic disease-modifying antirheumatic drug; D1/D2, DISCOVER-1/-2 trials; DBP, diastolic blood pressure; GUS, guselkumab; IGA, Investigator's Global Assessment of PsO; N, number of patients; NLR, neutrophil-to-lymphocyte ratio; NSAID, nonsteroidal anti-inflammatory drug; PASI, Psoriasis Area and Severity Index; PBO, placebo; PsD, psoriatic disease; PsO, psoriasis; Q8W, every 8 weeks; SBP, systolic blood pressure; V1/V2, VOYAGE-1/-2 trials.

Figure. Achievement of NLR <2.5 Through Week 48 (Total Cohort) or Week 100 (Biologic-naïve Cohort)



*p<0.05, **p<0.01, ***p<0.001 for GUS QBW vs PBO.
†included 156 (†), 34 (‡), 125 (¥), and 29 (§) PsO pts in randomized withdrawal from W28 to W76.
P-values based on logistic regression adjusting for treatment group; psoriatic disease type (PsA vs PsO); sex; prior biologic use; BL age, NLR, metabolic syndrome, and use of PsA medications (conventional synthetic disease-modifying antirheumatic drugs, corticosteroids, nonsteroidal anti-inflammatory drugs).
Nonresponder imputation was used for missing data through W16; 'as observed' data are summarized post-W16.
BL, baseline; CV, cardiovascular; GUS, guselkumab; N, number of patients; NLR, neutrophil-to-lymphocyte ratio; PBO, placebo; PsA, psoriatic arthritis; PsO, psoriasis; pts, patients; Q8W, every 8 weeks; W, week.

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Abstract N°: 2677

Effectiveness and Safety of Brodalumab in Patients with Plaque Psoriasis with and without Psoriatic Arthritis in the Canadian Real-World Setting: 6-Month Follow-up Interim Results from the CARE Study

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Introduction & Objectives:

Plaque psoriasis (PsO) accounts for over 80% of psoriasis cases and is associated with a number of comorbidities including psoriatic arthritis (PsA).1 Brodalumab, an interleukin 17 receptor A (IL-17RA) antagonist, is approved in Canada for the management of moderate-to-severe PsO in adult patients who are candidates for systemic therapy or phototherapy.2

The CARE study aims to evaluate real-world outcomes of brodalumab amongst adult patients with PsO in Canada. The objective of this interim analysis was to describe the effectiveness and safety of brodalumab in PsO patients with and without PsA at 6 months post-initiation (M6).

Materials & Methods:

CARE is an ongoing Canadian multi-center, 12-month prospective, observational study in adult PsO patients who initiated brodalumab between October 2021 and February 2024 as part of routine care. Baseline demographics and clinical characteristics were collected from medical charts or provided by the patient. In this interim analysis, patients who completed the baseline and M6 visits were stratified by PsA comorbidity status (patients with PsA: PsO+PsA, without PsA: PsO-only).

Brodalumab effectiveness was evaluated with the physician-assessed Psoriasis Area and Severity Index (PASI) and Static Physician's Global Assessment (sPGA) scores, and safety was evaluated with rates of adverse events (AEs), serious adverse events (SAEs) and treatment persistence. All study data was descriptively evaluated and summarized with complete case analysis.

Results:

A total of 278 patients were included in the interim analysis, of which 47 were PsO+PsA (male: 53.2%; Caucasian: 80.9%; mean age: 52.2 years, SD: 13.1) and 231 were PsO-only (male: 58.0%; Caucasian: 74.9%, mean age: 50.7 years, SD: 13.9) (**Table 1**). Longer PsO disease duration (≥10 years) and higher frequency of comorbidities of interest (≥2) were more common in the PsO+PsA group (75.0%, 33/44; 57.5%, 27/47) than the PsO-only group (51.1%, 115/231; 38.1%, 88/231). Hypertension was the most frequently reported comorbidity for both groups (PsO+PsA: 23.4%, 11/47; PsO-only: 26.0%, 60/231).

At M6, PASI 75/90/100 were observed in 88.9% (40/45), 80.0% (36/45), and 53.3% (24/45) of PsO+PsA patients, and 79.6% (180/226), 69.0% (156/226), and 50.0% (113/226) of PsO-only patients, respectively (**Table 2**). Over three-quarters of PsO+PsA patients (82.2%; 37/45) achieved an sPGA of clear (0) or almost clear (1), as did 75.0%

(171/228) of PsO-only patients. Most patients achieved a 2-grade or more improvement of sPGA score compared to baseline (PsO+PsA: 84.4%, 38/45; PsO-only: 76.3%, 174/228).

All PsO+PsA and 96.1% (222/231) of PsO-only patients remained on brodalumab at M6. Reasons for discontinuation among the 9 PsO-only patients were due to adverse events (4/9), lack of efficacy (4/9), and patient decision (1/9).

During the 6-month follow-up period, 36 AEs were reported in 46.8% (22/47) of PsO+PsA patients and 187 in 42.0% (97/231) of PsO-only patients. No SAEs occurred in PsO+PsA patients compared to 1.7% (4/231) of PsO-only patients. Almost all AEs were mild or moderate (PsO+PsA: 100%, 36/36; PsO-only: 98.4%, 184/187) and most were deemed unrelated to brodalumab (PsO+PsA: 61.1%, 22/36; PsO-only: 60.4%, 113/187) (**Table 3**).

Conclusion:

PsO patients with and without PsA showed improvements in psoriasis signs. Few patients experienced adverse events, and most were persistent on brodalumab treatment for six months following initiation.

Table 1. Baseline Demographics and Clinical Characteristics

Baseline Demographics and Clinical Characteristics	PsO+PsA[a]	PsO-only[a]
Number of Patients	47	231
Age in years, mean (SD)	52.2 (13.1)	50.7 (13.9)
Sex – male, n (%)	25 (53.2)	134 (58.0)
Race – Caucasian, n (%)	38 (80.9)	173 (74.9)
BMI (kg/m^2), mean (SD)	29.08 (6.25)	30.11 (7.02)
Disease Duration[b]		
N	44	225
0 to <10 years, n (%)	11 (25.0)	110 (48.9)
10 to <20 years, n (%)	15 (34.1)	43 (19.1)
20 years or more, n (%)	18 (40.9)	72 (32.0)
Number of Comorbidities of Interest[c]		
N	47	231
None, n (%)	0 (0.0)	88 (38.1)
1, n (%)	20 (42.6)	55 (23.8)
2 – 4, n (%)	24 (51.1)	72 (31.2)
5 or more, n (%)	3 (6.4)	16 (6.9)
Comorbidities of Interest[d]		
Hypertension, n (%)	11 (23.4)	60 (26.0)
Type 2 diabetes mellitus, n (%)	4 (8.5)	37 (16.0)
Obesity, n (%)	4 (8.5)	23 (10.0)
Depression, n (%)	6 (12.8)	32 (13.9)
Anxiety, n (%)	6 (12.8)	22 (9.5)

PsA: Psoriatic Arthritis, PsO: Plaque Psoriasis, SD: Standard Deviation

[a]Patients were stratified by psoriatic arthritis (PsA) comorbidity status at baseline (patients with PsA: PsO+PsA, patients without PsA: PsO-only).

[b]Percentages are calculated using non-missing values as denominator.

[c] Comorbidities of interest include the following: Psoriatic arthritis, other autoimmune disease, other inflammatory disease, other dermatological conditions, cardiovascular disease, diabetes, obesity, depression, and other mental health conditions.

[d]More than one comorbidity could be selected for each patient.

Table 2. PASI 75, PASI 90, PASI 100, and sPGA at the 6-Month Follow-up Visit by PsA status

Physician Reported Outcomes	PsO+PsA[a]	PsO-only[a]
Number of Patients	47	231
PASI Response		
N	45	226
PASI 75, n (%)	40 (88.9)	180 (79.6)
PASI 90, n (%)	36 (80.0)	156 (69.0)
PASI 100, n (%)	24 (53.3)	113 (50.0)
sPGA (0,1)		
N	45	228
n (%)	37 (82.2)	171 (75.0)
sPGA improvement of grade 2 or more		
N	45	228
n (%)	38 (84.4)	174 (76.3)

PASI: Psoriasis Area and Severity Index, sPGA: Static Physician's Global Assessment, PsA: Psoriatic Arthritis, PsO: Plaque Psoriasis

[a]Patients were stratified by psoriatic arthritis (PsA) comorbidity status at baseline (patients with PsA: PsO+PsA, patients without PsA: PsO-only).

Table 3. Adverse events (AEs) Reported Over 6 Months by PsA status

Physician Reported Outcomes	PsO+PsA[a]	PsO-only[a]
Number of Patients	47	231
Patients with any AE, n (%)	22 (46.8)	97 (42.0)
Patients with any SAE, n (%)	0 (0.0)	4 (1.7)
AE Severity		
Number of Events	36	187
Mild, n (%)	19 (52.8)	111 (59.4)
Moderate, n (%)	17 (47.2)	73 (39.0)
Severe, n (%)	0 (0.0)	3 (1.6)
Assessment of relationship to brodalumab		
Number of Events	36	187
Related, n (%)	1 (2.8)	14 (7.5)
Probable, n (%)	1 (2.8)	7 (3.7)
Possible, n (%)	7 (19.4)	22 (11.8)
Unlikely, n (%)	5 (13.9)	31 (16.6)
Not Related, n (%)	22 (61.1)	113 (60.4)

AE: Adverse Event, PsA: Psoriatic Arthritis, PsO: Plaque Psoriasis, SAE: Serious Adverse Event

[a]Patients were stratified by psoriatic arthritis (PsA) comorbidity status at baseline (patients with PsA: PsO+PsA, patients without PsA: PsO-only).

References:

1. Armstrong AW, Read C. Pathophysiology, Clinical Presentation, and Treatment of Psoriasis: A Review. JAMA 2020;323(19):1945-1960. DOI: 10.1001/jama.2020.4006.
2. Monograph SP. SILIQ™ Product Monograph. 2019.

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Abstract N°: 2678

Apremilast's cardioprotective effect in psoriasis and anti-atherosclerotic impact on monocytes

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Introduction & Objectives: Psoriasis is a chronic systemic inflammatory disease that is associated with an increased risk for cardiovascular disease (CVD). It is hypothesized that chronic systemic inflammation accelerates the development of CVD comorbidities. However, the underlying mechanisms and the impact of systemic therapy on the risk for developing CVD in individeuals with psoriasis remains unclear. Our objective was to investigate the effects of apremilast on CVD development through a retrospective cohort study and the impact of treatment on the monocyte transcriptome through a prospective cohort study.

Materials & Methods: A retrospective cohort study was conducted using a global health research network consisting of over 100 million patient's annonymous medical records. The two cohorts included individuals diagnosed with psoriasis between the ages of 18 – 80 years old who 1) started treatment with apremilast and 2) started topical corticosteroid (TCS) within 1 year of psoriasis diagnosis. Patients with a history of using any other systemic therapy for psoriasis were excluded from each group. Individuals were matched for age, sex, weight, diabetes, nicotine use, alcohol use, chronic kidney disease, aspirin, antilipemics, and anticoagulants. The relative risk (RR) with 95% confidence interval (CI) for developing CVD and lab abnormalities within five years of their psoriasis diagnosis was determined. Additionally, we conducted a prospective cohort study at our institituion consisting of 14 individuals with psoriasis. Whole blood was obtained at baseline and 16 weeks after starting treatment with paremilast. CD14+ monocytes were negatively selected from whole blood for transcriptome analysis.

Results: There were 8,364 individuals in each group (apremilast vs TCS) after matching for confounding variables. Those who started apremilast had a lower RR of new onset heart failure (RR 0.71; CI 0.59-0.84), myocardial infarction (0.63; 0.63-0.87), cerebral infarction (0.51; 0.46-0.73), deep vein thrombosis (0.73; 0.63-0.97), hypertension (0.71; 0.64-0.79), cholesterol > 200 mg/dL (0.68; 0.62-0.76), and low-density lipoprotein >160 mg/dL (0.64; 0.54-0.77) within 5 years relative to those treated with TCS. The top differentially expressed genes (pre vs post treatment) in monocytes included several genes involved in lymphocyte proliferation, migration, adhesion, and fatty acid metabolism. Transcriptome analysis revealed that the top pathways affected by apremilast treatment included NADPH oxidase complex, regulation of vesicle fusion, and lipoprotein clearance.

Conclusion: Apremilast treatment reduces the risk for new onset CVD, hypertension, hyperlipidemia, and thrombotic events in individuals with psoriasis compared to those using TCS alone. This cardioprotective effect may be mediated through anti-atherosclerotic transcriptomic changes in monocytes.

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Abstract N°: 2700

Effectiveness and Safety of Brodalumab in Patients with Plaque Psoriasis by Body Mass Index in the Canadian Real-World Setting: 6-Month Follow-up Interim Results from the CARE Study

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Introduction & Objectives:

Plaque psoriasis, the most common type of psoriasis, is associated with a number of comorbidities including cardiometabolic diseases.1 Brodalumab is an interleukin 17 receptor A antagonist (IL-17RA) indicated in Canada for the treatment of moderate-to-severe plaque psoriasis (PsO) in adult patients who are candidates for systemic therapy or phototherapy.2 The CARE study aims to describe the real-world outcomes of brodalumab in patients with moderate-to-severe PsO in Canada.

Materials & Methods:

CARE is an ongoing multicenter, prospective, observational study involving adult PsO patients who initiated brodalumab as part of routine care in Canada between October 2021 and February 2024. Baseline demographics and clinical characteristics were collected from patient medical charts or provided by the patient. In this interim analysis, patients were stratified by body mass index (BMI) status at baseline: non-obese: < 30 kg/m2, obese: 30 to < 40 kg/m2, severe obese: ≥ 40 kg/m2. The physician-reported Psoriasis Area and Severity Index (PASI) responses, Static Physician's Global Assessment (sPGA) scores at baseline and 6 months post-initiation (M6) were used to assess the effectiveness of brodalumab. The safety profile of brodalumab was evaluated based on rates of discontinuation, adverse events (AEs), and serious adverse events (SAEs). Complete case analysis was used to descriptively assess and summarize all study data.

Results:

204 patients with verified baseline and M6 data, and data required to calculate BMI were included in this interim analysis. The majority of patients were non-obese at baseline (55.4%, 113/204), while 36.3% (74/204) were obese, and 8.3% (17/204) were severely obese. The mean ages were similar across the BMI categories and most patients were male and Caucasian (**Table 1**).

At M6, PASI 75/90/100 were achieved by 87.3% (96/110), 75.5% (83/110) and 55.5% (61/110) of non-obese, 74.0% (54/73), 64.4% (47/73) and 49.3% (36/73) of obese, and 70.6% (12/17), 52.9% (9/17), and 17.6% (3/17) of severe obese patients, respectively (**Table 2**). Most patients achieved an sPGA of clear (0) or almost clear (1) (non-obese: 80.9%, 89/110; obese: 72.6%, 53/73; severe obese: 52.9%, 9/17), and a 2-grade or more improvement of the sPGA score compared to baseline (non-obese: 80.9%, 89/110; obese: 75.3%, 55/73; severe obese: 64.7%, 11/17).

All non-obese patients remained on brodalumab at M6, compared to 90.5% (67/74) of obese and 94.1% (16/17)

of severe obese patients. Among the 7 obese patients that discontinued by M6, the most frequent reasons were adverse event (4/7), followed by lack of efficacy (2/7). One severe obese patient discontinued brodalumab due to lack of efficacy.

Over the 6-month follow-up period, any AE and any SAE were reported by 46.0% and 1.8% of non-obese patients (n=113), 40.5% and 1.4% of obese patients (n=74), and 41.2% and 0.0% of severe obese patients (n=17), respectively (**Table 3**). Most AEs were mild for non-obese patients (67.0%, 67/100), mild (48.2%, 27/56) or moderate (50.0%, 28/56) for obese patients, and moderate for severe obese patients (70.0%, 7/10). The majority of AEs were deemed not related to brodalumab (non-obese: 53.0%, 53/100; obese: 60.7%, 34/56; severe obese: 90.0%, 9/10).

Conclusion:

Across BMI subgroups, adult patients with moderate to severe PsO observed improvements in psoriasis signs, experienced few adverse events, and persisted on brodalumab 6 months post-initiation.

Table 1. Baseline Demographics and Clinical Characteristics

Baseline Demographics and Clinical Characteristics	Non-obese[a]	Obese[a]	Severe obese[a]
Number of Patients	113	74	17
Age in years, mean (SD)	50.5 (14.6)	50.2 (12.4)	48.2 (10.2)
Sex – male, n (%)	61 (54.0)	49 (66.2)	10 (58.8)
Race – Caucasian, n (%)	78 (69.0)	62 (83.8)	17 (100.0)
BMI (kg/m^2), mean (SD)	25.2 (3.2)	33.7 (2.8)	45.2 (5.1)
Disease Duration[b]			
N	112	73	17
0 to <10 years, n (%)	48 (42.9)	27 (37.0)	10 (58.8)
10 to <20 years, n (%)	28 (25.0)	18 (24.6)	2 (11.8)
20 years or more, n (%)	36 (32.1)	28 (38.4)	5 (29.4)
Number of Comorbidities of Interest[c]			
N	113	74	17
None, n (%)	42 (37.2)	17 (23.0)	5 (29.4)
1, n (%)	29 (25.7)	23 (31.1)	7 (41.2)
2 – 4, n (%)	35 (31.0)	31 (41.9)	4 (23.5)
5 or more, n (%)	7 (6.2)	3 (4.1)	1 (5.9)
Comorbidities of Interest[d]			
Hypertension, n (%)	25 (22.1)	19 (25.7)	4 (23.5)
Psoriatic arthritis, n (%)	23 (20.4)	10 (13.5)	2 (11.8)
Type 2 diabetes mellitus, n (%)	14 (12.4)	12 (16.2)	2 (11.8)
Depression, n (%)	13 (11.5)	12 (16.2)	1 (5.9)
Anxiety, n (%)	11 (9.7)	10 (13.5)	1 (5.9)

BMI: Body Mass Index, SD: Standard Deviation

[a]Patients were stratified by Body Mass Index (BMI) status at baseline (non-obese: < 30 kg/m^2, obese: 30 to <40 kg/m^2, severe obese: ≥ 40 kg/m^2).

[b]Percentages are calculated using non-missing values as denominator.

[c]Comorbidities of interest include the following: Psoriatic arthritis, other autoimmune disease, other inflammatory disease, other dermatological conditions, cardiovascular disease, diabetes, obesity, depression, and other mental health conditions

[d]More than one comorbidity could be selected for each patient.

Table 2. PASI 75, PASI 90, PASI 100, and sPGA at the 6-Month Follow-up Visit by BMI status

Physician Reported Outcomes	Non-obese[a]	Obese[a]	Severe obese[a]
Number of Patients[b]	110	73	17
PASI 75, n (%)	96 (87.3)	54 (74.0)	12 (70.6)
PASI 90, n (%)	83 (75.5)	47 (64.4)	9 (52.9)
PASI 100, n (%)	61 (55.5)	36 (49.3)	3 (17.6)
sPGA (0,1), n (%)	89 (80.9)	53 (72.6)	9 (52.9)
sPGA improvement of grade 2 or more, n (%)	89 (80.9)	55 (75.3)	11 (64.7)

PASI: Psoriasis Area and Severity Index, sPGA: Static Physician's Global Assessment
[a]Patients were stratified by Body Mass Index (BMI) status at baseline (non-obese: < 30 kg/m^2, obese: 30 to < 40 kg/m^2, severe obese: ≥ 40 kg/m^2).
[b]Only patients with a recorded sPGA score, and patients for whom the change in PASI and sPGA from baseline to the 6-month follow-up visit can be evaluated are included in the count.

Table 3. Adverse events (AEs) and Serious Adverse Events (SAEs) Reported Over 6 Months by BMI status

Adverse Events	Non-obese[a]	Obese[a]	Severe obese[a]
Number of Patients	113	74	17
Patients with any AE, n (%)	52 (46.0)	30 (40.5)	7 (41.2)
Patients with any SAE, n (%)	2 (1.8)	1 (1.4)	0 (0.0)
AE Severity			
Number of Events	100	56	10
Mild, n (%)	67 (67.0)	27 (48.2)	3 (30.0)
Moderate, n (%)	31 (31.0)	28 (50.0)	7 (70.0)
Severe, n (%)	2 (2.0)	1 (1.8)	0 (0.0)
Assessment of relationship to brodalumab			
Number of Events	100	56	10
Related, n (%)	11 (11.0)	3 (5.4)	0 (0.0)
Probable, n (%)	5 (5.0)	1 (1.8)	0 (0.0)
Possible, n (%)	11 (11.0)	8 (14.3)	0 (0.0)
Unlikely, n (%)	20 (20.0)	10 (17.9)	1 (10.0)
Not Related, n (%)	53 (53.0)	34 (60.7)	9 (90.0)

AE: Adverse Event; SAE: Serious Adverse Event
[a]Patients were stratified by Body Mass Index (BMI) status at baseline (non-obese: < 30 kg/m^2, obese: 30 to <40 kg/m^2, severe obese: ≥ 40 kg/m^2).

References:

1. Armstrong AW, Read C. Pathophysiology, Clinical Presentation, and Treatment of Psoriasis: A Review. JAMA 2020;323(19):1945-1960. DOI: 10.1001/jama.2020.4006.
2. Monograph SP. SILIQ™ Product Monograph. 2019.

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Abstract N°: 2783

Clinical characteristics of skin pain in patients with psoriasis

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Introduction & Objectives:

Psoriasis is a common inflammatory disease that is often associated with pruritus and pain. The objective of this study was to evaluate the clinical characteristics of skin pain among patients with psoriasis.

Materials & Methods:

A total of 106 patients diagnosed with psoriasis were included in the study (34% female; mean age 42.1 ± 13.0 years). Disease severity was assessed using Psoriasis Area and Severity Index (PASI). Itch severity was evaluated using Numeric Rating Scale (NRS) and 4-Item Itch Score (4IIS). The intensity of skin pain was measured through NRS, Short Form McGill Pain Questionnaire (SF-MPQ), Visual Analog Scale (VAS), and Douleur Neuropathique-4 (DN4).

Results:

During the past week, 84.9% of psoriasis patients reported pruritus, while 50% of them reported skin pain. The average NRS for itch was 4.52 ± 2.88, and the 4IIS yielded a mean score of 6.79 ± 4.37. In terms of the intensity of cutaneous pain, the mean NRS was 2.42 ± 2.96; SF-MPQ score averaged 4.84 ± 7.51; and VAS score was 1.92 ± 2.65. Furthermore, 17% of adult psoriasis patients reported neuropathic pain.

In 84,9% of the participants, skin pain was concurrent with areas affected by pruritus, while 18,9% of patients exhibited cutaneous pain encompassing all pruritic areas. The pain NRS demonstrated significant correlations with SF-MPQ ($r=0.531$, $p<0.001$), VAS ($r=0.779$, $p<0.001$), itch NRS ($r=0.551$, $p<0.001$), and 4IIS ($r=0.569$, $p<0.001$). No association was found between pain NRS and PASI or disease duration.

Conclusion:

Pruritus and skin pain are highly prevalent symptoms in psoriasis patients. The identified correlations provide insights into the complex nature of pain and itch in this condition. The severity of psoriasis does not influence the intensity of cutaneous pain.

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Abstract N°: 2788

Outcome of Conventional Systemic Treatment for Psoriasis at a University Hospital in Thailand

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Introduction & Objectives:

Psoriasis, particularly in its moderate to severe forms, often necessitates systemic therapy. While the advent of biologic therapies has revolutionized the treatment landscape for psoriasis, conventional systemic treatment remains the mainstay, particularly in settings with limited resources. This study aims to investigate the efficacy and drug survival duration of three conventional drugs – methotrexate, cyclosporine, and acitretin – in the management of psoriasis.

Materials & Methods:

A cohort study was conducted utilizing retrospective data from patients who underwent treatment with any of the three systemic drugs at a university hospital between January 1, 2015, and December 31, 2023.

Results:

The study comprised 84 patients, encompassing 133 sessions of oral systemic treatment. The median follow-up duration was 378 days (range=7-2,789). Methotrexate was the most frequently prescribed drug (95 patients, 72.5%), followed by acitretin (26 patients, 19.9%), and cyclosporine (10 patients, 7.6%). At the 16-week follow-up, poor response rates were 8.6% for methotrexate, 10.0% for acitretin, and 28.5% for cyclosporine. Adverse effects led to drug discontinuation in 14 patients (10.5%) out of 133 therapy sessions, with discontinuation rates of 9.5% for methotrexate, 11.5% for acitretin, and 20% for cyclosporine. The primary reason for drug discontinuation was clinical improvement (58.4%), while lack of efficacy and adverse events accounted for the remainder (42.6%). Excluding discontinuations due to clinical improvement, methotrexate demonstrated a one-year drug survival rate of 83.8%, superior to cyclosporine (41.1%) ($p < 0.001$), though not significantly different from acitretin (82.3%).

Conclusion:

All three drugs showed good or moderate efficacy in treating psoriasis. Methotrexate and acitretin exhibited superior drug survival rates compared to cyclosporine. Conventional systemic treatment remains an effective option for psoriasis management, particularly in resource-limited settings.

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Abstract N°: 2798

Evaluation of the risk of psoriatic arthritis in patients with psoriasis undergoing biological treatment. Global population study (TRINETX)

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TITLE

Evaluation of the risk of psoriatic arthritis in patients with psoriasis undergoing biological treatment. Global population study (TRINETX)

Authors

Raquel Rivera, Beatriz Joven, Gema Hernandez-Ibarburu, Carmen García-Donoso, Pablo L. Ortiz-Romero.

Introduction & Objectives:

Biological treatments are very effective in the control of psoriasis but there are no conclusive data regarding the prevention of psoriatic arthritis (PsA).

Our objective is to compare the incidence of PsA between patients receiving first- or second-line biological treatment for psoriasis vulgaris.

Materials & Methods:

Retrospective study based on electronic history data included in Trinetx, a global network of electronic records of 213,342,203 patients, up to December 2023. Patients with psoriasis without PsA who had started first-line biological treatment with TNF inhibitor (iTNF), iIL12-23, iIL17 and iIL23.

The incidence of APs was compared in the different cohorts at 5 years (relative risk, RR) and throughout the follow-up in those 5 years (Hazard ratio, HR) using the 1st line iTNF population as a comparator. Additionally, the cumulative incidence of PsA among study cohorts (iIL-12/23, iIL23, and iIL17) in patients receiving these treatments as second-line therapy was evaluated, comparing them with the iTNF cohort in the first line (RR) and in 3 years.

To perform the analysis, the cohorts were matched by propensity score matching and adjusted for different known risk factors for PsA (time since the onset of psoriasis, sex, nail psoriasis, obesity, alcohol or tobacco abuse, previous conventional treatments).

Results:

1.175.000 were identified with psoriasis, without PsA (928.1200), who started iTNF (24.700), iIL12-23 (6,020), iIL17 (5,440) and iIL23 (5,830). After adjusting for the different factors, we can compare a population of 5.480 iIL12-23, 4.910 iIL17 and 5.640 iIL23 patients with respect to iTNF, of which 350, 460 and 240 developed PsA respectively.

The risk of developing PsA in 1st line was 32% lower with iIL12-23 [RR -3,3 (6,4-9,7); HR 0,68 (0,59-0,78)] and 42% lower with iIL-23 [RR -6,3 (4,3-10,6); HR 0.58 (0,50; 0,68)] at 5 years. In the 2nd line, the risk was 30% lower with iIL-12/23 [RR -3,1 (6,2-8,1); HR 0,70 (0,58-0,86)] and 29% lower with iIL23 at 3 years [RR -4 (5,9-9,9); HR 0,71

(0,51-0,99)] versus an iTNF in the 1st line.

iIL-23, both in 1st line [HR 0.54 (0.45- 0.64)] and 2nd line [HR 0.58 (0.48- 0.81)], are less likely to develop PsA compared to anti-IL-17 at 5 years (46%) and 3 years (42%).

Conclusion:

Big data analysis offers an opportunity to obtain information on the efficiency of drugs in real life. This is the first study to analyze the incidence of PsA in matched, adjusted cohorts with a 5-year follow-up. According to these data, iIL12-23 and iIL23 reduce the incidence of PsA compared to iTNF and iIL17, both in naïve and bio-experienced patients.

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Abstract N°: 2803

Safety in patients with latent tuberculosis who received concomitant anti-tuberculosis medications: Analysis of 11 studies of guselkumab in psoriatic disease

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Introduction & Objectives: Certain psoriatic disease treatments, including tumor necrosis factor inhibitors (TNFi), increase risk of latent tuberculosis infection (LTBI) activation.1,2 Current psoriatic disease treatment guidelines recommend tuberculosis (TB) screening before initiating systemic therapy.3,4 We report safety outcomes in LTBI+ patients (pts) with moderate-to-severe psoriasis (PsO) or active psoriatic arthritis (PsA) who received guselkumab (GUS) treatment for up to 5 years (y).

Materials & Methods: Safety data were pooled from 11 phase 2/3 studies (7 PsO, 4 PsA). GUS was generally administered as 100-mg subcutaneous injections at Week (W)0, W4, then every 8 weeks (q8w) in PsO studies and W0, W4, then q4w/q8w in PsA studies. Pts randomized to placebo (PBO) crossed over to GUS at W16 and W24 in the PsO and PsA studies, respectively. All pts were screened for TB at baseline. Pts with active TB were excluded. Pts with LTBI were eligible if appropriate LTBI treatment was to be initiated prior to/with the first study drug administration or if appropriate treatment had been completed within 5y. Safety was reported for the PBO-controlled period, y-by-y, and through the end of follow-up (PsO, up to 5y; PsA, up to 2y).

Results: Among all randomized pts, 10.0% (70/697) from Asia-Pacific, 7.3% (51/698) from Western Europe, 7.3% (179/2453) from Eastern Europe, and 5.3% (74/1407) from North America had LTBI. LTBI treatment initiation occurred prior to (88.2% [330/374]), with (6.1% [23/374]), or after (5.6% [21/374]) the first dose of study drug (median, -8.0 days; interquartile range, -20.0 to -2.0). LTBI treatments included isoniazid (82.1%), rifampicin (11.8%), and other medications (17.4%); 89.8% received monotherapy. No new-onset TB or LTBI activation was observed in any GUS-treated pt. During the PBO-controlled period, rates of adverse events (AEs) and serious AEs (SAEs) were similar for GUS- and PBO-treated pts in the LTBI+ and LTBI- groups (**Table 1**). Through the end of follow-up, GUS-treated LTBI+ and LTBI- pts had similar cumulative rates of AEs and SAEs. Through 1y, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) elevations were more common in the LTBI+ vs. LTBI- group; 2%/1.7% of LTBI+ pts had CTCAE Grade 3 ALT/AST elevations vs. 0.5%/0.5% of LTBI- pts (no LTBI+ pts and 1 LTBI- pt had Grade 4 elevations) (**Table 2**). From 1-5y (after ~98% of LTBI+ pts completed prophylaxis [median (interquartile range) treatment duration=185 (124-274) days]), the proportions of LTBI+ pts with elevated ALT/AST were generally similar to those in the LTBI- group.

Conclusion: No cases of new-onset TB or LTBI activation were observed in up to 5y of treatment with GUS. GUS safety was generally similar in LTBI+ and LTBI- pts. Consistent with the known safety of LTBI medications,5

ALT/AST elevations were more common in LTBI+ versus LTBI- pts through 1y; however, 2.0%/1.7% of LTBI+ pts had Grade 3 elevations and none had Grade 4 elevations. Rates of ALT/AST elevation were generally similar in LTBI+ and LTBI- pts post-LTBI treatment. The absence of observed TB risk in GUS-treated pts suggests GUS may be a better treatment option than TNFi in high-risk pts, including those in TB-endemic regions.

References

1Kaushik et al. *J Am Acad Dermatol.* 2019;80:43-53

2Gialouri et al. *Mediterr J Rheumatol.* 2022;33(Suppl 1):150-61

3Menter et al. *J Am Acad Dermatol.* 2019;80:1029-72

4Coates et al. *Nat Rev Rheumatol.* 2022;18:465-79

5Tostmann et al. *J Gastroenterol Hepatol.* 2008;23:192-202

Table 1. Safety in Guselkumab-Treated LTBI+ and LTBI- Patients

	Placebo-Controlled Period				Through End of Reporting Period	
	Placebo		Guselkumab		All Guselkumab	
	LTBI+	LTBI-	LTBI+	LTBI-	LTBI+	LTBI-
Treated patients, N	71	990	188	2069	313	4086
Mean duration of follow-up, weeks	19.6	19.4	20.2	19.8	129.0	127.9
Mean exposure (no. of administrations)	6.8	7.4	7.0	7.2	24.9*	24.2*
Patients with active TB, n	0	0	0	0	0	0
Patients with ≥1 AE, n (%)	33 (46.5%)	475 (48.0%)	90 (47.9%)	999 (48.3%)	227 (72.5%)	3048 (74.6%)
Patients with ≥1 serious AE	2 (2.8%)	23 (2.3%)	4 (2.1%)	42 (2.0%)	38 (12.1%)	414 (10.1%)

*LTBI+, N=310; LTBI-, N=3909 (data not available for the PsO Phase 3 Japan registration study).

Table 2. Guselkumab-Treated Patients With Elevated ALT and AST by Year*

	Through Year 1		Year 1 Through Year 2		Year 2 Through Year 3		Year 3 Through Year 4		Year 4 Through Year 5	
	LTBI+	LTBI-	LTBI+	LTBI-	LTBI+	LTBI-	LTBI+	LTBI-	LTBI+	LTBI-
Patients with increased ALT, n (%)										
N	296	3846	238	3128	155	1798	93	1096	83	1048
CTCAE Grade 1	114 (38.5%)	1232 (32.0%)	53 (22.3%)	702 (22.4%)	29 (18.7%)	330 (18.4%)	18 (19.4%)	234 (21.4%)	20 (24.1%)	194 (18.5%)
CTCAE Grade 2	10 (3.4%)	74 (1.9%)	1 (0.4%)	31 (1.0%)	1 (0.6%)	16 (0.9%)	0	9 (0.8%)	2 (2.4%)	3 (0.3%)
CTCAE Grade 3	6 (2.0%)	20 (0.5%)	1 (0.4%)	8 (0.3%)	0	1 (0.1%)	1 (1.1%)	1 (0.1%)	0	3 (0.3%)
CTCAE Grade 4	0	0	0	0	0	0	0	0	0	0
Patients with increased AST, n (%)										
N	296	3846	237	3117	155	1792	93	1093	82	1046
CTCAE Grade 1	93 (31.4%)	849 (22.1%)	38 (16.0%)	412 (13.2%)	17 (11.0%)	189 (10.5%)	15 (16.1%)	120 (11.0%)	12 (14.6%)	95 (9.1%)
CTCAE Grade 2	9 (3.0%)	69 (1.8%)	0	24 (0.8%)	1 (0.6%)	7 (0.4%)	1 (1.1%)	3 (0.3%)	1 (1.2%)	3 (0.3%)
CTCAE Grade 3	5 (1.7%)	20 (0.5%)	1 (0.4%)	11 (0.4%)	2 (1.3%)	4 (0.2%)	0	3 (0.3%)	0	3 (0.3%)
CTCAE Grade 4	0	1 (<0.1%)	0	0	0	0	0	0	0	0

CTCAE, United States National Cancer Institute Common Terminology Criteria for Adverse Events.
*Results do not include data from the PsO Phase 2 X-PLORE study, which did not report CTCAE toxicity grading.

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Abstract N°: 2826

Psoriasis and vitiligo: when the association is accompanied by colocalization

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Introduction:

Psoriasis and vitiligo are common inflammatory dermatoses affecting respectively about 2% and 1% of the general population with a significant impact on patients' quality of life. Their association is known but rare. We report a new case.

Case presentation:

A 58-year-old female patient, followed for an extensive psoriasis vulgaris, evolving for 25 years without associated joint involvement, and for a non-segmental vitiligo that appeared 5 years later. After failure of acitretin and intolerance to methotrexate, she was treated with PUVA therapy for 3 years with a partial and temporary repigmentation of her vitiligo and an incomplete improvement of her psoriasis. On clinical examination, the psoriasis lesions were located mainly on achromic macules of vitiligo, on the trunk and on the limbs. The biological evaluation was unremarkable. The anti-nuclear antibody test was negative. The patient was a candidate for an anti-TNF alpha biological treatment.

Discussion:

Although the association between psoriasis and vitiligo has been reported since the 19th century, the underlying pathophysiological mechanisms are still not fully understood. This association is rare: a study (Sandhu et al, 2004) of 4700 cases of psoriasis, collected over 14 years, revealed only 38 subjects with vitiligo lesions. Another Italian study (Percivalle et al, 2009) of 712 patients with vitiligo, conducted over a period of 26 years, identified only 21 patients with psoriasis. The colocalization of the lesions of the two conditions, as in our patient's case, is even rarer and raises an etiopathogenic problem.

The Koebner phenomenon, corresponding to the appearance of a pre-existing dermatosis on a healthy skin area following a trauma, is commonly found in psoriatic patients. It is also described in vitiligo. It seems unlikely that this phenomenon alone is responsible for the coexistence of the two diseases. According to the most advanced theory CD8+ T lymphocytes play a dominant role, inducing a loss of melanocytes and a production of IL-17 cytokines.

The onset of vitiligo precedes that of psoriasis in 62 to 81% of cases, however in our observation, psoriasis was the initial dermatosis. Simultaneous onset remains exceptional.

The association of psoriasis and vitiligo represents a therapeutic challenge. Anti-TNF alpha drugs, which have been used for many years in the treatment of psoriasis, can be proposed. However, the development of paradoxical vitiligo has been documented in some patients under biotherapy.

Conclusion:

The association of psoriasis with vitiligo, particularly in the form of lesion colocalization, is rare with a largely unknown pathogenesis. Further research is required to improve its understanding and propose effective therapies.

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Abstract N°: 2853

A multimodal model for the classification of psoriasis and common inflammatory skin diseases trained with clinical and dermoscopic images

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Introduction & Objectives:

Psoriasis is a common chronic inflammatory disease that imposes both physiological and psychological burdens on patients. The diagnosis of psoraisis and other inflammatory diseases requires comprehensive clinical information, which cannot be achieved by artificial intelligence models trained solely on a single modality. The objective of this study is to establish a multimodal AI model capable of identifying psoriasis and common inflammatory cutaneous diseases by utilizing both clinical and dermoscopic modalities and tackling the above issues

Materials & Methods:

We proposed a framework of spatial alignment multimodal contrastive learning (SAMCL), which utilizes data augmentation and a transformer backbone to obtain token embeddings from dermoscopic and clinical images. A spatial alignment module addresses scale discrepancies, aligning extracted tokens. A multimodal balanced contrastive learning loss is employed to align features intra- and inter-modally, while addressing class imbalances. A dual-branch transformer fusion module integrates multimodal representations for effective classification.

Results:

The model achieved better results than the single modality models or two fusion models in the eight-classification and binary classification task with accuracy of 0.818 and 0.911. It also performed better compared with 11 multimodel state-of-the-art methods on Derm7pt dataset, achieving higher accuracy, average precision, and average F1-score with 0.807, 0.750 and 0.696, respectively.When assisting dermatologists, the model significantly improved the diagnostic accuracy, sensitivity, precision, specificity, and F1-score, from 0.775, 0.787, 0.812, 0.967, and 0.784 by 20 dermatologists independently to 0.890, 0.907, 0.906, 0.984, and 0.903, respectively. Then, the visual heat maps help to understand how the model captures features in clinical or dermoscopic images of diseases in these test data.

Conclusion:

This study has developed a multimodel learning framework that integrates clinical and dermoscopic image data to assist in the diagnosis of psoriasis and common inflammatory diseases. This model holds the potential to enhance dermatologists' diagnostic capabilities.

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Abstract N°: 3010

Identifying super responders who remain treatment free for more than 2 years after guselkumab withdrawal: data from the Phase 3b GUIDE trial in psoriasis

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Introduction & Objectives:

The ongoing GUIDE study investigates disease modifying effects of guselkumab (GUS) in patients with moderate-to-severe psoriasis. Patients with PASI =0 at Week (W) 20 + 28 were defined as super responders (SRes). Following withdrawal of GUS in part 3 of GUIDE, SRes who had initiated treatment with GUS early rather than late in the disease course remained treatment free longer and had better PASI outcomes through W116. Here, we report data identifying SRes who maintain response after withdrawal from GUS through W164 (>24 months after the last GUS dose).

Materials & Methods:

GUIDE is a Phase 3b, randomised, double-blind, multicentre trial comprising 3 parts. In part 1 (W0–28), patients received GUS 100 mg at W0, 4, 12, and 20. Of 880 patients enrolled, 303 (34.4%) achieved super response. In part 2 (W28–68), SRes were randomised to GUS 100 mg every 8 weeks (q8w) or an extended dosing interval of q16w, stratified by short disease duration (SDD; ≤24 months) or long disease duration (LDD; >24 months). In part 3 (W68–220), 273 SRes with PASI <3 at W68 were withdrawn from GUS, receiving their last dose at W60 (q8w) or W52 (q16w). Patients were eligible for re-treatment upon loss of response, defined as PASI >5. We report observed cases for outcomes using the ITT set; *P* values are nominal.

Results:

In total, 26 SRes (9.5%, n=26/273) remained treatment free for >2 years after GUS withdrawal. Baseline mean values were generally similar for SRes who remained treatment free vs those who were retreated before W164 (n=215/273): age (40.7 vs 39.5 years), BMI (26.6 vs 27.1 kg/m2), PASI (16.1 vs 18.9), and DLQI (20.0 vs 18.6), respectively. In addition, 57.7% vs 70.2% were male, 3.8% vs 8.4% received biologic therapy prior to GUIDE, and 46.2% vs 50.6% received GUS q16w dosing in part 2, respectively.

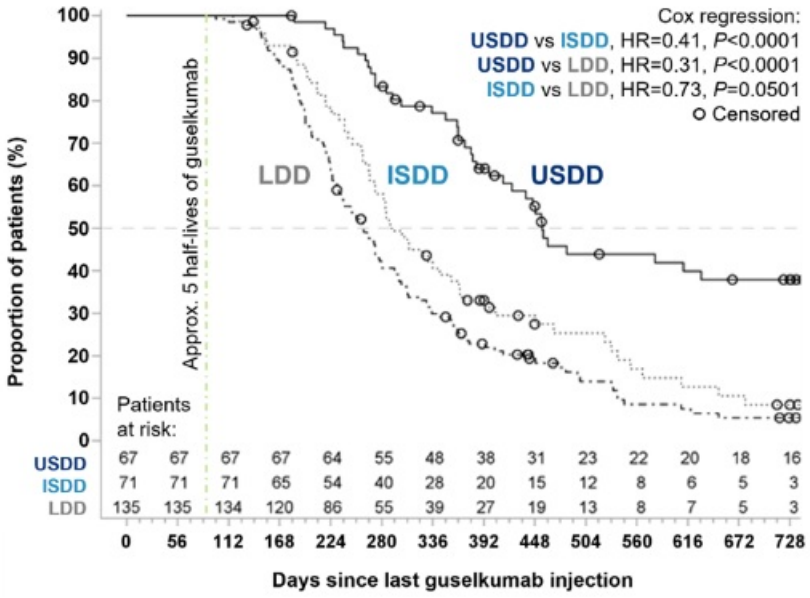
When comparing patients based on disease duration, ultra-short disease duration (USDD, <15 months) patients were more likely to remain treatment free for >2 years vs intermediate-short disease duration (ISDD, 15–24 months; HR=0.41, *P*<0.0001) or LDD patients (HR=0.31, *P*<0.0001; Figure 1). At W164, 25.4% (n=17/67) of USDD, 5.6% (n=4/71) of ISDD, and 3.7% (n=5/135) of LDD patients remained treatment free. Among the treatment free group, 88.5%, 57.7% and 46.2% had PASI <3, ≤1 and =0 at W164, respectively (Figure 2); mean PASI was 1.0 at W164 and had remained low throughout the withdrawal period. Among individual SRes, 5 maintained PASI =0 at

all visits to W164, while others had a low but slightly oscillating PASI, with no steady increase over time (Figure 3).

Conclusion:

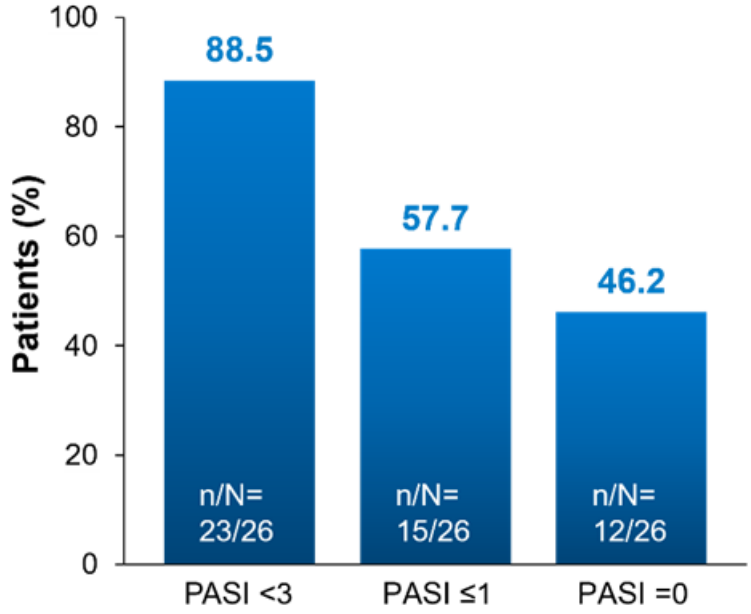
This is the first major study to characterise patients who maintained disease control for >2 years after psoriasis treatment withdrawal. Patients with short disease duration, particularly those treated with GUS within 15 months of symptom onset, were more likely to remain treatment free than those with longer disease duration. Among patients remaining treatment free for >2 years, some maintained completely clear skin at all visits, while the disease oscillated along minimal levels for others. These findings demonstrate that GUS treatment can have durable effects on disease activity in a subset of patients even after long-term withdrawal. Along with previous GUIDE data showing sustained normalisation of immunological biomarkers in psoriatic skin and serum, these findings indicate that GUS may have disease modifying properties in a subset of patients, and that the extent of disease modification may be considered on a continuum.

Figure 1. Proportion of patients who remain treatment free by disease duration (USDD <15 months, ISDD 15–24 months, or LDD >24 months)



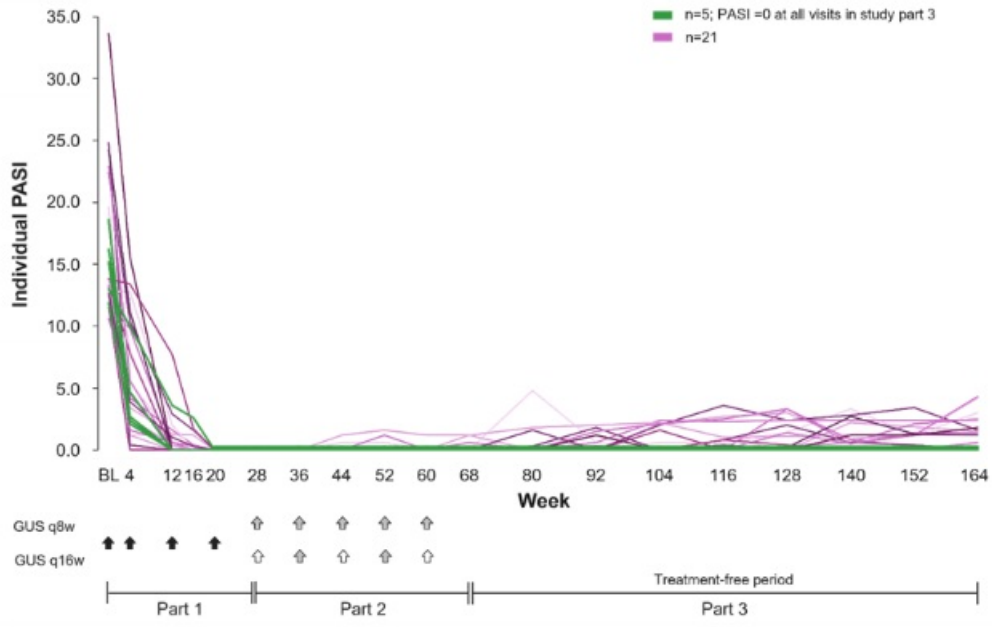
Median treatment-free duration was 259 days for LDD, 291 days for ISDD, and 456 for USDD patients. *P* values are considered nominal. Loss of maintenance of response was defined as PASI >5, at which point treatment was re-initiated. The treatment-free observation period is ongoing.
HR, hazard ratio; ISDD, intermediate-short disease duration; LDD, long disease duration; PASI, Psoriasis Area and Severity Index; USDD, ultra-short disease duration.

Figure 2. Absolute PASI at W164 among SRes who remained treatment free (OC analysis)



OC, observed cases; PASI, Psoriasis Area and Severity Index; SRes, super responders.

Figure 3. Individual PASI scores over time among SRes who remained treatment free to W164 (OC analysis, n=26)



Treatment was withdrawn at W52 or W60, for patients who received guselkumab q16w and q8w, respectively, during part 2 of GUIDE. Patients included in this analysis are those who remained treatment free to W164 (n=26).
SRes who had PASI =0 at all visits in study part 3 are represented by the green solid lines (n=5). Black arrows represent open-label guselkumab injections (W0 to W28), grey arrows represent guselkumab injections in the q8w and q16w groups (W28 to W60, randomized and blinded), and white arrows represent placebo injections.
BL, baseline; GUS, guselkumab; PASI, Psoriasis Area and Severity Index; q8w, every 8 weeks; q16w, every 16 weeks; SRe, super responder; W, Week.

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Abstract N°: 3018

Calcipotriol and betamethasone dipropionate (cal/bdp) cream, a new way to treat mild to moderate psoriasis. About 5 cases from head to toe.

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Introduction & Objectives:

- Topical treatment represents a keystone in the management of psoriasis, as around 70–80% of patients with mild-to-moderate disease can be successfully controlled with topical therapies. Topical agents are the first-line treatments in psoriasis and they can be combined with phototherapy or systemic therapy when topical treatment alone is unlikely to adequately control psoriasis.

Materials & Methods:

- The fixed-dose combination of calcipotriol (CAL) and betamethasone dipropionate (BDP) represents the first-line choice in topical psoriasis treatment. A CAL/BDP cream based on polyaphron dispersion (PAD) Technology has emerged as a novel formulation for a more convenient topical treatment of psoriasis. This technology also demonstrated to increase the cosmetic acceptability and to provide the desirable sensory properties for a topical psoriasis treatment. CAL/BDP cream is applied topically once daily to affected areas for up to 8 weeks.

Results:

- We report 5 cases of psoriasis in different locations with great impact on the quality of life of those patients in which CAL/BDP cream significantly improved psoriasis and quality of life resulting in marked treatment satisfaction.

Conclusion:

- As a conclusions, CAL/BDP PAD technology cream is an effective and safe treatment for plaque psoriasis, especially for locations difficult to treat, while providing superior patient satisfaction and improved quality of life.

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Abstract N°: 3124

Observational study to assess the real-life descriptive effectiveness in patients with moderate to severe plaque psoriasis treated with Brodalumab stratified by patients with BMI>30 and patients with BMI ≤ 30. The BROACTIVE Study. 2 years - results.

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Introduction & Objectives: Brodalumab has been shown to be an effective and safe treatment of moderate to severe plaque psoriasis in both clinical trials and observational studies. Overweight and obesity are common in patients with psoriasis. The present analysis aims to describe patients' baseline demographic characteristics and the effectiveness of brodalumab treatment in obese (Body Mass Index [BMI]>30) vs non-obese patients.

Materials & Methods: BROACTIVE is a prospective, observational, non-interventional, multicenter, non-comparative cohort study under routine clinical practice conditions with retrospective data collection, currently being conducted in Spain. Patients included were aged ≥18 years, diagnosed with moderate-to-severe plaque psoriasis and at least had received one previous systemic treatment. Data were collected from medical records at Spanish public hospitals: from 12 ±4 weeks after brodalumab initiation (baseline) to patient inclusion in the study to a follow-up period of 24 months (6 follow-up visits). In the current analysis patients were stratified into two groups according to baseline BMI: BMI>30 and BMI ≤ 30. Health-related quality of life (QoL) was measured by the Dermatology Life Quality Index (DLQI). Treatment persistence is defined as number of patients who discontinued brodalumab during the period analyzed.

Results: 165 patients have been recruited and 80 patients attained 24 months' follow-up period. A total of 69 patients had a BMI of >30.0, with a mean (standard deviation [SD]) of 35.9 (4.8), and 92 had a BMI ≤ 30, with a mean (SD) of 25.9 (2.7). Mean age was similar for both groups: 51.5 (12.0) for BMI>30.0 and 49.6 (13.2) for BMI≤ 30. Regarding brodalumab effectiveness, absolute PASI ≤1 was achieved by 33 (48.5%; N=68) patients with BMI >30.0 and 57 (62.6%; N=91) with BMI ≤ 30.0 patients with 2 (2.9%; N=68) and 2 (2.2%; N=89) for patients prior to treatment initiation, for both categories, respectively. At 12, 18 and 24 months of treatment, absolute PASI ≤1 was reached by 23 (62.2%; N=37), 24 (77.4%; N=31) and 19 (79.2%; N=24) patients with BMI>30.0 and 40 (70.2%; N=57), 38 (73.1%; N=52) and 39 (81.2%; N=48) of patients with BMI ≤30.0. The corresponding PASI ≤3 response rates were 86.5% (32/37), 96.8% (30/31), and 95.8% (23/24) for patients with BMI>30 and 94.7% (54/57), 92.3% (48/52), and 93.8% (45/48) for patients with BMI ≤30. For both categories, there was a notable decrease in DLQI score, from 3.8 (±5.9) and 2.8 (±4.7) at 3 months to 1.9 (±3.9) and 1.7 (±3.4) after 24 months of treatment, for patients with BMI>30.0 and BMI≤30.0, respectively. Persistence rates for brodalumab at 12, 18 and 24 months, were 84.1%, 81.1%, and 77.4% forpatients with BMI >30.0 and 94.8%, 90.6% and 84.6% for patients with BMI ≤30.0.

Conclusion: The findings of our ongoing study provide real-world evidence on brodalumab effectiveness for obese patients and low rates of treatment discontinuation for both obese and non-obese patients with moderate-to-severe plaque psoriasis in Spanish public hospitals.

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Abstract N°: 3127

GUIDE trial results after withdrawal in part 3: Long-term remission in patients with psoriasis treated with guselkumab within 15 months from onset of symptoms

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Introduction & Objectives:

GUIDE, an ongoing, Phase 3b, randomized, double-blind trial examines early intervention with guselkumab (an IL-23 inhibitor) in patients with moderate-to-severe psoriasis. Super-responder patients (Psoriasis Area and Severity Index [PASI]=0 at Weeks 20 and 28) with PASI<3 at Week 68 were withdrawn from guselkumab treatment in part 3 of the GUIDE trial and followed through Week 220. Super responders with short disease duration (guselkumab initiated ≤2 years from symptom onset) remained treatment-free longer than super responders who had long disease duration (guselkumab initiated >2 years from symptom onset) with a median treatment-free period of 378 versus 259 days, respectively. Here, we further investigate the impact of disease duration on the median treatment-free period and long-term remission after guselkumab treatment withdrawal in super responders.

Materials & Methods:

In part 1 of GUIDE, patients received guselkumab 100 mg at Week 0, 4, 12, and 20. In part 2, super responders were randomized and received guselkumab 100 mg every 8 weeks or every 16 weeks through Week 68, stratified by short versus long disease duration. Of 880 patients enrolled in GUIDE, 303 (34.4%) were super responders. Among these, 273 were withdrawn from guselkumab at Week 68 and included in part 3 (135 [49.5%] long disease duration, 138 [50.5%] short disease duration). Of the short disease duration patients, 71 [26.0%] had intermediate-short disease duration [15–24 months], and 67 [24.5%] had ultra-short disease duration [<15 months]).

Results:

Following guselkumab withdrawal, 35.5% of short disease duration and 18.5% of long disease duration patients remained treatment-free through Week 116 (PASI ≤5 at all visits). Among the short disease duration patients, 43.3% of ultra-short disease duration and 28.2% of intermediate-short disease duration patients remained treatment-free through Week 116. Median treatment-free period was 449 days for ultra-short disease duration patients versus 291 days for intermediate-short disease duration patients (hazard ratio [HR]: 0.39; 95% confidence interval: 0.24–0.62; nominal p<0.001). Among patients with completely clear skin (PASI=0) at Week 116/Week 128/Week 140, 60.9%/76.5%/76.9% had ultra-short disease duration, 21.7%/17.6%/15.4% had intermediate-short disease duration, and 17.4%/5.9%/7.7% had long disease duration, respectively.

Conclusion:

After treatment withdrawal, super responders treated with guselkumab within <15 months from symptom onset remained treatment-free longer and were more likely to have clear skin than super responders treated within 15–24 months. Our findings suggest that very early treatment with guselkumab may modify disease mechanisms and counter disease progression in moderate-to-severe psoriasis.

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Abstract N°: 3150

Anxiety and depression in patients with psoriasis: the effectiveness of therapy with the IL-23 inhibitor guselkumab

Irina Vladimirova

Introduction & Objectives: Psoriasis is a chronic immune-mediated systemic disease that is closely associated with comorbid depression and anxiety disorders. Today, a new direction of therapy is represented by biological therapy. One promising drug is the IL-23 inhibitor guselkumab.

Purpose of the study. To study the effectiveness of therapy with the interleukin-23 inhibitor (guselkumab) and the dynamics of indicators of symptoms of anxiety and depression in patients with moderate and severe psoriasis.

Materials & Methods: A retrospective study of 25 patients diagnosed with widespread vulgar psoriasis was conducted. Initial indicators were assessed using the PASI, BSA, sPGA, DLQI, and VAS (itching scale) indices. Anxiety and depression scores were assessed using the HADS and GAD-7 scales. All patients received treatment with guselkumab according to the standard regimen. The effectiveness of therapy was assessed by the dynamics of PASI, BSA, sPGA, DLQI, VAS, HADS, GAD-7 indicators after 12 weeks of therapy with the interleukin-23 inhibitor (guselkumab).

Results: In the study group of patients there were 25 patients, of which 15 (60%) were men and 10 (40%) women, ages ranged from 20 to 60 years, on average - 41 (35.00; 47.00) years, age of onset of psoriasis – from 2 years to 44 years, on average 18 (10.00; 21.00) years, i.e., the manifestation of psoriasis predominated in young people.

Anxiety was observed in 15 (60%) patients with psoriasis, depression was present in 9 (36%) patients with psoriasis, and 16 (64%) patients reported the absence of depressive symptoms on the HADS-T/D scale. According to the GAD-7 anxiety scale, 2 (8%) patients declared no anxiety; anxiety was observed in 23 (92%) patients: minimal level of anxiety - in 7 (28%), moderate level of anxiety - in 3 (12%), average level of anxiety – in 6 (24%) and high level of anxiety – in 7 (28%). The distribution of depression scores statistically significantly shows higher scores in women compared to men, which may indicate that women are more susceptible to depression in psoriasis. After 12 weeks of therapy with guselkumab, the intervals were significantly reduced from 0.0 to 2.7 on the PASI index, on the BSA index - from 0 to 5, on the sPGA index - from 0 to 1, on the VAS itching intensity scale - from 0 to 4, according to the DLQI index - from 0 to 9. We observed a statistically significant association between higher PASI scores, severity of depression ($p < 0.001$) and severity of anxiety ($p < 0.001$). After 12 weeks of guselkumab therapy, after achieving a PASI index of 100, there were no indicators of depression, the level of anxiety reached minimal values on all scales used ($p < 0.001$). The analysis showed that patients with psoriasis on the HADS-T scale before and after treatment with guselkumab showed statistically significant changes ($p < 0.001$). During the analysis, statistically significant changes were observed in patients with psoriasis on the HADS-D scale before and after treatment ($p < 0.001$). During the analysis, statistically significant changes were observed in patients with psoriasis on the GAD-7 scale before and after treatment with guselkumab ($p < 0.001$).

Conclusion: In the presented study, the drug guselkumab (IL-23 inhibitor) proved highly effective in severe psoriasis with comorbid depression and anxiety. Complete cleansing of the skin from the psoriatic process was achieved by the 12th week of therapy and a complete reduction of depression symptoms without additional prescription of antidepressants in all patients.

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Abstract N°: 3191

Efficacy, tolerability, and capability to modulate systemic inflammation of "non-biologic" therapies for psoriasis: apremilast, methotrexate and NB-UVB phototherapy.

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Introduction & Objectives: Psoriasis (Pso) is a chronic, recurrent, and immune-mediated inflammatory disease of the skin and its treatment depends on the severity of the disease but also the clinical characteristics of the patient. Patients with moderate to severe psoriasis may benefit from systemic therapies divided into phototherapy and conventional or biological treatments. The latter represents an innovative approach to the treatment of moderate-to-severe psoriasis, but many patients may not respond satisfactorily. In addition, possible contraindications, long half-life, subcutaneous administration, their high costs, as well as continuous clinical and laboratory monitoring, limit access to treatment for a significant percentage of psoriasis patients. This prospective observational cohort study aims to investigate the efficacy and the tolerability of apremilast, methotrexate (MTX), and narrowband ultraviolet B (NB-UVB) in patients with moderate to severe chronic plaque psoriasis up to 16 weeks as well as, their ability to modulate systemic inflammation in real-life conditions and laboratory setting.

Materials & Methods: For this purpose, 28 adult patients with moderate-severe psoriasis were enrolled. The patients were treated with Apremilast (n=13), MTX (n=15), and NB-UVB phototherapy (n=9) independently of the study. Disease assessment was performed at baseline (W0) and after 16 weeks (W16) of treatment, using the Psoriasis Area Severity Index (PASI), Body Surface Area (BSA), Physician's Global Assessment (PGA), and Dermatology-Life-Quality-Index (DLQI). Blood samples were collected from all study participants at time 0 and week 16. The analysis of systemic levels of several key mediators involved in the pathogenesis of psoriasis was performed by multiplex ELISA assay and Real-Time PCR.

Results: Our results demonstrated that PASI 75 was achieved by 60% of patients treated with apremilast, 88% of patients in the MTX group, and 50% of patients treated with NB-UVB at W16. A 50% reduction in BSA and a 2-point reduction in PGA were observed in 100% of patients in the MTX and apremilast groups and 70% of patients treated with NB-UVB. Moreover, a reduction of 5 points in the DLQI was achieved in more than 70% of the patients in the three therapy groups. Lastly, the analysis of gene and protein expression profiles of inflammatory mediators showed a statistically significant reduction in the expression of several proinflammatory cytokines (TNF-alpha, IL-1 beta, IL-17, IL-22, IL-33, IL-15) and an increase in the anti-inflammatory cytokine IL-10 in each group of patients under investigation, albeit to a greater extent in patients treated with apremilast.

Conclusion: Apremilast, methotrexate, and NB-UVB phototherapy are effective and well-tolerated treatments in patients with moderate-to-severe psoriasis. Apremilast shows a better ability to modulate systemic inflammation with a more transversal action due to its both anti-inflammatory and immunoregulatory activity.

EA DV CONGRESS
AMSTERDAM 25-28 SEPTEMBER 2024
EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 3192

Epidemiology, clinical characteristics, treatment patterns, and mortality of generalized pustular psoriasis in Finland – a population-based national register study

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Introduction & Objectives: Generalized pustular psoriasis (GPP) is a rare, chronic, and severe inflammatory skin disorder characterized by sudden eruption of sterile pustules and can be life-threatening if untreated. Diagnosis and treatment can be difficult due to amongst others the heterogeneity of symptoms and lack of standardized international guidelines. The objectives of the present study were to assess the epidemiology, clinical characteristics, treatments, and mortality of patients diagnosed with GPP in a specialty care setting in Finland.

Materials & Methods: This non-interventional, retrospective cohort study utilized data from several national Finnish health registers. Patients with two GPP diagnosis (ICD-10: L40.1) at a dermatology clinic in specialty care were included. Two age- and gender-matched comparator groups were additionally included: a) a population with psoriasis vulgaris (PV; ICD-10: L40.0) and b) a population-based control group without a GPP or PV diagnosis. Diagnosis and comorbidities were assessed using ICD-10 codes and pharmacy dispensed medications by the ATC codes. The data collection period was from 1996 to 2021.

Results: In total, 286 GPP patients were included in the study of which 54% were female and the mean (SD) age was 56 (17.9) years. The mean follow-up time for these patients was 12.7 years. The period prevalence of GPP was 4.7 per 100.000 persons and the mean annual incidence rate was 0.42 per 100.000 persons. The prevalence was found to be slightly higher in woman compared to men (5.3 vs. 4.1) and increased by age and was the highest in the >70 age category (9.9). The most common comorbidities found among GPP patients are presented in Figure 1. Topical corticosteroids (CS; n=262, 92%), conventional systemic drugs (n=180, 63%) and systemic CS (n=158, 55%) were the most prescribed GPP-related medications (Figure 2). Approximately one-third (36%) of GPP patients died during follow-up and the mortality rate (95% CI) was 3.3 (2.7-4.00) per 100 person years (Figure 3). The most common recorded causes of death were ischemic heart disease (8%) and malignancies of bronchus and lung (2%). The survival rate of GPP patients was 86% at 5 years and 72% at 10 years.

Conclusion: This study provides a comprehensive overview on the epidemiology, clinical characteristics, treatments, and mortality of GPP patients in Finland during a long follow-up period. Our results show that compared to matched controls, the comorbidity burden, medication use, and mortality rates are considerably higher for GPP demonstrating the high disease burden and need for improving health care practices for these patients.

Figure 1: Prevalence of selected comorbidities among GPP patients compared to matched control groups

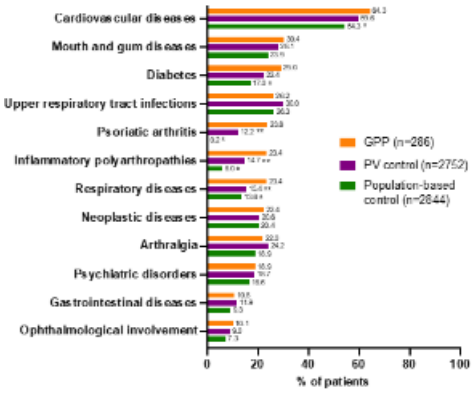


Figure 2: Use of GPP-related medications during follow-up among GPP patients compared to matched control groups

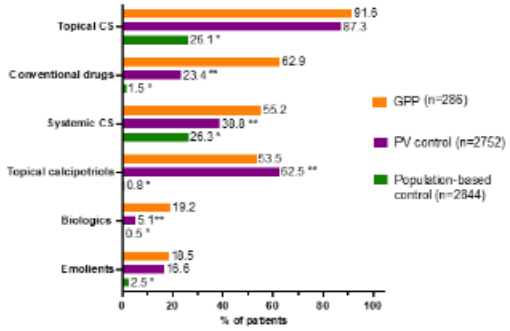
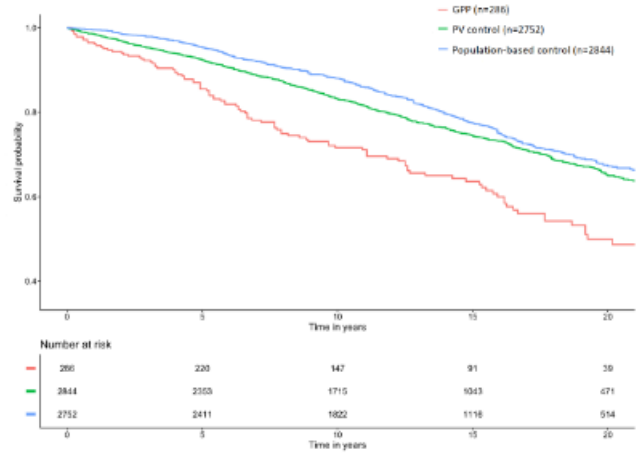


Figure 3: Kaplan-Meier estimates of mortality rates of GPP compared to matched control groups



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Abstract N°: 3207

Efficacy and safety of risankizumab: multicentric real-life experience in Tuscany

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Introduction & Objectives: The therapeutic scenario for patients affected with moderate-to-severe psoriasis has been dramatically changed by the introduction of biological drugs with a specificity of action and an ever-increasing efficacy and safety profile over the last 20 years. Anti-IL-23 drugs represent the latest class of monoclonal antibodies introduced and, to date, three different drugs have been approved in Italy, guselkumab, tildrakizumab and risankizumab. In Tuscany, regional legislation provides for well-regulated access to the most recently introduced molecules, due to the availability of biosimilar drugs with a lower economic impact compared to originator molecules. However, psoriasis therapy requires customization based on the clinical features of the disease (e.g. severity, locations) and of the patient (e.g. sex, age, comorbidities) and on the experience of the prescribing doctor. We therefore report the real-life experience in 8 centers in Tuscany on the efficacy and safety of risankizumab in patients affected with moderate-to-severe psoriasis.

Materials & Methods: Patients affected with moderate-to-severe psoriasis candidate to systemic biologic treatment, underwent risankizumab therapy according to local regulatory guidelines and to clinical need.

Clinical and demographic data were recorded at each visit and entered into a shared database.

Results: As early as week 4 of treatment, we observed a reduction in PASI of approximately 70% (median PASI 4.4, IQR:2.6-8), with PASI90 being gained at week 16 (median PASI 1, IQR:0-2.3). These results were also maintained in the long term with 104/191 (54.5%) patients reaching at least 1 year of continuous therapy. Risankizumab therapy was discontinued in 7/191 patients (3.7%), due to primary inefficacy at week 16 in 1/191 patients and loss of efficacy after the first year of treatment in 2/191. In the remaining patients, the discontinuation was linked to concomitant events, including transition to another center. In only one patient, therapy was interrupted due to the onset of an adverse event (paradoxical atopic dermatitis). In total, 191 patients were treated (72F, 119 M; median age 55 years, IQR44-65). Patients were on average overweight (BMI 26.6, IQR24.2-29.4) and had joint involvement in approximately 20% of cases (38/191), while 60.2% (115/191) of patients had at least one systemic comorbidity. The median baseline PASI was 12.7 (IQR9-17), and the median DLQI was 22 (IQR18-25). Involvement of the scalp, palmoplantar regions, nails, genitals and face was present in 47.6% (91/191), 36.1% (39/1919), 32.5% (62/191), 20.4% (39/1919) respectively. and 6.3% (12/191) of treated patients. Only 16/191 (8.4%) patients were naïve to traditional systemic therapies, while 34/191 (17.8%) were naïve to biological drugs. Multi-failure patients (≥3 biological therapies) were 28/191 (14.7%).

Conclusion: Treatment with risankizumab is associated with a high rate of efficacy and an excellent safety profile

both in the short and long term of treatment, regardless of the patient’s baseline clinical features, associated comorbidities and disease history, even in our real-life clinical experience, confirming the data already published in the literature.

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Abstract N°: 3221

Shared genetic architecture and pleiotropic loci between psoriasis and obesity.

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Introduction & Objectives: Several mechanisms have been proposed to mediate psoriasis risk in obese individuals. For instance, metabolic overload due to a high-fat diet can reduce gut microbiota diversity. Recently, we have shown that psoriasis and obesity share a distinct, T helper 17-driven profile that participates in the inflamed biopsies of both tissues. Here, we conducted a systematic exploration to characterize the heritable influence of obesity in psoriasis.

Materials & Methods: We leveraged genome-wide association (GWAS) summary statistics from large-scale meta-analyses in psoriasis (n=44164), body mass index (BMI) and waist-hip ratio (WHR; n =~700000) individuals of European ancestry. We conducted univariable and multivariable Mendelian randomization (MR) analyses to compute the direct effect of independent obesity traits in psoriasis. After prioritizing the most relevant obesity trait for psoriasis, we performed a genome-wide pleiotropy analysis at a single-variant level under the conjunctional false discovery rate (conjFDR) framework, investigating for concordant and discordant pleiotropic effect and colocalization in pleiotropic loci. Third, we integrated genome-wide association data with gene expression data across 49 tissues from GTEx v8 to delineate genome-wide transcriptomic correlation patterns and bi-directional relationships.

Results: We observed significant causal estimates of BMI (β (95% CI): 0.41 (0.27-0.54) and WHR (β (95% CI): 0.34 (0.12-0.56)) in psoriasis in univariable MR. Both effects were attenuated in multivariable MR. However, the multivariable MR BMI estimated retained similar directions with the primary analysis with overlapping 95% CIs, hence prioritized for downstream analyses. Under the conjFDR framework, we identified 126 independent significant variants spanning across 45 independent pleiotropic loci. More than half (65.87%) of the independent variants showed concordant effects in both traits (7 colocalized), mapped in genes enriched for nuclear activity. Strikingly, genes mapped in discordant variants (34.13%; 1 colocalized) were enriched for T cell activation and lymphocyte differentiation. Global correlation patterns from transcriptome-wide association studies (TWASs) across 49 GTEx v8 tissues revealed positive correlations in lung (rho=0.353, P=0.0002), pancreas (rho=0.444, P=0.0006) and vagina (rho=0.812, P=0.0002). Genetically predicted gene expression of BMI was causally associated with increased psoriasis risk in primary fibroblast (β=0.53, P=8.37×10-5), liver (β=0.358, P=5.72×10-4) and tibial nerve (β=0.431, P=9.7×10-4).

Conclusion: Here, we characterized the genetic architecture that governs the co-occurrence between psoriasis and obesity by employing a genome-wide pleiotropy scan. The mixed association pleiotropic signals between both traits, along with discordant enriched patterns for T cell pathways suggest that the comorbidity rate is not strongly impacted by the genetic background.

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Abstract N°: 3252

ESK-001, an allosteric TYK2 inhibitor, modulates disease and TYK2-related pathway transcriptomic biomarkers in Psoriasis STRIDE trial patients

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Introduction & Objectives:

TYK2 is a validated therapeutic target with potential applications in many immune-mediated indications. Variants within the *TYK2* gene, such as P1104A, lead to loss of TYK2 kinase function, and protects for an array of diseases, including psoriatic arthritis, systemic lupus erythematosus, IBD, and multiple sclerosis. P1104A homozygotes are conferred a greater magnitude of protection against disease than heterozygotes, suggesting that complete blockage of TYK2 kinase activity is important for maximal therapeutic benefit.

ESK-001 is an oral, highly selective small molecule allosteric inhibitor of TYK2. In the ESK-001 STRIDE trial, a phase 2 placebo-controlled dose ranging study in moderate-to-severe plaque psoriasis, the primary and secondary endpoints were all met at the highest doses with clear dose dependent improvement in efficacy. We undertook extensive transcriptomic analysis of disease-related pathways in both blood and skin of patients in order to define dose response, maximum target inhibition, and optimal dosing for subsequent trials.

Materials & Methods:

RNA-sequencing (RNA-seq) of both blood and skin punch biopsy samples was conducted at multiple time points in the STRIDE PsO trial for transcriptomic analysis. Whole blood was collected for RNA-seq from participants at baseline, week 2, week 4, week 8, week 12, and week 16 (post 4-week washout). Skin punch biopsies were collected from a subset of patients, consisting of paired lesional and non-lesional samples at baseline, and a lesional sample at week 12. Paired-end stranded libraries were generated and sequenced with a target depth of 100 million paired-end reads. Reads were aligned to the genome and transcriptome using STAR, and transcripts were quantified with Salmon. Gene level counts were aggregated in R and normalized with the DESeq2 package.

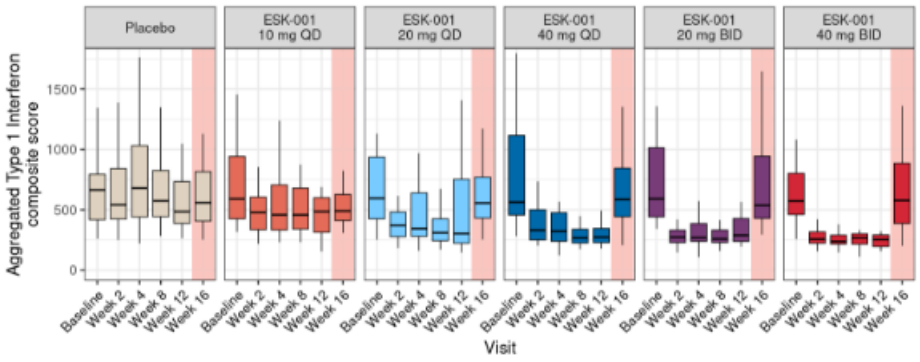
Results:

Blood RNA-seq confirmed ESK-001 dose-dependent inhibition of TYK2. Transcriptomic analysis confirmed ESK-001 maximal target engagement at the 40 mg BID dose via both type 1 interferon gene signature (Figure 1) and a novel pharmacodynamic biomarker. RNA-seq in skin shows return to baseline non-lesional levels of several key disease biomarkers, such as IL23, IL17's, and β-defensins after 12 weeks of ESK-001 treatment.

Conclusion:

RNA-Seq of blood and skin biopsies demonstrated that ESK-001 inhibited its target in a dose dependent fashion, with maximum inhibition of disease and TYK2 relevant pathways at the 40 mg BID dose. Disease-relevant transcriptomic analyses indicate a return of key psoriasis biomarkers to non-lesional baseline levels. These effects are in line with biomarker data previously reported by high-efficacy biologics such as secukinumab. Our RNA-seq results indicate a compelling relationship between maximal target engagement and markers of disease activity, further supporting the selection of 40 mg BID as the dose for the Phase 3 pivotal trial.

Figure 1



Blood samples collected at trough. All patients on study with available samples included in analysis.
Week 16 is 4 weeks post-dose (wash-out)

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Abstract N°: 3288

An observational and prospective study of Secukinumab in secondary nonresponse patients with psoriasis after switching from TNFα inhibitors

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Introduction & Objectives:

Biologic therapy successfully improves the quality of life of psoriatic patients. Unfortunately, not all patients have a sustained response. There is a lack of data on the outcomes profile of prospective observational study of TNFα inhibitors switching to secukinumab (SEC) in the real-world.

Objective: We sought to assess the efficacy of this treatment option in prospective, observational study and analyzed differences of super-responders (SR) group and non-super responders (non-SR) group.

Materials & Methods:

This prospective study included 11 patients with psoriasis, who had a documented history of secondary non-response to TNFα inhibitors. Flow cytometry was used to analyze the IL-23p19 in lesional skin at switch time.

Results:

Analysis indicated eight patients (72.73%) achieved PASI-75 and PASI-90 at week 24. In SR group, all patients achieved PASI-90, and five (67.5%) achieved PASI100 at week 24. Cytometry found that the percentage of IL-23p19 in anti-presenting cells (APCs) in Non-SR group was higher than SR group at the time of switching.

Conclusion:

The high percentage of IL-23p19 in epidermal APCs could explain worse response in non-SR group and indicated that cytometry analysis might provide a clue at the switch time of biologics.

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Abstract N°: 3307

The L-shaped association between weightadjustedwaist index and all-cause mortality in individuals with psoriasis: results from NHANES database retrospective cohort study

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[1]the First Affiliated Hospital of Fujian Medical University, Dermatology,[2]the First Affiliated Hospital of Fujian Medical University

Introduction & Objectives:

While obesity is widely recognized as a robust risk factor contributing to both the onset and exacerbation of psoriasis—a chronic, immune-mediated skin disorder—the relationship between the Weight-Adjusted-Waist Index (WWI), an emerging metric for the nuanced evaluation of obesity, and mortality rates specifically within the psoriatic population is uncharted territory in current medical academic research. This study investigated the associations of WWI with all-cause mortality among individuals with psoriasis.

Materials & Methods:

Data from the National Health and Nutrition Examination Survey (2003-2004, 2005-2006, 2009-2010, 2011-2012, and 2013-2014). Death outcomes were determined by linkage to National Death Index (NDI) records through December 31, 2019. Cox proportional hazards model and the two-piecewise Cox proportional hazards model were used to elucidate the nonlinear relationship between WWI and all-cause mortality in psoriasis patients.

Results:

A total of 577 participants were enrolled in the NHANES study, and 69 all-cause deaths occurred. After multivariable adjustment, higher WWI was significantly and nonlinearly associated with higher risk of all-cause mortality among participants with psoriasis. In addition, we found an L-shaped association between WWI and all-cause mortality, with WWI turning at 10.50cm/√kg for all-cause mortality. Among patients whose WWI was greater than the breakpoint, there was a 63% increase in the risk of death for each unit increase in WWI (HR 1.63; 95% CI 1.04, 2.56).

Conclusion:

Non-linear associations of WWI with all-cause mortality were observed in American patients with psoriasis, with a critical threshold of 10.50cm/√kg above which the risk of all-cause mortality increased significantly.

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Abstract N°: 3321

Real-Life Evaluation of Risankizumab in Treatment-Naïve Psoriasis Patients: Safety and Effectiveness in a 2-year multicentric retrospective study.

Magí Brufau Cochs[1], Elena Canal-Garcia[2], Elena del Alcázar[2], José Manuel Carrascosa[2], Josep Manel Fernández-Armenteros[3], Marta Ferran-Farres[4], Fernando Gallardo[4], Jordi Mollet-Sanchez[5], Gloria Aparicio[5], Rosa Fornons-Servent[6], Jaume Notario[6], Jorge Arandes-Marocci[7], Eva Vilarrassa-Rull[8], Anna López-Ferrer[8], Lluis Puig[8], Miriam Sidro-Sarto[1], Josep Riera-Monroig[1]

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Introduction & Objectives:

Risankizumab, a humanized monoclonal antibody that specifically targets the p19 subunit of IL23, was approved by the European Medicines Agency in 2019 for managing moderate to severe psoriasis. Nonetheless, limited real-world clinical data exists, especially concerning patients being treated with Risankizumab as their initial biological therapy (commonly known as naïve patients). Hence, the objective of this study is to illustrate the safety and effectiveness features of Risankizumab in the short and mid-term for treatment-naïve psoriasis patients.

Materials & Methods:

This is a retrospective, observational, multicentric study of biologic-naïve adult patients who received Risankizumab for the management of Psoriasis, regardless of psoriasis type. Data collection encompassed from November 2020 through April 2024. Epidemiological, effectiveness and safety data were recorded until the 104th week of treatment. Additionally, a chart review of each patient was conducted.

Results:

Sixty-seven patients were included, being 43.0% female and mean age of 57.7 years. The main clinical presentation was plaque psoriasis (92.5%), while 19.4% exhibited inverted psoriasis either alone or in combination with other types of psoriasis. In terms of epidemiological data, 30% of patients had prior history of malignancies, 77.6% had at least 1 cardiovascular risk factor, and 20.9% presented with latent tuberculosis. Furthermore, up to 15% had documented history of hepatitis B virus, hepatitis C virus or Human immunodeficiency virus infection. The mean baseline severity indexes for psoriasis were as follows: PASI: 12.3 ± 6.6; BSA: 17.1% ± 13.7; DLQI: 13.8 ± 6.3. After 2 years, 20 patients completed the follow-up. The effectiveness outcomes measured as observed were at weeks 4, 16, 52, and 104 were the following: [PASI75: 45.5%, 81.1%; 93.1% y 95.0%]; [PASI 90: 34.1%; 69.8%; 89.7% y 85.0%]; [PASI100: 15.9%; 58.5%; 72.4% y 70.0%], with similar results in patients with inverted psoriasis. Of note, more than 65% of patients maintained a PASI<1 from week 16 onwards, and over 78% maintained a PASI<3. There were 14 documented adverse reactions (11 were classified as mild and 3 as moderate, with upper respiratory infections accounting for 35.7% of these reactions). Regarding the drug survival, there were a total of 8 drug discontinuation, 6 of which occurred within the first 6 months of treatment, and the remaining 2 at week 52. Notably, 5 of these cases discontinued the treatment for reasons unrelated to safety and effectiveness. There were no reports of major cardiovascular events, tuberculosis reactivation or progression in malignancy.

Conclusion:

Risankizumab exhibited a favourable safety and effectiveness profile over the short and medium term for treatment-naive patients with psoriasis, yielding results similar to those observed in clinical trials for overall population.

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Abstract N°: 3330

Unraveling the Therapeutic Potential of Huaier in Psoriasis: Insights into the Molecular Targets and Pathways Through Network Pharmacology and Transcriptomics

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Introduction & Objectives:

The aim of this study was to elucidate the pathogenesis of psoriasis by means of network pharmacology and transcriptomics, and to explore the specific targets and molecular mechanisms of Huaier prescription in the treatment of psoriasis.

Materials & Methods:

Initially effective small molecules of Huaier were chosen from the HERB database and their corresponding target genes were retrieved from the TCMSP database. Psoriasis-associated genes were obtained using gene cards, OMIM,and DisDent databases.The overlap between chemical component targetsand disease-relatedgeneswas calculatedto identify potential therapeutic target sof Huaier for psorias is treatment.Furthermore, psoriasis-related chip data were retrieved from the GEO database, and a weighted gene co-expression network analysis (WGCNA) was conducted to construct a gene co-expression network. The optimal β value was determined using the scale-free network law, and dynamic tree-cut clustering was performed to identify gene modules associated with psoriasis. Differential analysis, GO enrichment analysis, and KEGG enrichment analysis were carried out to reveal psoriasis-related genes and pathways.By integrating network pharmacology analysis with WGCNA findings, we identified core targets of Huaier for treating psoriasis. Subsequently, protein-protein interaction and topological analyses were conducted to determine essential targets and key chemical components involved in Huaier's treatment of psoriasis.Enrichment analysis was conducted to identify the pathways targeted by Huaier in psoriasis. A pharmacophore model was built using PharmMapper, and molecular docking simulations were performed with AutoDockTools 1.5.6 to screen core targets for Huaier. HaCaT cells were used to establish a psoriasis cell model, and various experiments including lentivirus transfection, CCK8 assay, EdU staining assay, scratch assay, RT-qPCR, and Western blotting were conducted to investigate the effects of Huaier on psoriasis HaCaT cell behavior and STAT1-mediated inflammatory response. An IMQ-induced mouse model resembling psoriasis-like skin lesions was established to evaluate the therapeutic effect of Huaier on psoriatic skin lesions.

Results:

Network pharmacology analysis identified 101 potential targets of Huaier for psoriasis treatment. Enrichment analysis revealed that Huaier's treatment pathways may involve oxidative stress, cell proliferation, and immune cell regulation in psoriasis. WGCNA and differential expression analysis identified 202 genes closely associated with psoriasis, including six potential therapeutic targets of Huaier. Molecular docking and pharmacophore model construction pinpointed STAT1 as the core gene. Cell experimental results demonstrated significant upregulation of STAT1 in psoriasis HaCaT cells, while Huaier inhibited STAT1 expression to attenuate excessive proliferation and inflammatory factor expression. Animal experimental results showed that by inhibiting STAT1 expression and activation, Huaier improved symptoms of IMQ-induced psoriatic skin lesions.

Conclusion:

STAT1 is identified as Huaier's core therapeutic target in treating psoriasis, and it is significantly upregulated in

psoriasis. Huaier improves the excessive proliferation of keratinocytes and the expression of inflammatory cytokines in psoriasis by inhibiting STAT1 expression and activation.

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Abstract N°: 3339

Apremilast in Patients With Moderate to Severe Genital Psoriasis: Week 32 Results From the Phase 3 DISCREET Study

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Introduction & Objectives: Genital psoriasis (PsO) is associated with painful and bothersome symptoms, impaired quality of life (QoL), and negatively impacted sexual health. Up to 63% of patients (pts) with PsO experience genital PsO over the course of their disease, but it is often overlooked and undertreated. Apremilast, an oral phosphodiesterase 4 inhibitor, is the first oral medication to be studied in pts with genital PsO using clinical measures specific for genital PsO. The objective of this analysis is to evaluate the efficacy and safety of apremilast in pts with genital PsO at Week 32 in the DISCREET trial.

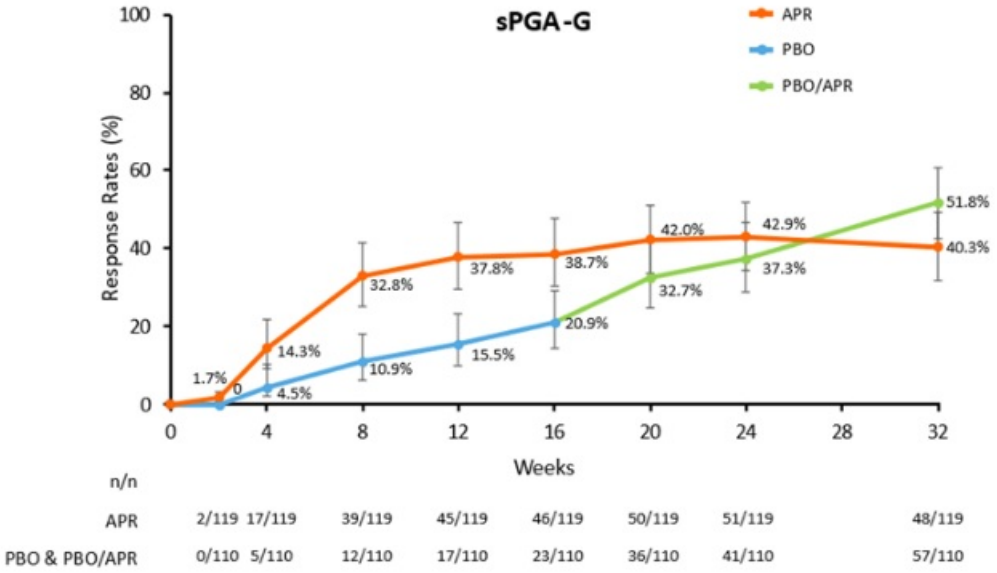
Materials & Methods: DISCREET was a phase 3, randomized, double-blind, placebo (PBO)-controlled trial evaluating apremilast 30 mg BID (APR) as a treatment in pts with moderate to severe genital PsO (defined as a modified static Physician Global Assessment of Genitalia [sPGA-G or Genital PGA] score ≥3). Pts were randomized 1:1 to APR or PBO for 16 weeks. At Week 16, pts entered an APR extension period during which all pts received APR for an additional 16 weeks. Primary results at Week 16 have been previously reported. Here, we report outcomes for exploratory endpoints at/through Week 32. Non-responder imputation was used to handle missing responses. Change from baseline data are reported as data as observed.

Results: In the 16-week PBO-controlled period, 146 pts were randomized to PBO and 143 pts to APR; 229 pts continued treatment in the APR extension period (75.3%, 110 PBO/APR; 83.2%, 119 APR/APR). At Week 32, 51.8% and 40.3% of PBO/APR and APR/APR pts, respectively, achieved a Genital PGA response (a score of 0 [clear] or 1 [almost clear] with a ≥2point reduction from baseline); response rates over time are shown in **Figure 1**. Overall sPGA response rates at Week 32 (a score of 0/1 with a ≥2-point reduction from baseline) were 33.6% (PBO/APR) and 30.3% (APR/APR). Genital Psoriasis Itch Numeric Rating Scale (GPI-NRS) responses (a ≥4point reduction in score from baseline for pts with a baseline score ≥4) were reported in 48.4% (PBO/APR) and 46.5% (APR/APR) of pts at Week 32; response rates over time are shown in **Figure 2**. Mean (95% CI) change from baseline in Dermatology Life Quality Index (DLQI; range, 0 to 30) at Week 32 was -7.4 (-8.8, -6.0) and 6.1 (-7.4, -4.7) in the PBO/APR and APR/APR cohorts, respectively. For DLQI-Q9 ("Over the last week how much has your skin caused any sexual difficulties?"; range, 0 to 3), mean (95% CI) change from baseline at Week 32 was -0.9 (-1.1, -0.6) and -0.7 (-1.0, -0.5) in the PBO/APR and APR/APR cohorts, respectively. Mean (95% CI) change from baseline to Week 32 in the Genital Psoriasis Symptoms Scale (GPSS; range, 0 to 80) was -25.7 (-30.4, -21.1) and -25.0 (-29.9, -20.1) in the PBO/APR and APR/APR cohorts, respectively. **Figure 3** depicts percentage change from baseline in BSA, DLQI, DLQIQ9, and GPSS at Week 32. The most common treatment-emergent adverse events were diarrhea, nausea, headache, and nasopharyngitis (**Table 1**).

Conclusion: DISCREET is the first randomized, PBO-controlled study of an oral systemic therapy using specific

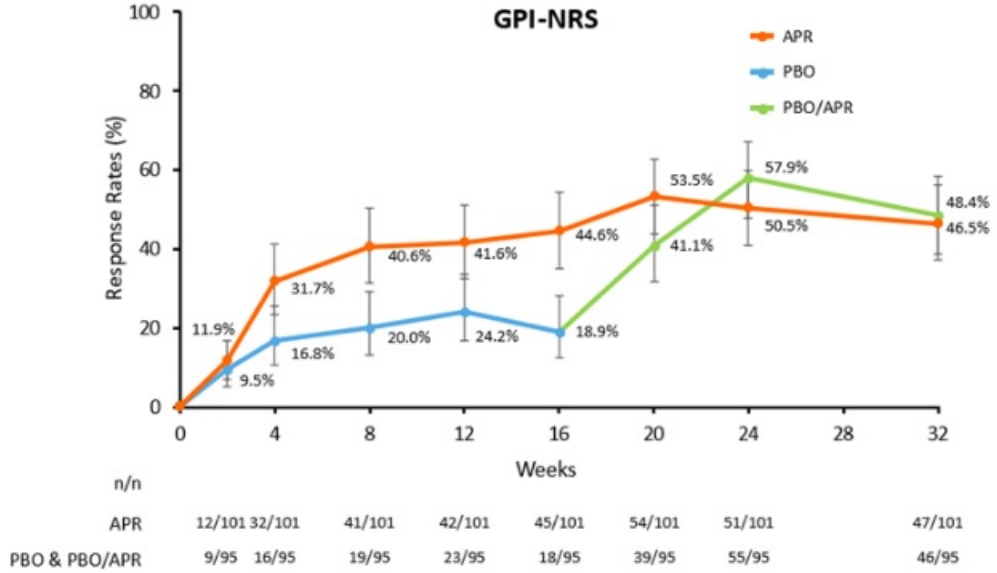
clinical measures of genital PsO. Pts had clinically meaningful improvements in disease severity, symptoms, and QoL at Week 16, with similar results at Week 32 following APR extension, irrespective of the treatment group during the PBOcontrolled period. Over the 32-week exposure period, safety outcomes remained consistent with the known safety profile of APR. APR is a safe and effective treatment for pts with genital PsO.

Figure 1. Genital PGA (sPGA-G) response rates over 32 weeks



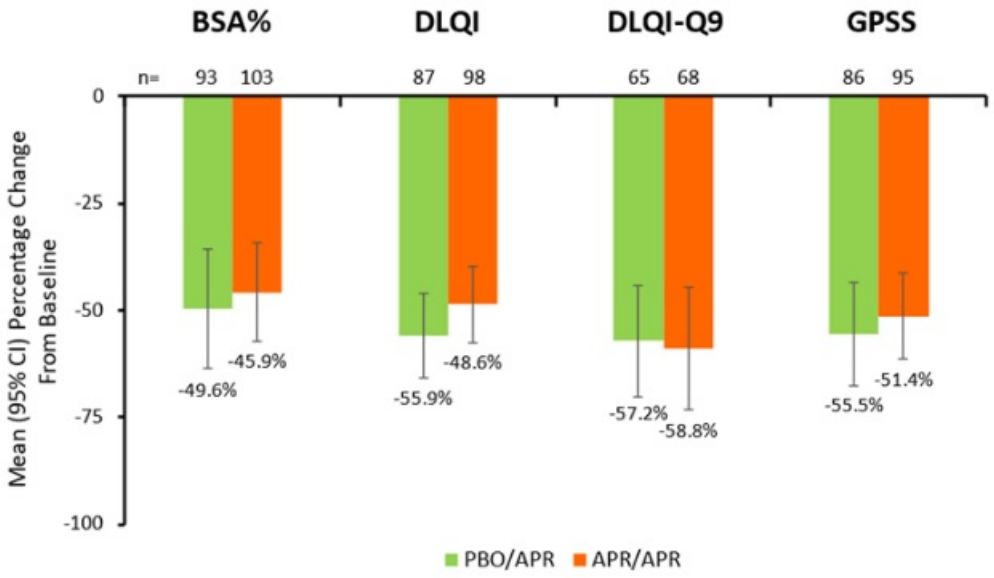
Includes patients who entered the APR extension period. Non-responder imputation method used for missing data. Error bars represent 95% CI based on the Wilson-score method. Genital PGA response is defined as a score of 0 (clear) or 1 (almost clear) with a ≥2-point reduction from baseline. APR, apremilast 30 mg twice daily; CI, confidence interval; PBO, placebo; PGA, Physician Global Assessment; sPGA-G, modified static Physician Global Assessment of Genitalia.

Figure 2. GPI-NRS response rates over 32 weeks



Includes patients with a baseline GPI-NRS ≥4 who entered the APR extension period. Non-responder imputation method was used for missing data. Error bars represent 95% CI based on the Wilson-score method. GPI-NRS scores range from 0 (no itch) to 10 (worst itch imaginable). GPI-NRS response is defined as a ≥4-point reduction (improvement) from baseline. APR, apremilast 30 mg twice daily; CI, confidence interval; GPI-NRS, Genital Psoriasis Itch Numeric Rating Scale; PBO, placebo.

Figure 3. Percentage change from baseline in DLQI, DLQI-Q9, and GPSS at Week 32



Includes patients who entered the APR extension period and had data at Week 32. Error bars represent 95% CI. Total DLQI score ranges from 0 to 30; higher scores represent a poorer quality of life. Question 9 of the DLQI asks, "Over the last week how much has your skin caused any sexual difficulties?" Total GPSS score ranges from 0 (no genital psoriasis symptoms) to 80 (worst imaginable genital psoriasis symptoms). APR, apremilast 30 mg twice daily; BSA, body surface area; CI, confidence interval; DLQI, Dermatology Life Quality Index; DLQI-Q9, Dermatology Life Quality Index Question 9; GPSS, Genital Psoriasis Symptoms Scale; PBO, placebo.

Table 1. Overview of TEAEs during all-APR exposure

	APR patients as treated N=252, PY=107.0	
	n (%)	**EAIR/100 PY**
Overview		
Any TEAE	174 (69.0)	424.5
Any serious TEAE	5 (2.0)	4.7
Any serious drug-related TEAE	1 (0.4)	0.9
Any TEAE leading to APR withdrawal	16 (6.3)	15.0
Any fatal TEAE	0	0
TEAEs in ≥5% of patients		
Diarrhea	64 (25.4)	77.5
Nausea	49 (19.4)	56.3
Headache	45 (17.9)	50.6
Nasopharyngitis	21 (8.3)	20.9

Includes all patients who received ≥1 dose of APR on study (1 patient in the PBO/APR cohort who entered the APR extension phase did not receive APR). APR, apremilast 30 mg twice daily; EAIR, exposure-adjusted incidence rate; PY, patient-years; TEAE, treatment-emergent adverse event.

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Abstract N°: 3392

Real-World Efficacy and Safety Profile of Two Weekly Secukinumab Dosing in Patients with Moderate-to-Severe Psoriasis: A Retrospective Study from a UK Centre

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Introduction & Objectives:

Secukinumab is a fully human monoclonal antibody which selectively neutralizes interleukin (IL)-17A, a key cytokine involved in the pathogenesis of psoriatic disease. It has proven long-lasting efficacy as well as favourable safety profile in the management of psoriatic disease. The standard maintenance regimen after the loading sequence is 300 mg every 4 weeks (Q4W). Obesity is a common comorbidity in psoriasis patients that can influence response to biologic treatment. The mean serum concentration of secukinumab has been found to be 40% lower in patients weighing ≥90 kg compared to those who weigh <90 kg. A randomized control trial comparing 2 weekly (Q2W) to Q4W maintenance dosing in psoriasis patients weighing ≥90kg demonstrated a significantly higher proportion of patients achieving PASI 90 in the Q2W cohort (1). Q2W maintenance dose of secukinumab was approved by the European Medicines Agency in March 2022 for patients ≥90kg. This is a retrospective study to assess the real-world efficacy and safety profile of Q2W secukinumab dosing in patients with moderate-to-severe psoriasis from a tertiary dermatology unit in the UK.

Materials & Methods:

Patients prescribed Q2W secukinumab were identified from pharmacy records between June 2022 and January 2024. Clinical records were reviewed to determine demographics, indication, duration, previous systemic immunosuppression, psoriatic disease activity (e.g. PASI/DLQI) and adverse events of Q2W secukinumab dosing.

Results:

We identified 19 patients who were prescribed secukinumab Q2W (Table 1). There were 11 males (58%) and 8 females (42%). The mean and median ages were 52.5 and 56 years, respectively. The mean weight for patients was 109.3kg (median 107.3kg). The mean BMI was 35.6 kg/m2. The majority of patients (n=13, 68%) were biologic naïve. 13 patients (68%) were uptitrated from Q4W dosing to Q2W dosing. 6 patients (32%) commenced Q2W dosing immediately following the loading sequence. After at least 16 weeks, PASI 100 was achieved in 67% of patients (n=4) started directly on Q2W maintenance. The remaining 33% of patients (n=2) achieved PASI 90 (Figure1). In the Q4W to Q2W uptitration cohort (n=13), PASI 100 was achieved in 4 patients (31%) and PASI 90 achieved in 5 patients (38%) after at least 16 weeks (Figure 2). Adverse events were reported by 3 patients (16%) prescribed Q2W maintenance dosing, leading to one discontinuation. These were recorded as intertrigo, tinea and cutaneous yeast infections. The mean duration of secukinumab Q2W in our cohort was 9 months (range 4 to 19 months).

Conclusion:

Our data have demonstrated that secukinumab Q2W is effective and well tolerated in patients with moderate-to-severe psoriasis who weigh ≥90kg in a UK dermatology unit. Additional efficacy was achieved in patients who were uptitrated from Q4W to a Q2W maintenance regimen. This is most likely due to higher secukinumab trough concentrations in Q2W patients compared to Q4W. Patients should be counselled with regards to adverse effects including yeast and fungal infections.

References:

1. Augustin M et al.. Secukinumab dosing every 2 weeks demonstrated superior efficacy compared with dosing every 4 weeks in patients with psoriasis weighing 90 kg or more: results of a randomized controlled trial. Br J Dermatol. 2022 Jun;186(6):942-954.

Table1:

Demographic/Baseline characteristics	Direct to Q2W, n = 6	Dose up titrated from Q4W to Q2W, n = 13
Age (years), mean (range)	52.5 (18 – 67)	
Sex, male, n(%)	11 (58%)	
Weight (kg), mean (range)	109.3 kg (77.4 – 134)	
BMI (Kgm $^{-2}$), mean (range)	35.6 (28.1 – 48.7)	
Time since first diagnosis of plaque psoriasis (years), mean	15.8	
Previous exposure to biologic psoriasis therapy	8 (42%)	
Duration on Q2W dosing (months), mean (range)	9 (4-19)	
Baseline PASI score, mean	12.8	15.6
PASI Q4W after ≥16 weeks, mean	N/A	6.5
PASI Q2W after ≥16 weeks, mean	0.5	2.4
Adverse effects, n (%)	0 (0%)	3 (23%)

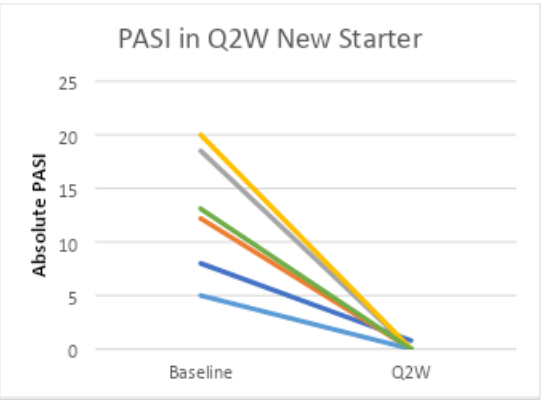

Figure 2.

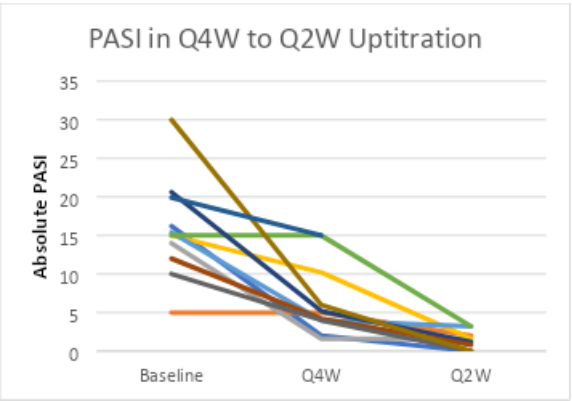

Figure 1.

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Abstract N°: 3442

Patient preference over other topicals, perception of cream usability, treatment adherence and satisfaction among patients with mild-to-moderate scalp psoriasis using calcipotriene and betamethasone dipropionate cream with PAD technology (CAL/BPD PAD cream) in routine clinical practices in Europe. An interim analysis of the PRO-SCALP study

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Introduction & Objectives: Poor accessibility, difficulty in administering and unacceptable cosmetic appeal of topical therapies may negatively influence patient perception of usability, adherence, satisfaction, and preference for scalp treatments [1,2]. The objective of this analyses was to evaluate preference over previously used topicals, perception of cream usability, adherence, and satisfaction with treatment at week 8 (w8), among patients with mild-to-moderate scalp psoriasis using CAL/BPD PAD cream in routine clinical practices in Europe.

Materials & Methods: This single-arm, prospective cohort study (PRO-SCALP) was conducted in adults with mild-to-moderate scalp psoriasis who were newly initiated on CAL/BDP PAD cream as part of usual care in Germany, Spain and the United Kingdom. Patients and clinicians completed assessments at baseline and w8. Preference for current treatment over past topical treatments was assessed using a 5-item questionnaire (Qr), with items scored on a Likert scale (0=strongly disagree to 3=strongly agree). Patients reported satisfaction with overall usability of CAL/BDP PAD cream and using the cream again in the future on a rating scale (0=not at all to 10=very much). Patients reported treatment adherence on a scale of 0=lowest adherence to 100=highest adherence. Patients reported their treatment satisfaction using the 9-item validated TSQM-9 Qr, with 3 questions each related to effectiveness, convenience of use, and global satisfaction with treatment; each domain score range was 0 (least satisfaction) to 100 (most satisfaction). This interim analysis was performed when at least 50% of planned study population completed the end-of-study assessments at w8.**

Results: A total of 152 patients were included in the analyses, and 134 patients had evaluable patient-reported data. Patient preference (strongly agree/agree) for CAL/BPD PAD cream was evident from 83.58% reporting current treatment as more effective, 71.64% reporting easier to use, 70.15% reporting having fewer side-effects, 79.10% reporting more tolerable, and 82.84% reporting overall preference for CAL/BPD PAD cream (vs. previous topicals). Overall, 70.90% and 82.84% of patients (scoring 8/9/10) respectively reported high satisfaction with overall usability of the cream and said they would use it again. Patients' self-reported mean (SD) adherence score was 77.01 (23.61). Mean (SD) treatment satisfaction scores were - effectiveness: 75.99 (23.85), convenience of use: 70.15 (21.25), global satisfaction: 76.12 (22.50).

Conclusion: In real-world clinical practice settings in Europe, majority of patients with mild-to-moderate scalp psoriasis using CAL/BPD PAD cream reported higher adherence, preference for using CAL/BPD PAD cream in comparison to previous topicals, higher satisfaction with treatment and usability of the cream, and higher interest in using the cream again in the future.

\1. J Am Acad Dermatol. 2009;60(6):962-71.

\2. Cutis. 2010;86(3 Suppl):5-31; quiz 32.

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Abstract N°: 3445

Impact of calcipotriene and betamethasone dipropionate cream with PAD technology (CAL/BPD PAD cream) on patient symptoms, functioning, emotions, level of itching, and sleep quality among patients with mild-to-moderate scalp psoriasis in routine clinical practices in Europe. An interim analysis of the PRO-SCALP study

Andreas Pinter*[1], José Luis López Estebaranz[2], Anthony Bewley[3], Jordi Galván[4], Siva Narayanan[5], Volker Koscielny[4], Ismail Kasujee[4]

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Introduction & Objectives: Scalp psoriasis imposes significant burden on patients, including itching, sleep deprivation and psychosocial burden [1,2]. Effective treatments for scalp psoriasis are essential to improve QoL of patients. The objective of this analyses was to evaluate the impact of CAL/BDP PAD cream on the level of itching on the scalp, patient symptoms, functioning and emotions, and sleep quality at week 8 (w8), among patients with scalp-psoriasis treated with CAL/BDP PAD cream in real-world practices in Europe.

Materials & Methods: This single-arm, prospective cohort study (PRO-SCALP) was conducted in adults with mild-to-moderate scalp psoriasis who were newly initiated on CAL/BDP PAD cream as part of usual care in Germany, Spain and the United Kingdom. Patients and clinicians completed surveys at baseline (BL) and w8. Patients reported their worst level of itching on scalp using scale of 0 (no-itching) to 10 (worst-itching imaginable). Patients completed 23-item validated Scalpdex questionnaire with 3 domains: symptoms (3 items; addresses hurt, itch, bleeds), functioning (5 items; addresses daily activities), and emotions (15 items; addresses feelings); each item has a 5-point Likert scale of never (0) to all the time (100); individual item scores, domain scores and the overall score respectively range from 0 to 100 (higher score indicates severe impairment). Patients reported the number of days their scalp psoriasis affected sleep, and separately reported how well they slept at night in previous week, on a Likert-scale (1=very well to 5=very badly). This interim analysis was performed when at least 50% of planned study population completed the end-of-study assessments at w8.

Results: A total of 152 patients were included in the analyses, and 134 patients (mean age: 48.40 years; female: 69.40) had evaluable patient-reported data. At w8, statistically significant ($p<0.0001$) decrease in mean (SD) itch scores from BL of -3.87 (3.26) was observed. At w8, statistically significant ($p<0.0001$) decrease in mean (SD) scores from BL were observed for the overall score, and for symptoms, functioning, and emotions domains of Scalpdex, respectively. Significantly less patients (w8: 8.21% vs. BL: 30.60% [-22.39%; $p<0.0001$)] reported their sleep was affected >=3 days per week. Significantly more patients (w8: 64.93% vs. BL: 36.57% [+28.36%; $p<0.0001$]) reported sleep quality as very well/rather well, in the past week.

Conclusion: In real-world clinical practice settings in Europe, majority of patients with mild-to-moderate scalp psoriasis using CAL/BPD PAD cream reported significant improvement in itching, symptoms, functioning and emotions, and sleep quality.

\1. Møller AH, et al. Patient Relat Outcome Meas. 2015;6:167-77.

\2. WHO Global report on psoriasis. https://apps.who.int/iris/ha.

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Abstract N°: 3509

Comparative Efficacy and Safety of Tildrakizumab for Moderate-to-Severe Plaque Psoriasis: Systematic Literature Review (SLR) and Network Meta-Analysis (NMA)

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Introduction & Objectives: Tildrakizumab is an anti-interleukin-23 p19 monoclonal antibody approved for treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Our aim was to compare tildrakizumab 100mg Q12W (TIL100mg) and other biologics in terms of clinical efficacy and safety, and to explore changes in treatment efficacy over time.

Materials & Methods: MEDLINE®, Embase, CENTRAL, and grey literature sources were searched up to January 10, 2024 to identify RCTs that compared biologics against placebo or each other. Bayesian random effects NMAs adjusted for placebo group response were performed to assess the comparative efficacy via PASI (Psoriasis Area and Severity Index) 75/90/100, PGA (Physician's Global Assessment) 0/1, DLQI (Dermatology Life Quality Index) 0/1 at week 12 (w12), w16, and w28, and safety (any adverse event [AE], and discontinuation due to AE at w12) of TIL100mg against other biologics. Findings were expressed in terms of the number needed to treat (NNT) with 95% credible intervals (CrI), as well as risk differences (RD; **Table 1**). NNTs nearest 1 and RDs nearest 100% were indicative of preferred treatments for efficacy outcomes.

Results: One hundred and three RCTs were included in the NMA, including three RCTs of TIL100mg. NNT and RD measures of benefit for TIL100mg from NMAs were comparable to those associated with other biologics for all endpoints at wk 28 (**Table 1**). For PASI-75 response, TIL100mg demonstrated greater response than placebo at each of w12 (NNT 1.75, 95% CrI 1.56 to 1.99), w16 (NNT 1.42, 95% CrI 1.34 to 1.56), and w28 (NNT 1.36, 95% CrI 1.32 to 1.46); a similar trajectory over time was also identified for PASI-90 (w12: NNT 2.51, 95% CrI 2.02 to 3.31; w16: NNT 1.94, 95% CrI 1.60 to 2.44; w28: NNT 1.56, 95% CrI 1.45 to 1.85), PASI-100 (w12: NNT 10.13, 95% CrI 6.88 to 16.77; w16: NNT 6.08, 95% CrI 4.60 to 9.00; w28: NNT 4.01, 95% CrI 3.26 to 5.35), PGA 0/1 (w12: NNT 2.18, 95% CrI 1.82 to 2.67; w16: NNT 1.63, 95% CrI 1.43 to 1.89; w28: NNT 1.51, 95% CrI 1.36 to 1.80), and DLQI 0/1 (w12: NNT 3.17, 95% CrI 2.45 to 4.34; w16: NNT 1.61, 95% CrI 1.39 to 2.78; w28: NNT 2.15, 95% CrI 1.67 to 2.96). A similar safety profile was observed comparing TIL100mg to other treatments.

Conclusion: This SLR/NMA provides the most up-to-date assessment of comparative efficacy and safety of biologics for moderate-to-severe plaque psoriasis. TIL100mg was found to have a similar profile with respect to clinical efficacy and safety relative to other biologics across some key outcomes at 28 weeks of treatment and was associated with improved efficacy over time.

Table 1: Summary of NNT and RD Comparisons from NMAs of Clinical Efficacy Outcomes at 28 Weeks.

Comparator (vs Placebo)	PASI-75		PASI-90		PASI-100		PGA 0/1		DLQI 0/1	
	NNT (95% CrI)	RD (95% CrI)	NNT (95% CrI)	RD (95% CrI)	NNT (95% CrI)	RD (95% CrI)	NNT (95% CrI)	RD (95% CrI)	NNT (95% CrI)	RD (95% CrI)
GUS 100mg Q8W	1.33 (1.32, 1.36)	75.11 (73.36, 75.73)	1.48 (1.44, 1.56)	67.63 (64.09, 69.52)	2.14 (1.96, 2.37)	46.74 (42.26, 51.11)	1.36 (1.34, 1.44)	73.28 (69.42, 74.71)	1.73 (1.47, 2.37)	57.76 (42.27, 68.16)
RIS 150mg Q12W	1.33 (1.32, 1.36)	75.14 (73.54, 75.73)	1.47 (1.44, 1.55)	67.91 (64.38, 69.56)	1.85 (1.72, 2.07)	54.07 (48.24, 58.03)	1.36 (1.34, 1.41)	73.66 (70.79, 74.78)	N/A	N/A
BIM 320mg Q4W	1.33 (1.32, 1.38)	74.92 (72.24, 75.75)	1.48 (1.44, 1.58)	67.70 (63.13, 69.54)	1.78 (1.70, 1.96)	56.06 (51.00, 58.99)	1.36 (1.34, 1.44)	73.42 (69.35, 74.74)	1.90 (1.53, 2.59)	52.68 (38.54, 65.55)
UST 90mg Q12W	1.34 (1.32, 1.39)	74.84 (71.91, 75.68)	1.50 (1.44, 1.67)	66.79 (59.97, 69.29)	2.90 (2.44, 3.51)	34.48 (28.50, 40.97)	1.40 (1.34, 1.56)	71.56 (63.94, 74.45)	1.56 (1.42, 1.86)	64.21 (53.64, 70.22)
IFX 5mg/kg Q8W	1.34 (1.32, 1.40)	74.78 (71.50, 75.68)	1.52 (1.45, 1.76)	65.78 (56.86, 69.12)	N/A	N/A	1.38 (1.34, 1.53)	72.41 (65.41, 74.59)	1.57 (1.42, 2.24)	63.57 (44.66, 70.31)
SEC 300mg Q4W	1.35 (1.32, 1.40)	74.12 (71.22, 75.51)	1.62 (1.52, 1.75)	61.65 (57.14, 65.88)	2.42 (2.22, 2.68)	41.28 (37.25, 45.10)	1.47 (1.40, 1.56)	68.03 (64.19, 71.65)	1.81 (1.52, 2.44)	55.37 (40.97, 65.60)
IXE 80mg Q2W\Q4W	1.36 (1.32, 1.42)	73.73 (70.41, 75.49)	1.55 (1.46, 1.72)	64.54 (58.02, 68.67)	2.21 (1.95, 2.51)	45.31 (39.90, 51.20)	1.46 (1.36, 1.62)	68.72 (61.82, 73.68)	1.70 (1.45, 2.59)	58.75 (37.11, 69.20)
TIL100mg Q12W	1.36 (1.32, 1.46)	73.48 (68.58, 75.54)	1.56 (1.45, 1.85)	64.16 (54.19, 68.85)	4.01 (3.25, 5.35)	24.92 (18.68, 30.68)	1.51 (1.36, 1.80)	66.24 (55.41, 73.65)	2.15 (1.67, 2.96)	46.46 (33.82, 59.90)
CZP 400mg Q2W	1.37 (1.32, 1.53)	73.19 (65.50, 75.56)	1.55 (1.45, 1.97)	64.37 (50.65, 68.83)	3.43 (1.97, 12.39)	29.19 (8.07, 50.80)	1.41 (1.34, 1.65)	70.99 (60.63, 74.38)	1.96 (1.55, 2.64)	50.99 (37.88, 64.40)
BRO 210mg Q2W	1.37 (1.32, 1.62)	72.99 (61.82, 75.57)	1.56 (1.45, 2.14)	64.09 (46.77, 68.94)	2.07 (1.73, 4.61)	48.35 (21.70, 57.87)	1.42 (1.34, 1.74)	70.67 (57.57, 74.51)	N/A	N/A
UST 45mg Q12W	1.39 (1.33, 1.48)	71.75 (67.57, 75.12)	1.62 (1.47, 1.84)	61.56 (54.32, 67.88)	4.16 (3.40, 5.14)	24.02 (19.44, 29.38)	1.54 (1.39, 1.76)	64.93 (56.81, 72.09)	1.75 (1.51, 2.18)	57.13 (45.89, 66.29)
SEC 150mg Q4W	1.43 (1.35, 1.53)	70.04 (65.53, 73.89)	1.93 (1.70, 2.25)	51.77 (44.47, 58.87)	3.78 (3.12, 4.70)	26.44 (21.28, 32.05)	1.66 (1.51, 1.88)	60.19 (53.30, 66.30)	2.03 (1.53, 3.25)	49.15 (30.74, 65.57)
ETN 50mg BIW\QW	1.69 (1.55, 1.89)	59.03 (52.84, 64.44)	2.67 (2.16, 3.42)	37.40 (29.21, 46.23)	8.74 (6.14, 13.35)	11.44 (7.49, 16.30)	1.87 (1.52, 2.52)	53.48 (39.66, 65.87)	3.11 (1.98, 5.47)	32.15 (18.27, 50.51)
ADA 40mg Q2W	1.69 (1.58, 1.84)	59.34 (54.43, 63.44)	2.22 (1.93, 2.59)	44.96 (38.57, 51.93)	4.03 (3.50, 4.78)	24.80 (20.92, 28.56)	1.91 (1.70, 2.17)	52.40 (45.98, 58.71)	2.73 (2.00, 4.33)	36.58 (23.07, 50.03)

Estimates of the number needed to treat (NNT) and risk differences (RD) derived from random effects NMAs adjusted for placebo group response are presented for all interventions at 28 weeks. Values of NNT closer to 1 and RDs nearest 100% are indicative of preferred interventions. Interventions are sorted in terms of increasing magnitude of NNT (and decreasing magnitude of RD) for PASI 75 response.

Abbreviations: ADA – Adalimumab, BIM – Bimekbrumab, BIW – Twice Weekly, BRO – Brodalumab, CrI – Credible Interval, CZP – Certolizumab pegol, ETN – Etanercept, GUS – Guselkumab, IFX – Infliximab, IXE – Ixekizumab, PASI – Psoriasis Area and Severity Index, QAW – Every # weeks, QW – Once Weekly, RIS – Risankizumab, SEC – Secukinumab, TIL – Tildrakizumab, UST – Ustekinumab.

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EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 3561

Effectiveness and safety of deucravacitinib combined with calcipotriene/betamethasone dipropionate for treating moderate to severe plaque psoriasis

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Introduction & Objectives: Topical treatments are a potential add-on therapy for patients who do not respond adequately to systemic therapies for chronic plaque psoriasis. Deucravacitinib (Sotyktu; Bristol Myers Squibb) is an oral compound that selectively inhibits tyrosine kinase 2 by binding to its regulatory domain. This small molecule is approved to treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. However, some patients do not reach treatment goals with deucravacitinib, but may respond when other therapies are combined. Topical steroids are the most commonly used therapies in combination to treat moderate to severe psoriasis. Enstilar (calcipotriene 0.005%/betamethasone dipropionate 0.064%; C/BD), a topical foam, is also approved to treat plaque psoriasis. The objective of this study was to assess the effectiveness, safety, and quality of life in patients who received add-on C/BD when taking deucravacitinib for treating chronic plaque psoriasis.

Materials & Methods: This prospective, open-label, single-center study enrolled adults (≥18 years of age) with moderate to severe plaque psoriasis (defined as baseline physician global assessment [PGA] ≥3, body surface area [BSA] affected ≥10%, and psoriasis area severity index [PASI] ≥12), who took deucravacitinib (6 mg daily) for 8 weeks. Patients who achieved PASI ≥75 at week 8 continued on deucravacitinib alone up to week 24; those with PASI 25-74 at week 8 used add-on, daily topical C/BD foam for 4 weeks (up to week 12); and patients with <PASI 25 at week 8 were discontinued. Final patient follow up was up to week 24.

Results: Of 30 enrolled patients (mean age 45.4 years; 63% male), 18 completed 24 weeks. For patients with data available at week 8 (n=28), 5 (18%) achieved PASI 75, 20 (67%) reached PASI 25-74, and 3 did not reach PASI 25. Mean ± SD scores for PASI, PGA, %BSA, and dermatology life quality index (DLQI) in patients with PASI 24-75 at week 8 improved further with 4 weeks of C/BD add-on therapy (weeks 8 to 12), and were maintained up until week 24 (12 weeks after C/BD was discontinued) (**Table**). Numerically better scores were generally noted at all timepoints for patients who achieved PASI 75 at week 8 and received deucravacitinib monotherapy for 24 weeks (**Table**). Few patients experienced adverse events (AEs), and none had serious AEs or discontinued due to AEs.

Conclusion: Adding daily tapinarof cream to an existing biologic was tolerable and helped patients achieve the NPF treatment goal. This approach may prevent the need for switching biologics when patients do not respond, preserving the safety and cost associated with their current biologic.

Table: Treatment outcomes (mean ± SD) with deucravacitinib monotherapy (patients with PASI 75 at week 8) and deucravacitinib plus a 4-week C/BD add-on therapy (patients with PASI 25-74 at week 8)
Outcome
PASI 25-74 (n=20)
PASI
PGA
%BSA
DLQI
PASI ≥75 (n=5)
PASI
PGA
%BSA
DLQI

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Abstract N°: 3565

The Beneficial Effect of Lactiplantibacillus plantarum IS-10506 in Improving Disease Severity and Immunology Biomarkers for Psoriasis Vulgaris: An Indonesian Randomized Controlled Trial

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Introduction & Objectives:

Psoriasis is a chronic autoimmune skin disease whose pathogenesis is still evolving. Recently, gut microbiota dysbiosis has been known to play an important role in inflammatory diseases, including psoriasis. Oral probiotics have proven to maintain microbiota homeostasis, gut barrier integrity, and modulate immune responses. *Lactiplantibacillus plantarum* IS-10506 (LIS), a probiotic strain isolated from fermented buffalo milk of Indonesian origin, is anticipated to be beneficial yet better suited for psoriasis patients in Indonesia. This study aimed to evaluate the efficacy of LIS in improving the clinical manifestation, serologic biomarkers, and gut microbiota of Indonesian psoriasis vulgaris patients.

Materials & Methods:

This study is a double-blind, randomized clinical trial comparing the effects of encapsulated LIS (2x1010 CFU/day) and placebo (skim milk powder), each given twice daily for 12 weeks. The eligible criteria were patients diagnosed with mild to moderate psoriasis vulgaris (Psoriasis Area and Severity Index/ PASI score <10) aged 18–70 years with no history of taking immunosuppressive systemic treatment, oral antibiotics, proton pump inhibitors, and laxatives in the last 3 months before sampling. This trial was conducted on a total of 49 patients, divided into intervention (n = 24) and control groups (n = 25). Both groups received topical corticosteroid and emollient as standard therapy. The before-after effects of supplementation were evaluated through several parameters, including PASI scores, serum cytokines (IL-17, TNF-α, IL-10, Foxp3), and gut microbiota profiles. This research protocol was granted ethical clearance by the Dr. Soetomo General Academic Hospital's Ethics Committee for Clinical Research (No. 0315/KEPK/XI/2021).

Results:

The effectiveness of LIS was found to be more beneficial than a placebo. After 12 weeks, PASI scores in the probiotic group showed a notable decrease within and between groups, as seen in Table 1. The immunological biomarkers in the probiotic group demonstrated remarkable improvement after intervention; the intragroup comparison can be seen in Table 2. As opposed to the placebo, LIS had significant differences in the delta value (before and after treatment) of IL-17, TNF-α, IL-10, and Foxp3 levels ($p=0.025$; $p= 0.022$; $p= 0.002$; $p= 0.045$, respectively). All analyses used a 95% confidence interval (95% CI), with a p-value considered statistically significant if <0.05. Based on the microbiome composition, there was no significant difference in alpha and beta diversity between groups before and after intervention. Relative abundance at the genera level exhibited a decrease of *Bacteroidetes* and an increase of *Prevotella* in the probiotic group, closer to healthy control, although it was not statistically significant

Table 1. Differences in PASI score between LIS and placebo

	PASI score Baseline (mean ± SD)	PASI score Week 6 (mean ± SD)	PASI score Week 12 (mean ± SD)	Before-after (within group) p-value
LIS (n = 23)	4.22 ± 2.27	3.54 ± 2.81	3.38 ± 3.71	**0.001***
Placebo (n = 24)	5.63 ± 2.87	5.21 ± 2.75	4.29 ± 2.39	**0.022***
Intergroup p-value	0.066	**0.024***	**0.049***	

Note: *statistically significant, (p< 0.05; CI 95%)

Table 2. Differences in serum cytokines between LIS and placebo

	IL-17		Before-after (within group) p-value
	Baseline	**Week 12**	
LIS (n = 23)	72.02 ± 24.11	49.91 ± 31.29	**0.013***
Placebo (n = 24)	57.80 ± 42.09	61.88 ± 36.26	0.331
	TNF-α		
	Baseline	**Week 12**	
LIS (n = 23)	112.13 ± 43.25	83.71 ± 32.57	**0.001***
Placebo (n = 24)	95.07 ± 54.06	90.44 ± 47.71	0.493
	IL-10		
	Baseline	**Week 12**	
LIS (n = 23)	238.16 ± 208.40	334.94 ± 214.24	**0.000***
Placebo (n = 24)	222.05 ± 208.03	212.75 ± 166.71	0.797
	Foxp3		
	Baseline	**Week 12**	
LIS (n = 23)	8.29 ± 4.30	10.21 ± 6.44	**0.048***
Placebo (n = 24)	9.90 ± 23.70	8.56 ± 5.88	0.331

Note: *statistically significant, (p< 0.05; CI 95%)

Conclusion:

This clinical trial proves that *Lactiplantibacillus plantarum* IS-10506 has the potential to be an adjuvant therapy for psoriasis vulgaris patients through ameliorating gut microbiota, suppressing inflammation, and improving clinical outcomes.

Keyword: psoriasis, probiotic, disease severity, inflammation, gut microbiome

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Abstract N°: 3566

Risk factors associated with liver stiffness progressing measured by sound touch elastography among psoriatic patients receiving biologics

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Risk factors associated with liver stiffness progressing measured by sound touch elastography among psoriatic patients receiving biologics

Introduction & Objectives:

Metabolic dysfunction-associated fatty liver disease (MAFLD) is a condition of excessive fat accumulation in the liver due to inflammation or abnormal metabolic conditions. Based on previous literature, patients with psoriasis are more likely to develop MAFLD or its advanced subtype than healthy controls, and traditional systematic treatment, in particular, methotrexate, is related to inducing liver injury or even liver fibrosis. Comparatively, in the era of target therapy, the evidence of noninvasive liver stiffness measurement (LSM) could be more transparent. This retrospective study aims to profile the LSM changes after using biologics among psoriasis patients and explore the contributing factors of liver stiffness progressing by sound touch elastography (STE).

Materials & Methods:

We extracted medical records of patients with psoriasis who examined STE between January 1st, 2018, and August 1st, 2022, from the hospital information system (HIS) of a tertiary hospital in China. Then, patients were further enrolled if they were: 1. aged over 18, without gender restriction; 2. diagnosed plaque psoriasis (ICD-10 code 40.0), with or without psoriatic arthritis based on CASPAR (the Classification Criteria for Psoriatic Arthritis); 3. examined STE twice and received biologics monotherapy between two STEs. Patients were excluded if they: 1. combined with active hepatitis virus infection (hepatitis B, hepatitis C); 2. had alcohol consumption over 15g per day on average; 3. were diagnosed with autoimmune liver disease. We set the cut-off STE value as 6.5 kPa, classifying patients as subgroups with STE abnormal and normal results. Then, we did the descriptive analysis and conducted univariate and multivariate logistic regression models through GraphPad Prism and R studio software. P values less than 0.05 were set as statistically significant.

Results:

In total, we detected 392 psoriatic patients who examined STE one or more times from January 1st, 2018, to August 1st, 2022, in the West China Hospital of Sichuan University. Then, according to the inclusion and exclusion criteria, 42 out of 392 patients were finally enrolled. At baseline, 7 out of 42 patients (16.67%) were examined with abnormal STE results, and 22 patients (52.38%) were reviewed with abnormal STE values after using biologics. Then, through the paired t-test, the mean STE values elevated 1.17 ± 2.31 kPa after a follow-up of 1.41 ± 0.52 years. Moreover, the results of multivariate logistic regression models presented the odd ratio for abnormal follow-up STE values per year of psoriasis duration is 1.12 (95% CI 1.02, 1.26) and per unit of BMI is 1.36 (1.07-1.88), respectively. Thus, long psoriasis duration and high BMI were risk factors for suffering elevated liver stiffness measurement after biological treatment.

Conclusion:

In conclusion, with a limited sample size, this retrospective study performed an exploratory analysis. Our findings indicated that those who suffered from psoriasis for a long time or combined with overweight and obesity issues are more likely to suffer LSM enhancement. In the future, studies could further focus on supplementing the evidence of the long-term influence of biologics on LSM among patients with psoriasis.

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Abstract N°: 3567

Asia-Pacific Consensus Recommendations on the Management of Generalised Pustular Psoriasis

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Introduction & Objectives:

Generalised pustular psoriasis (GPP) is a rare, heterogeneous, and potentially life-threatening skin disease characterised by primary, sterile, macroscopically visible pustules with or without systemic symptoms. Environmental, genetic, and lifestyle factors contribute to variations in GPP epidemiology and presentation. Currently, there is limited evidence from the patient population in the Asia-Pacific (APAC) region, resulting in a general paucity of information on the effective management of patients with GPP in this region. This modified Delphi panel study aimed to gain advanced insights and facilitate the development of APAC region-specific consensus recommendations on the management of GPP.

Materials & Methods:

A systematic literature review (SLR) was conducted to identify published literature and develop consensus statements. A Steering Committee (SC) of eight GPP experts from the APAC region guided this study. Twelve additional experts from the region were invited to participate in one round of Delphi survey followed by a virtual consensus meeting. The threshold for consensus was set at ≥80% agreement.

Results:

A total of 140 statements were developed based on the SLR and the collective expertise of the SC. Twenty GPP experts from 10 countries evaluated the statements. The panellists managed an average of 39 GPP cases over the last 5 years and the majority (75%) had ≥20 years of clinical experience. The mean age of the panellists was 53.4 years and 55% were male.

In the Delphi survey (Round 1), 80 statements (57%) achieved consensus. Statements falling below the agreement threshold were revised or removed after in-depth deliberation. The revised statements were subjected to voting in a virtual consensus meeting (Round 2). Following Round 2, the cumulative number of statements in consensus reached 106.

The experts agreed that GPP is a rare, serious, and potentially life-threatening condition distinct from plaque psoriasis. Mirroring the global trends,1 the experts concurred that the immediate therapeutic goal is rapid resolution of cutaneous and systemic symptoms of GPP, while long-term treatment goals are the maintenance of response and prevention of future flares.

The experts reached consensus on the definition and severity classification of GPP flares, and recommended first-line and maintenance treatment options for adult GPP based on its severity, and GPP in childhood and during pregnancy. These consensus outcomes have been synthesised into treatment algorithms to guide dermatologists in the APAC region in their clinical decision-making processes.

The discourse on treatment strategies advocates timely access to rapidly acting and highly effective biologics in managing acute flares, with interleukin-36 inhibitors as the preferred option, if available. Efforts should be directed towards improving the accessibility of biologics across APAC for optimal management of GPP.

Conclusion:

This is the first consensus on the management of GPP in the APAC region. The consensus emphasised the importance of tailoring treatment according to the severity of GPP flares and taking into account each patient's unique clinical circumstances.

References:

1. Puig L, *et al. J Eur Acad Dermatol Venereol.* 2023;37(4):737-752.

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Abstract N°: 3576

Simultaneous Genital Skin Clearance and Patient Reported Outcome Responses at Weeks 24 and 52 in Patients with Moderate-to-Severe Genital Psoriasis Treated with Ixekizumab: an analysis of the Phase 3 Clinical Trial IXORA-Q

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Introduction & Objectives: To evaluate ixekizumab (IXE) efficacy through evaluation of simultaneous genital skin clearance with patient reported outcomes (PRO) responses.

Materials & Methods: In IXORA-Q (NCT02718898)(1, 2), patients with moderate-to-severe genital psoriasis received 80 mg IXE or placebo every 2 weeks (W) through W12 after which they received open-label 80 mg IXE every 4W through W52. This *post-hoc* analysis evaluated simultaneous genital skin clearance (static Physician's Global Assessment of Genitalia zero score [sPGA-G(0)]) with the following meaningful PRO responses at W24 and W52: (i) zero itch score on the Genital Psoriasis Symptoms Scale [GPSS-Itch(0)], (ii) Patient's Global Assessment of Genital Psoriasis [PatGA-G (2-point improvement)], zero score on [PatGA-G(0)], (iii) Dermatology Life Quality Index 0 or 1 [DLQI(0,1)], and (iv) score of 0–10 on the Quick Inventory of Depressive Symptomatology-Self Report–16-items (QIDS-SR16). Response rates were summarized as observed data.

Results: Baseline demographics were similar between treatment subgroups. Generally, sPGA-G(0) and meaningful PRO responses were maintained from W24 to W52. At W24 and W52, simultaneous response rates for sPGA-G(0) with each of the PROs were: 57.9 % (n=33/57) and 62.3% (n=33/53) for GPSS-Itch(0), 44.9% (n=31/69) and 47.7% (n=31/65) for PatGA-G(0), 61.2% (n=41/67) and 61.3% (n=38/62) for PatGA-G ≥2-point improvement, 43.5% (n=30/69) and 44.6% (n=29/65) for DLQI(0,1) and 65.2% (n=45/69) and 68.2% (n=45/66) for QIDs-SR16 score of 0-10.

Conclusion: IXE demonstrated both simultaneous genital skin clearance outcomes and meaningful PRO responses at W24 and W52.

Disclosure: Presented at American Academy of Dermatology, San Diego, 8-12 March 2024.

References:

\1. Ryan C, Menter A, Guenther L, Blauvelt A, Bissonnette R, Meeuwis K, et al. Efficacy and safety of ixekizumab in a randomized, double-blinded, placebo-controlled phase IIIb study of patients with moderate-to-severe genital psoriasis. Br J Dermatol. 2018;179(4):844-52.

\2. Guenther L, Potts Bleakman A, Weisman J, Poulin Y, Spelman L, Burge R, et al. Ixekizumab Results in Persistent Clinical Improvement in Moderate-to-Severe Genital Psoriasis During a 52 Week, Randomized, Placebo-

Controlled, Phase 3 Clinical Trial. Acta Derm Venereol. 2020;100(1):adv00006.

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Abstract N°: 3605

Early Improvement in Nail and Scalp Psoriasis from a Prospective Observational Study of Patients with Psoriasis in Special Areas (PSoSA) Initiating Ixekizumab: Results from the First Interim Analysis

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Introduction & Objectives: Ixekizumab (IXE) has demonstrated efficacy in treating moderate-to-severe plaque psoriasis, including in special body areas such as nails and scalp. However, real-world data are limited. We present results from the first interim analysis of a real-world study of patients with Psoriasis in Special Areas (PSoSA).

Materials & Methods: PSoSA is a US-based, single-arm, prospective, multicenter, observational study enrolling adult patients with a confirmed diagnosis of moderate-to-severe plaque psoriasis and nail involvement, with or without scalp involvement, whose dermatologist has prescribed IXE, consistent with FDA on-label dosing. Improvement in nail psoriasis (modified Nail Psoriasis Severity Index [mNAPSI]) and scalp psoriasis (Psoriasis Scalp Severity Index [PSSI]) were assessed at weeks (W) 4 and 12.

Results: This first interim analysis included 92 patients, of which 79 and 58 had W4 and W12 follow-up. Patients experienced early improvement in nail and scalp psoriasis. Mean (±SE) percent change from baseline were –12.4%±5.8% (W4) and -28.3%±7.9% (W12) for mNAPSI and 57.6%±9.4% (W4) and -56.2%±19.0% (W12) for PSSI. By W12, 38.2% (n/Nx=21/55) of patients achieved partial nail clearance (mNAPSI50). As early as W4, 32.3% (n/Nx=20/62) of patients achieved total scalp clearance (PSSI100), and the proportion increased to 58.7% (n/Nx=27/46) by W12. A subpopulation of patients who previously used biologics showed numerically smaller improvement in nail and scalp psoriasis compared to the overall population at W4 and W12 (PSSI only).

Conclusion: This first interim analysis of the PSoSA study demonstrates improvement in nail and scalp psoriasis as early as W4 among patients initiating IXE in a real-world setting.

Disclosure: Presented at American Academy of Dermatology, San Diego, 8-12 March 2024.

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Abstract N°: 3626

German PPBest Registry - Epidemiological and clinical analysis of patients with pustular psoriasis. Objectives, methodology and baseline data.

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Background:

Psoriasis is a chronic inflammatory skin disease that affects about 2 to 3% of the German population. The dis-ease is divided into further clinical subtypes, including pustular psoriasis. Pustular psoriasis includes generalised pustular psoriasis (GPP) (Zumbusch type) and localised forms such as pustular palmoplantar psoriasis (PPP) and acrodermatitis continua suppurativa - Hallopeau's disease (ACH) (1). GPP can lead to a life-threatening inflammatory reaction in multiple organ systems. GPP, PPP, and ACH are rare skin conditions that can severely impact patients' quality of life, even though PPP and ACH are limited to the hands and feet. Compared with plaque psoriasis, we have limited knowledge of the disease characteristics, burden and comorbidities of the rare pustular forms of psoriasis. For example, PsoBest, the German psoriasis registry, does not include data on the care of patients with GPP, ACH and PPP (2), resulting in a lack of information.

Methods:

PPBest is a non-interventional, observational registry that prospectively enrols adult patients with a clinical diagnosis of pustular psoriasis. The registry follows patients diagnosed with GPP, PPP or ACH for 2 years, during which time they are treated according to the clinical routine specific to their site. The data presented were collected during inclusion visits at the University Medical Centre Bonn (UKB), the University Medical Centre Göttingen (UMG) and the Institute for Health Services Research in Dermatology and Nursing Professions (IVDP) of the University Medical Centre Hamburg-Eppendorf.

Results:

Between 2022 and April 2024, n = 90 participants were enrolled in PPBest. 68 subjects suffered from PPP (75.6 %), 14 (15.6 %) from GPP, 4 participants had ACH (4.4 %), 3 had psoriasis cum pustulatione (3.3 %) and one subject had other localised pustular psoriasis (1.1 %). The majority of participants were female (82.2 %, n = 74). At inclusion, the mean Dermatological Quality of Life Index (DLQI) was 7.9 (SD 8.2) for PPP, 10.1 (SD 11.2) for GPP and 10,8 (SD 8.7) for ACH. The mean Psoriasis Area and Severity Index (PASI) for PPP was 7.6 (SD 7.6), the mean PASI for GPP was 7.2 (SD 10.5) and mean PASI for ACH was 2.3 (SD 2.1). The majority of participants (76.7 %, n = 69) had received systemic therapies in the past. The most common treatment used at enrolment was apremilast for PPP (n = 11) and adalimumab for GPP (n = 3). 43.2 % (n = 38) had a relapsing course of dis-ease and 46.6 % (n = 41) had a chronic course. 29 patients (32.2 %) were smokers, 7 (8 %) drank alcohol more than once a week. Concomitant, 34.4 % (n = 31) had psoriasis vulgaris and 31.1 % (n = 28) psoriatic arthritis.

Conclusion:

In this PPBest registry cohort, the majority of patients suffered from PPP. Patients with GPP demonstrated a higher

level of distress. Only approximately one-third of the patients suffered from psoriasis vulgaris concur-rently, which may explain the selection of systemic therapies at inclusion. It was found that the majority of pa-tients had already been treated with systemic therapies, but still had elevated PASI levels at enrolment. This underlines the need to develop better treatment modalities for these rare diseases.

References:

1. Navarini AA et al. ERASPEN Network. European consensus statement on phenotypes of pustular psoriasis. J Eur Acad Dermatol Venereol. 2017 Nov;31(11):1792-1799.
2. Augustin M et al. German psoriasis registry PsoBest: objectives, methodology and baseline data. J Dtsch Dermatol Ges. 2014 Jan;12(1):48-57.

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Abstract N°: 3641

Efficacy and Safety of Netakimab Through 3 Years in Moderate-to-Severe Psoriasis: Long-Term Results from the PLANETA Phase-3 Randomized Controlled Trial

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Efficacy and Safety of Netakimab Through 3 Years in Moderate-to-Severe Psoriasis: Long-Term Results from the PLANETA Phase-3 Randomized Controlled Trial

Introduction & Objectives:

NETAKIMAB (NTK) is a high-affinity IL17-inhibitor, which successfully completed phase 1, 2 and 3 studies. NTK is effective in treating moderate-to-severe psoriasis over 52 weeks. We evaluated the long-term efficacy and safety of NTK for up to 3 years in the phase 3 BCD-085-7/PLANETA trial (NCT03390101).

Materials & Methods:

213 adult patients were randomized to receive NTK 120 mg Q2W or Q4W or placebo (PBO) through Wk 12, then all patients were switched to open-label NTK 120 mg Q4W through Wk 50. From Wk 54 only patients who achieved PASI75 at Wk 52 entered the long-term extension (LTE) period and continued NTK Q4W until Wk 154 (or Wk 166 for PBO arm).

Efficacy and health outcomes included proportion of patients achieving Psoriasis Area and Severity Index (PASI) 75/90/100, static Physician's Global Assessment (sPGA) (0-1) and (0), absolute PASI ≤ 5/ ≤ 3/ ≤ 2/ ≤ 1, Dermatology Life Quality Index (DLQI) (0-1) and absolute change in Nail Psoriasis Severity Index (NAPSI) in patients with nail involvement.

Results:

Of 198 patients who entered the LTE period, 147 completed 3 years of treatment with no significant deviation from schedule (< 7 days shifts from planned dates of injections). Among those population, 93.8% achieved PASI75 after 154 weeks of NTK treatment. PASI90 as well as sPGA (0-1) was reached by 81.3% and PASI100 as well as sPGA (0) – by 56.1% of patients (Figure 1, 2), 65.0% of patients achieved meaningful response as absolute PASI ≤ 1 (Figure 3), 79.7% of patients achieved DLQI (0-1) (Figure 4). The improvement in nail psoriasis from Wk 52 maintained throughout the study (Figure 5). The sustained clinical response for all efficacy and health measures was demonstrated from Wk 52.

Safey analysis was performed on all randomized patients (n=213). During 3 years of NTK treatment adverse events (AEs) were reported in 64.3% of patients. AEs grade 3-4 (CTCAE 4.03) - in 18.3%.

The most common AEs were neutropenia, blood cholesterol increased, hyperbilirubinemia, hyperglycemia, upper respiratory tract infection, alanine aminotransferase increased, lymphopenia, aspartate aminotransferase increased, and leukopenia. Despite the COVID-19 pandemic, the proportion of patients with respiratory tract infections in the study was low (8.9%). Pneumonia was reported in 1.9%, COVID-19 associated pneumonia - in 0.9% and coronavirus infection - also in 0.9% of patients. There were no cases of severe COVID-19 infection. The spectrum and frequency of reported treatment-related AEs were consistent with safety data reported in the previous NTK and other anti-IL17 trials. The 5 cases of treatment-related AEs were serious. No deaths were reported.

Conclusion:

The results demonstrate NTK 120 mg maintains long-term efficacy and favorable safety profile in patients with moderate-to-severe plaque psoriasis through 3 years of treatment.

Figure 1. PASI75/PASI90/PASI100 response rate during the long-term extension period (n=147)

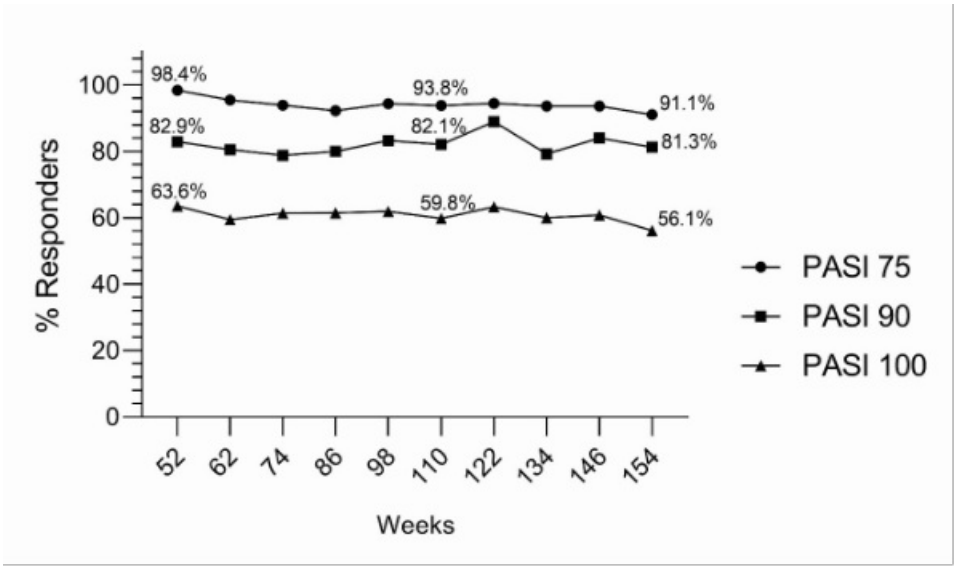


Figure 2. sPGA(0-1) and sPGA(0) response rate during the long-term extension period (n=147)

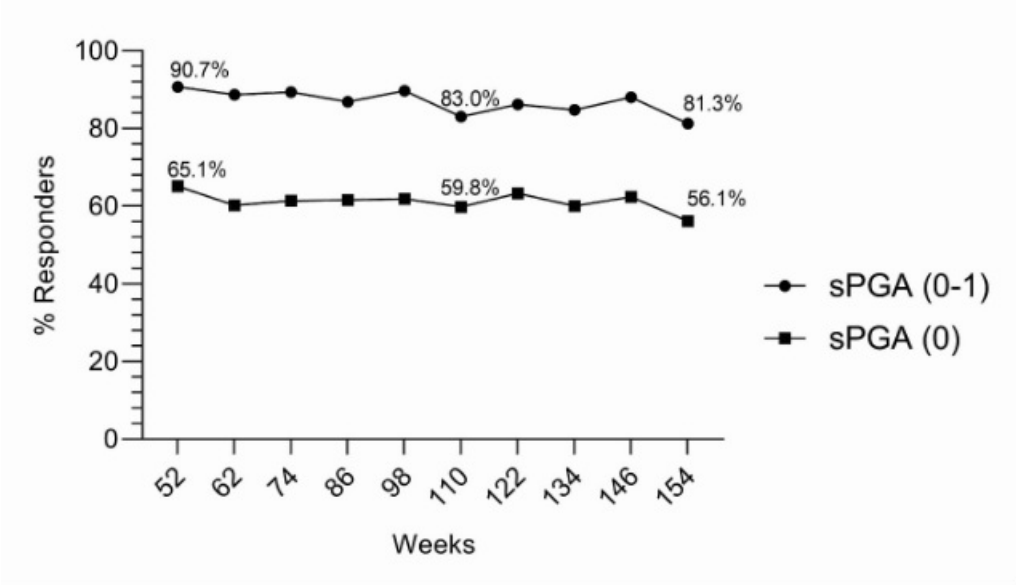


Figure 3. PASI ≤ 5/ ≤ 3/ ≤ 2/ ≤ 1 response rate during the long-term extension period (n=147)

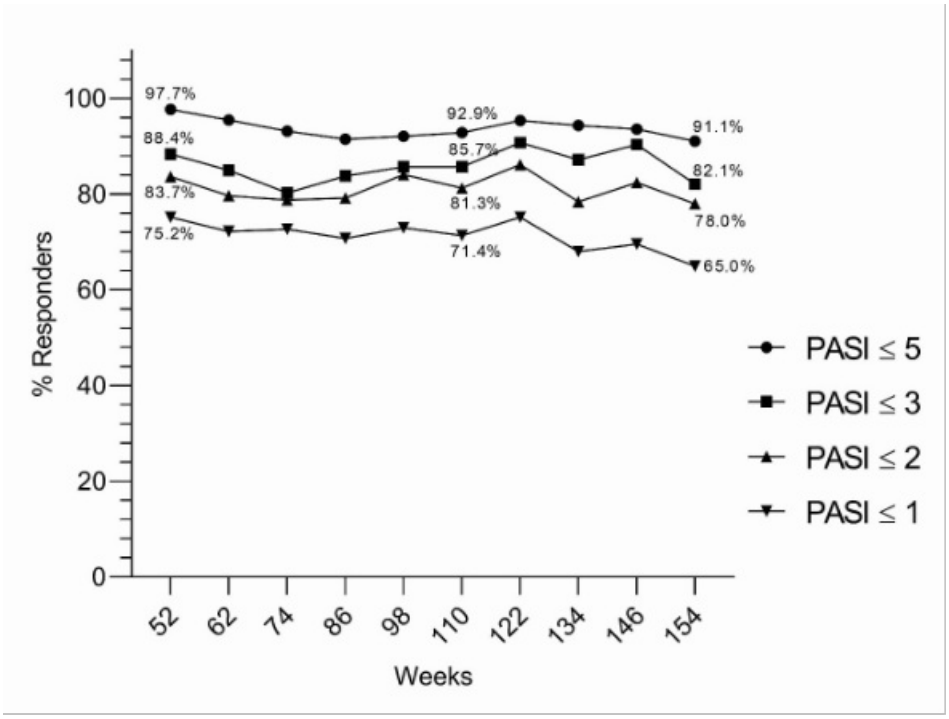


Figure 4. DLQI (0-1) response rate during the long-term extension period (n=147)

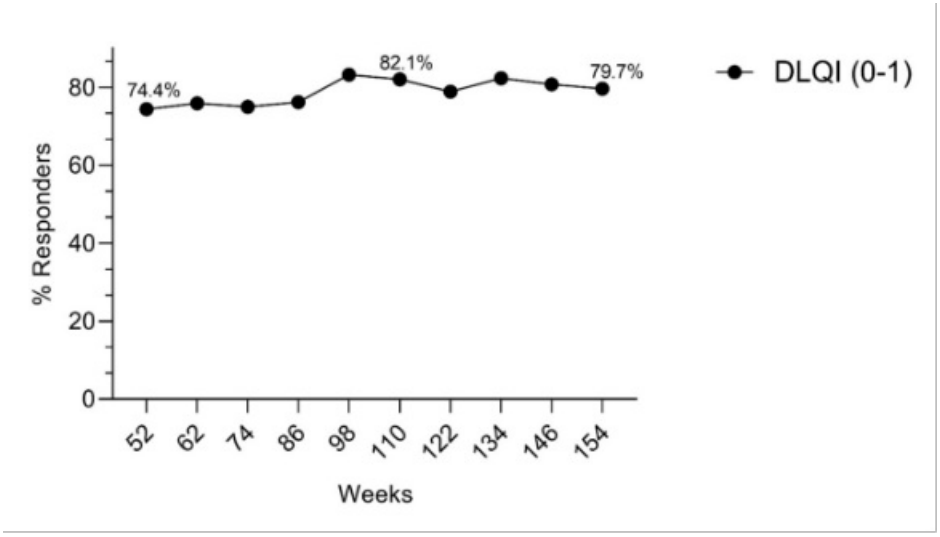
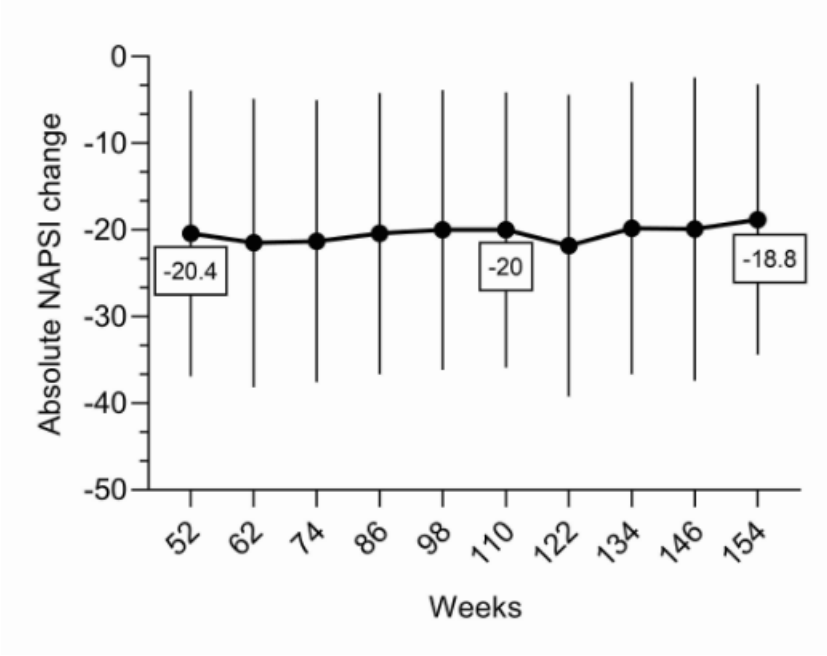


Figure 5. Absolute NAPSI change during the long-term extension period (n=147). Figure shows the mean values and standard deviation.


Absolute NAPSI change
0
-10
-20
-30
-40
-50
-20.4
-20
-18.8
52
62
74
86
98
110
122
134
146
154
Weeks

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Abstract N°: 3648

Self-Reported Triggers in Psoriatic Disease - a multi-national survey study

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Introduction & Objectives:

Psoriasis, a chronic disease, exhibits notable variability in disease activity over time among affected individuals. Moreover, patients often attribute specific triggers with these fluctuations. Mapping self-reported triggers has the potential to increase our understanding of disease pathophysiology, disease self-perception and disease dynamics. To study disease self-perception, we conducted a multi-national digital survey study, PSODEEP1, (ClinicalTrials.gov NCT05589298), in four countries (Chile, Denmark, Sweden and the Netherlands) between October 2022 and February 2024.

Materials & Methods:

Two among the twenty-eight items in PSODEEP1 were analysed to map self-reported triggers in psoriatic disease. These were "*Have you ever associated flare-ups/periods of increased disease activity with triggering factors (e.g. weight gain, stress, depressive mood, infections, medical drugs, alcohol, tobacco, sunburn or anything else)?"* and *"Please list factors that you personally associate with flare-ups/periods of increased disease activity."* The answers to the latter question were translated into English and organized into subgroups. The subgroups were in turn organized into seven overlying categories. Descriptive statistical analysis of data was performed.

Results:

Out of the total 3064 responses in PSODEEP1, 2716 were eligible for analysis after data cleaning. The mean age of the participants was 53.8 years with a slight female predominance (66.5 %). Sixty percent were diagnosed with psoriasis skin involvement (Pso) and psoriatic arthritis (PsA), 31 % with Pso only and 9 % with PsA only. Responses were in 63.1 % from Sweden, 15.5 % from the Netherlands, 11.2 % from Denmark and 10.2 % from Chile. The majority of respondents (N=1974, 72,7 %) reported one or more triggers that increased their disease activity (figure 1). Reported triggers were categorized into 7 categories with 25 subgroups (table 1). 'Psychological factors' was the largest category (N=1557, 57.3 %). The most frequently reported individual subgroup reported was 'stress', which was mentioned by 1502 patients (55.3 %), followed by infection mentioned by 481 patients (17.7 %) and alcohol mentioned by 294 patients (10.8 %).

Conclusion:

In this large multi-national survey study, the majority of respondents reported experiencing at least one trigger impacting their psoriatic disease activity. Psychological factors including stress emerged as the most triggers followed by factors related to 'health, activity and lifestyle'. Previous studies on psychological stress triggering psoriasis exacerbations have shown similar frequencies. Although self-reported data illustrate the self-perception of a patient's disease, further studies targeted at the biological mechanisms are required to validate whether the self-reported triggers are casually linked to a change in psoriasis disease activity. Possible limitations are variability in respondents' comprehension and interpretation of the questions. Addressing triggers in patients with psoriasis has the potential to lead to disease modification stressing the importance of further research on the topic.

Figure 1: Number of self-reported psoriasis triggers

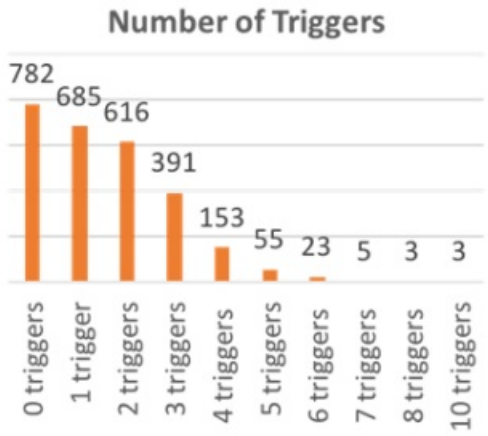

Table 1: Categories of self-reported triggers for psoriasis

Categories	N (% of all respondents)	Subgroups	N (% of all respondents)
1. Psychological factors	1557 (57.3)	Stress Life trauma/Sorrow Depression Anxiety Other psychiatric triggers	- 1502 (55.3) - 66 (2.4) - 218 (8.0) -109 (4.0) - 67 (2.5)
2. Medical conditions, medical procedures, hormones and drugs	665 (24.5)	Infection Vaccine Drugs Medical conditions/Other disease unspecified Medical procedures Hormonal changes Symptoms unspecified/malaise/inflammation	- 481 (17.7) - 16 (0.6) - 77 (2.8) - 67 (2.5) - 18 (0.7) - 69 (2.5) - 39 (1.4)
3. Health, activity and lifestyle	608 (22.4)	Weight gain Diet Lack of exercise Physical exertion Alcohol Tobacco	- 149 (5.5) - 248 (9.1) - 44 (1.6) - 62 (2.3) - 294 (10.8) - 49 (1.8)
4. Environmental factors	304 (11.2)	Weather Season	- 193 (7.1) - 111 (4.1)
5. Sleep disorder	118 (4.3)	Sleep disorder	- 118 (4.3)
6. External factors	97 (3.6)	Koebner Skin contact	- 73 (2.7) - 29 (1.1)
7. Uncategorized or not answered	93 (3.4)	Uncategorized/Other Not answered	- 52 (1.9) - 41 (1.5)

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Abstract N°: 3649

Long-Term Safety of Ixekizumab Treatment in Adult Patients with Psoriasis, Psoriatic Arthritis, or Axial Spondyloarthritis: A Post-hoc Analysis of End-Of-Study Program Data Relating to Major Adverse Cardiovascular Events.

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Introduction & Objectives: The objective of this study is to report long-term, end-of-study-program safety outcomes, relating to major adverse cardiovascular events (MACE), in adult patients with psoriasis (PsO), psoriatic arthritis (PsA), and axial spondyloarthritis (AxSpA) who received ≥1 dose of Ixekizumab (IXE) over 5 years (PsO) or 3 years (PsA, axSpA).

Materials & Methods: The** incidence of MACE was assessed across 25 randomized clinical trials (17 PsO, 4 PsA, 4 axSpA) examining long-term safety of IXE. MACE rates were analyzed for pooled studies by years of therapy, through March 2022. Exposure-adjusted incidence rates (IRs) per 100 patient-years, at successive year intervals are reported.

Results: The incidence of MACE was low among patients with PsO (IR=0.5), PsA (IR=0.5), and axSpA (IR=0.3). In the PsO cohort, of the 103 reported MACE cases, 20 were fatal (19.4%), 57 recovered (55.3%), and 17 recovered with sequelae (16.5%). Of the 12 reported MACE cases in the PsA cohort, 2 were fatal (16.7%), 9 recovered (75.0%), and 1 recovered with sequelae (8.3%). All 6 MACE cases reported in the axSpA cohort recovered (100.0%).

IRs were low and stable over the treatment periods. The most common types of MACE reported in the PsO, PsA and axSpA cohorts were non-fatal myocardial infarction (PsO: IR= 0.3; PsA: IR=0.3; axSpA: IR=0.3), nonfatal stroke (PsO: IR=0.1; PsA: IR=0.2) and vascular death (PsO: IR=0.1; PsA: IR=0.1). All MACE cases were confirmed by adjudication.

Conclusion: The incidence of MACE was low and stable over the IXE treatment periods examined.

Disclosure: Presented at American Academy of Dermatology, San Diego, 8-12 March 2024.

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Abstract N°: 3666

Comparison of psoriasis severity in patients treated with the Treat-to-Target strategy and standard care

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Introduction & Objectives: To evaluate psoriatic skin lesions in a comparative aspect of a groups of psoriatic arthritis (PsA) patients (pts) treated with a treat-to-target (T2T) strategy and standard care, with disease duration of more than 5 years.

Materials & Methods: A total of 103 pts were included in the study. The main group (MG) included 53 pts (28 female, 25 male) diagnosed with PsA treated in the early stage of PsA (up to 2 years) with T2T strategy for 24 months (mos). In the MG, the mean age at the time of the study was 45.7±12 years, Me of PsA duration 90 [72; 99] mos. After the end of follow-up, patients were treated "on demand" depending on disease activity according to clinical guidelines. The control group (CG) consisted of 50 pts (26 females, 24 males), mean age 43,5±12,4 years, Me duration of PsA 72 [65; 102] mos. Patients from the CG were treated until inclusion in the study according to standard care (real clinical practice, without using the T2T strategy). During the current follow-up, all pts underwent standard rheumatologic clinical examination, including DAPSA activity index for PsA, assessment of skin psoriasis by BSA (%) and absence of nail psoriasis. The number of pts (in %) who achieved minimal disease activity (MDA) was determined. M±SD, Me [Q25; Q75], Mann-Whitney test were performed. The corresponding odd ratios (OR) were calculated with their confidence intervals (CI 95%). All $p<0.05$, were considered to indicate statistical significance.

Results: After more than 5 years of follow-up the probability of reaching MDA is higher in the MG (T2T) (odd ratio 11, 95% CI 3.49 – 35.14). In the MG achievement of MDA was detected in 49% (26 pts) and MDA in CG was achieved in 4 pts (8%). The odds of achieving low severity skin psoriasis (BSA less 3%) and absence of nail lesions with psoriasis were similar in both groups: BSA less 3% OR 1.41 (95% CI 0.62-3.16), absence of nail psoriasis OR 1.55 (95% CI 0.66-3.61). Statistically significant differences were found when analyzing PsA activity, Me DAPSA MG - 10.8 [2.7;21] and Me DAPSA CG - 29.2 [13.2;38], p=0.00. No differences were found when comparing the skin psoriasis in two groups: Me BSA MG 1 [0,2;4] and Me BSA CG 1 [0,5;7], p=0,43.

Conclusion: The T2T strategy has been shown to be effective when compared with standard care in pts with PsA in the long term (follow-up of more than 5 years) when assessed for DAPSA and MDA activity. However, in long-term follow-up, treatment with the T2T strategy and standard care had the same effect on psoriasis lesions of the skin and nails.

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Abstract N°: 3672

Absolute PASI reductions in a phase 2b trial of the selective oral TYK2 inhibitor, zasocitinib (TAK-279), in moderate-to-severe plaque psoriasis

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Introduction & Objectives:

TAK-279 (previously NDI-034858) is a highly selective, allosteric, oral inhibitor of tyrosine kinase 2 (TYK2), computationally designed to bind to the Janus homology 2 pseudokinase domain of TYK2.1 In a recent phase 2b trial in patients with moderate-to-severe psoriasis (NCT04999839), TAK-279 was well tolerated and demonstrated safety and efficacy versus placebo at doses ≥5mg once daily, with the 15mg and 30mg once daily doses achieving the highest levels of skin clearance at Week 12, as shown by PASI (Psoriasis Area and Severity Index) 75 (primary endpoint). Secondary efficacy endpoints (PASI 90 and PASI 100) were in accordance with the primary efficacy endpoint, with 33.0% of patients achieving PASI 100 at the highest TAK-279 dose (30mg).2 This analysis further evaluated the efficacy of the 15mg and 30mg doses of TAK-279 using a range of PASI measures.

Materials & Methods:

In this randomized, multicentre, double-blind, placebo-controlled trial, patients were randomized 1:1:1:1:1 to receive oral TAK-279 (2mg, 5mg, 15mg or 30mg) or placebo, once daily for 12 weeks. Mean PASI, mean change and mean percent change in PASI from baseline, and proportions of patients achieving PASI thresholds (≤2 and ≤1) were determined at Week 12. All analyses were pre-specified except for PASI thresholds (*post hoc*).

Results:

At baseline, mean (standard deviation [SD]) PASI scores were similar across TAK-279 15mg (n=53; 15.5 [4.5]), TAK-279 30mg (n=52; 17.6 [6.2]) and placebo (n=52; 18.3 [8.1]) groups. Mean PASI scores decreased as early as Week 2 and continued to decline throughout follow-up in the TAK-279 treatment groups, while scores decreased slightly in the placebo group. At Week 12, mean (SD) PASI scores were 2.5 (3.0) (least-squares [LS] mean change: −13.7; LS mean percentage change: −82.5%) in the 15mg group, 3.5 (5.0) (LS mean change: −14.1; LS mean percentage change: −77.8%) in the 30mg group and 13.4 (8.2) (LS mean change: −5.0; LS mean percentage change: −27.7%) in the placebo group (p<0.001 for both doses versus placebo) (**Figure 1**). At Week 12, higher proportions of patients treated with TAK-279 15mg and 30mg achieved a PASI threshold of ≤2 (56.6% and 55.8%, respectively) compared with no patients in the placebo group (**Figure 2**). A similar pattern was observed for a PASI threshold of ≤1 (32.1% and 32.7% for 15mg and 30mg, respectively, versus 0% for placebo) (**Figure 2**).

Conclusion:

TAK-279 was more effective at reducing absolute PASI scores and achieving a PASI threshold of ≤2 or ≤1 at the 15mg and 30mg doses compared with placebo in patients with moderate-to-severe plaque psoriasis over 12

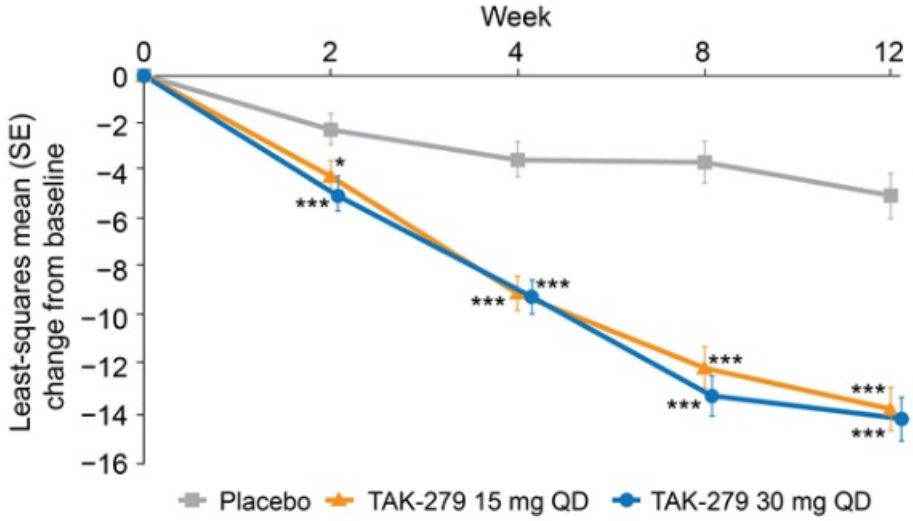
weeks. Further investigations of efficacy and safety of TAK-279 in phase 3 studies in psoriasis are ongoing (NCT0608804; NCT06108544).

References:

\1. Leit S et al. *J Med Chem* 2023;66:10473–96.

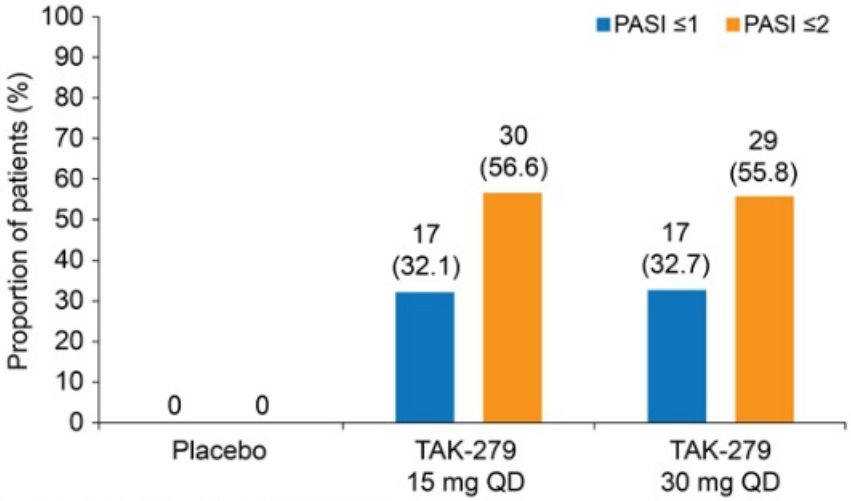
\2. Armstrong A *et al.* Oral presentation presented at the Annual Meeting of the American Academy of Dermatology, March 17–21, 2023, New Orleans, LA, USA.

Figure 1. Least-squares mean change from baseline in PASI over 12 weeks (mITT analysis set).



Least-squares means were derived from a mixed model for repeated measurements on the change from baseline in PASI.
The model includes treatment, visit (Weeks 2, 4, 8 and 12), treatment-by-visit interaction and previous treatment with biologics as fixed effects, and baseline score as a covariate. Baseline was defined as the last non-missing assessment before or on the day of first study treatment dosing.
*p<0.05, **p<0.01, ***p≤0.001, relative to placebo.
mITT, modified intent-to-treat; PASI, Psoriasis Area and Severity Index; QD, once daily; SE, standard error.

Figure 2. Proportions of patients achieving PASI thresholds ≤1 and ≤2 at Week 12 (mITT analysis set).



Data above bars represent n (%).
mITT, modified intent-to-treat; PASI, Psoriasis Area and Severity Index; QD, once daily.

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Abstract N°: 3694

Effect of skin clearance in patients with moderate-to-severe plaque psoriasis treated with vunakizumab on patient-reported outcomes: a post-hoc analysis of a randomised, phase 3 trial

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Introduction & Objectives: Vunakizumab is a novel interleukin 17A monoclonal antibody for moderate-to-severe plaque psoriasis. Here, we assessed the effect of skin clearance on patient-reported outcomes (PRO) in patients with moderate-to-severe plaque psoriasis who received vunakizumab.

Materials & Methods: Data for this post-hoc analysis were derived from a randomised, double-blind, placebo-controlled, multicentre, phase 3 trial (NCT04839016), which assessed the efficacy and safety of vunakizumab for moderate-to-severe plaque psoriasis. Eligible adult patients were randomized 2:1 to receive either vunakizumab 240 mg or placebo on weeks 0, 2, 4, and 8. At week 12, all patients received vunakizumab 240mg every 4 weeks until week 52. Patients who achieved different levels of skin clearance (Psoriasis Area and Severity Index [PASI] 100 or PASI 75-99) during the 12 weeks of treatment with vunakizumab were grouped to assess the change from baseline to week 52 in the Pruritus Numerical Rating Scale (NRS), the Dermatology Life Quality Index (DLQI) and the 36-Item Short Form Health Survey (SF-36). For longitudinal data (NRS total score, DLQI total score and SF-36 health utility), mixed-effect models for repeated measures were used to calculate their changes from baseline. The model was adjusted with PRO total score as the dependent variable and PASI status grouping, visit duration, baseline values, interaction between PASI status grouping and visit, and interaction between baseline and visit as covariates. Least square means and confidence intervals for the changes were calculated.

Results: During the 12 weeks of treatment with vunakizumab, 178 patients achieved PASI 100 and 255 patients achieved PASI 75-99. There was an improvement in PROs in both groups during the 52 weeks of treatment. Furthermore, patients who achieved PASI 100 during the 12-week treatment period showed a more pronounced downward trend in pruritus NRS scores and DLQI scores from baseline than those who achieved PASI 75-99 (Figures 1 and 2). Similarly, a more pronounced upward trend in the change from baseline in SF-36 health utility was also observed in patients who achieved PASI 100 during the 12-week treatment period (Figure 3).

Conclusion: Patients with moderate-to-severe plaque psoriasis who received vunakizumab and achieved PASI 75 or above benefited. For patients who achieved complete skin clearance (i.e. PASI 100), the reduction in pruritus, improvement in quality of life, and enhancement in self-assessed psychological and physiological health conditions were much better than for those with partial clearance (i.e. PASI 75-99), indicating that targeting PASI 100 as a treatment goal for moderate to severe plaque psoriasis could bring about more benefits.

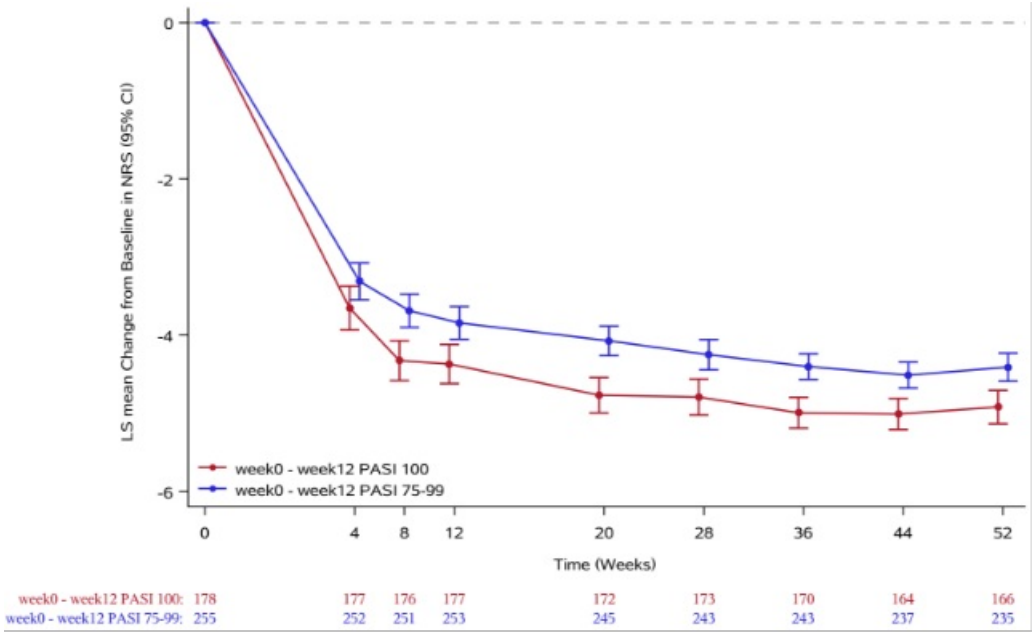

Figure 1. Changes from baseline in Pruritus Numerical Rating Scale (NRS) scores by each visit over a 52-week period

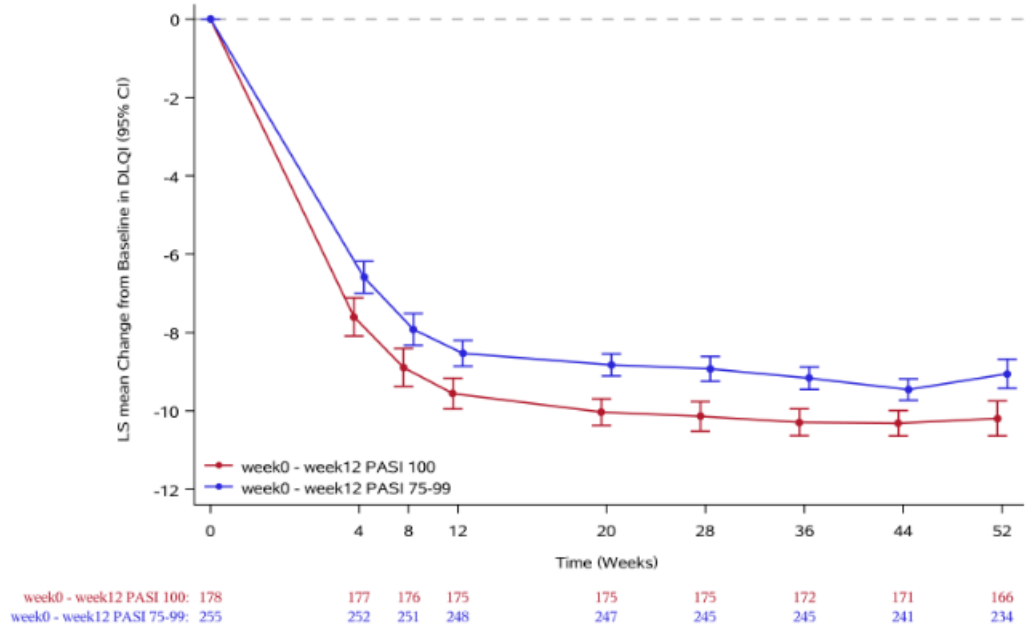

Figure 2. Changes from baseline in total scores on the Dermatology Life Quality Index (DLQI) by each visit over a 52-week period

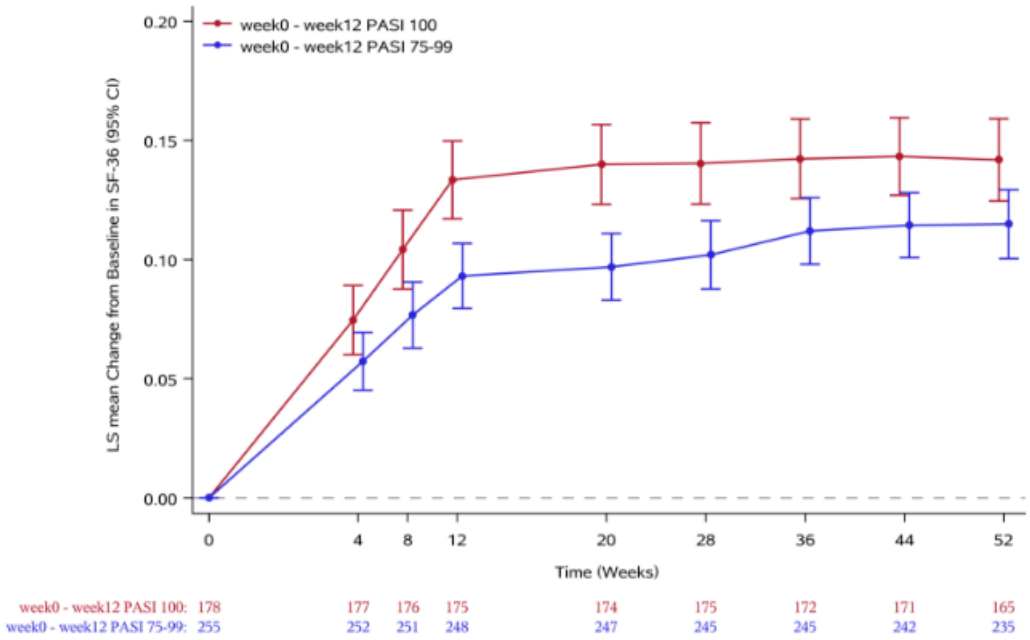

Figure 3. Changes from baseline in health utility on the 36-Item Short Form Health Survey (SF-36) by each visit over a 52-week period

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Abstract N°: 3728

Patients' experiences of reducing regular follow-ups: a qualitative study of patients with psoriasis receiving biological treatment

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Introduction & Objectives:

In Denmark, patients with psoriasis receiving biological treatment previously had regular follow-ups, typically every three months. This may be a challenge for patients, living far away from the hospital, especially when their disease is well controlled, and when they do not feel the need for visits. During the consultations focus were on patients' vital measures, skin status, topical treatment, dispensing of medicine and comorbidities. Thus, consultations had a biomedical focus and routine practices seemed prominent. Furthermore, both healthcare professionals and patients are frustrated by these quarterly mandatory check-ups and experienced them as time consuming and rigidly structured. Therefore, we changed current clinical practice based on patients' individual needs. Follow-up consultations were reduced to twice a year; one face-to face consultation at a dermatologist and one video consultations at a nurse.

Thus, the aim of this study was to investigate the patients' experiences of these changes.

Materials & Methods:

This was a qualitative study and data were collected through interviews (n=15) with patients. Interview transcripts were analysed using thematic analysis.

Results:

Patients expressed satisfaction with the overall change in clinical practice and expressed relief of not having to attend a face-to-face consultation every three months. They emphasized the time saved and the importance of not having to take time off from school or work. Thus, patients experienced a less disrupted daily life. In addition, patients experienced the nurse-led video consultations as convenient because it enabled them to attend a consultation while they were working and/or on a short break. Other patients could participate from home and perceived it as a relief not having to travel to the hospital, which was considered as exhausting. Furthermore, the contend of what to discuss during the video consultations was based on patients' needs.

Conclusion:

Reducing the number of follow-up consultations had a positive impact on patients everyday life. Inviting patients to address was is important to them to discuss facilitated a more patient-centred approach.

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Abstract N°: 3745

Zasocitinib (TAK-279), a selective oral TYK2 inhibitor, reduces BSA involvement in a phase 2b trial in moderate-to-severe plaque psoriasis

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Introduction & Objectives:

TAK-279 (previously NDI-034858) is a highly selective, allosteric, oral inhibitor of tyrosine kinase 2 (TYK2). TYK2 mediates signalling from cytokines involved in the pathogenesis of psoriasis and other immune-mediated inflammatory diseases.1,2 In a recent phase 2b trial in patients with moderate-to-severe psoriasis (NCT04999839), TAK-279 was well tolerated and demonstrated safety and efficacy with greater skin clearance at doses ≥5mg compared with placebo, with the two highest doses (15mg and 30mg) showing the strongest responses at Week 12.3 This analysis further evaluated the efficacy of the 15mg and 30mg doses of TAK-279 using body surface area (BSA) involvement.

Materials & Methods:

In this randomized, multicentre, double-blind, placebo-controlled trial, patients were randomized 1:1:1:1:1 to receive oral TAK-279 (2mg, 5mg, 15mg or 30mg) or placebo, once daily for 12 weeks. BSA outcome measures assessed at Week 12 were mean change in BSA from baseline, mean percentage change in BSA from baseline and the proportion of patients achieving a BSA threshold of ≤1% by visit. Mean change in BSA from baseline was pre-specified.

Results:

Baseline mean (standard deviation [SD]) absolute percentage BSA was generally consistent across TAK-279 15mg (n=53; 18.3 [10.3]), TAK-279 30mg (n=52; 22.2 [14.3]) and placebo (n=52; 21.3 [13.6]) groups. Mean percentage BSA decreased as early as Week 2 and continued to decrease throughout follow-up in the TAK-279 groups, whereas scores slightly decreased in the placebo group. At Week 12, mean (SD) percentage BSA was 4.4 (5.3) (least-squares [LS] mean change: −14.7; LS mean percentage change: −72.9%) in the 15mg group, 6.5 (12.5) (LS mean change: −15.7; LS mean percentage change: −73.1%) in the 30mg group and 18.2 (13.6) (LS mean change: −4.0; LS mean percentage change: −19.3%) in the placebo group (p<0.001 for both doses versus placebo) (**Figure 1**). From Week 8 onwards, a higher proportion of patients achieved a BSA threshold of ≤1% in the TAK-279 15mg and 30mg groups compared with the placebo group (35.8% and 44.2% versus 0% at Week 12, respectively) (**Figure 2**).

Conclusion:

Patients with moderate-to-severe plaque psoriasis who received the two highest doses of TAK-279 (15mg and 30mg) achieved greater reductions in BSA than patients who received placebo over 12 weeks. Further investigation of the efficacy and safety of TAK-279 in phase 3 studies in psoriasis is ongoing (NCT0608804;

NCT06108544).

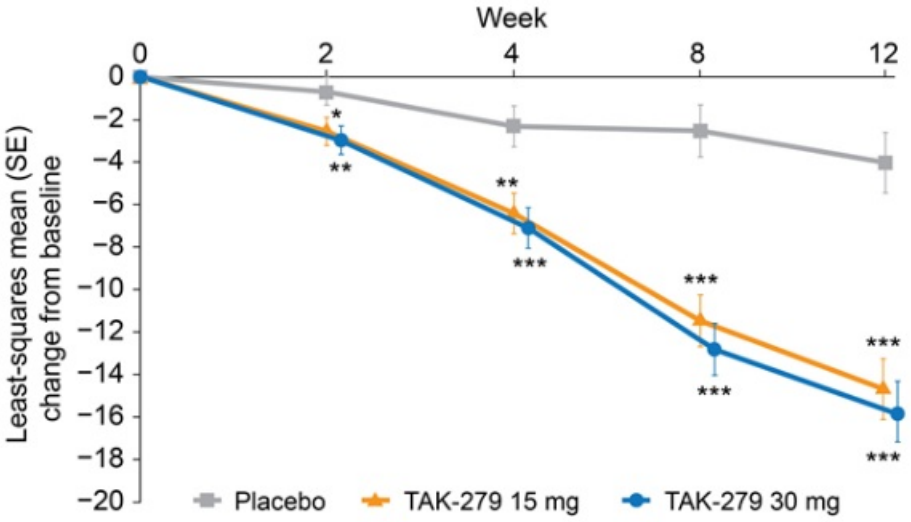
References:

\1. Leit S et al. *J Med Chem* 2023;66:10473–96.

\2. Rusiñol L, Puig L. *Int J Mol Sci* 2023;24:3391.

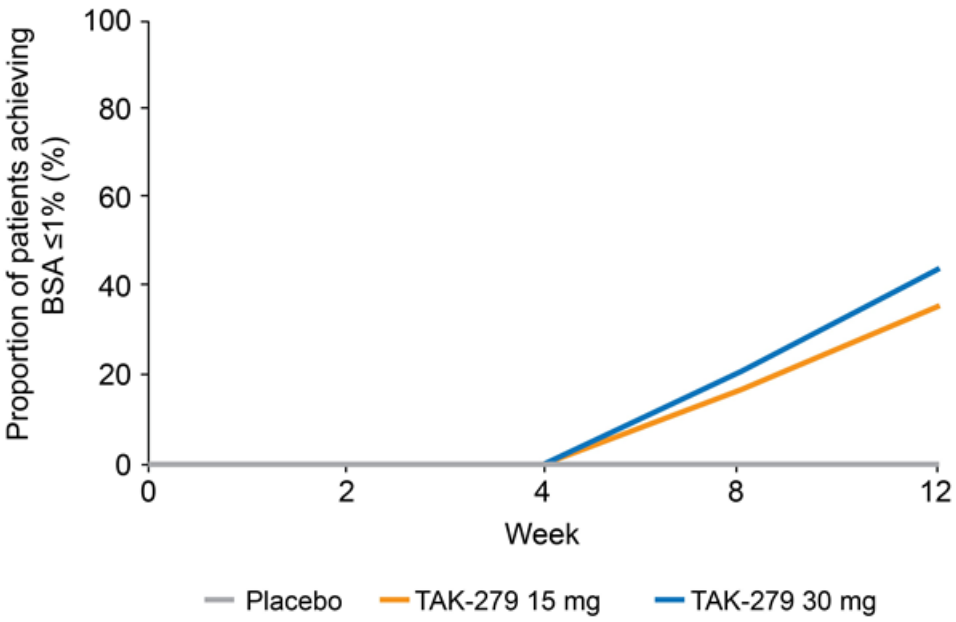
\3. Armstrong A *et al.* Oral presentation presented at the Annual Meeting of the American Academy of Dermatology, March 17–21, 2023, New Orleans, LA, USA.

Figure 1. Least-squares mean change from baseline in BSA (%) over 12 weeks (mITT analysis set).



Least-squares means were derived from a mixed model for repeated measurements on the change from baseline in BSA.
The model includes treatment, visit (Weeks 2, 4, 8 and 12), treatment-by-visit interaction and previous treatment with biologics as fixed effects, and baseline score as a covariate. Baseline was defined as the last non-missing assessment before or on the day of first study treatment dosing.
*p<0.05, **p<0.01, ***p<0.001, relative to placebo.
BSA, body surface area; mITT, modified intent-to-treat;
SE, standard error.

Figure 2. Proportion of patients achieving BSA ≤1% by visit (mITT analysis set).



BSA, body surface area; mITT, modified intent-to-treat.

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Abstract N°: 3758

Bimekizumab as-needed dosing in patients with psoriasis

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Introduction & Objectives: Despite significant advances in psoriasis treatment, there are still gaps that need to be addressed. In particular, as-needed dosing studies of psoriasis biologic therapies are limited, with some reported for older biologics, such as tumor necrosis factor (TNF)-alpha, interleukin (IL)-17A, and IL-23 inhibitors (1). Bimekizumab, the newest approved biologic for psoriasis, is a novel IL-17A/F inhibitor, with very high PASI90 or PASI100 responses and a fast onset of action (2). Here, real-world clinical data on as-needed dosing for bimekizumab are reported.

Materials & Methods: In this retrospective case series, medical records from 19 patients with moderate-to-severe psoriasis treated with bimekizumab from May 2023 to March 2024 at the Psoriasis Unit of the Grupo Jaen (Madrid, Spain) were evaluated. Patients were managed with an off-label, as-needed dosing strategy, with all patients initially receiving two 320 mg doses at Weeks 0 and 4; subsequent 320 mg doses were administered only if a given patient dropped below a PASI90 response. The main outcome was the percentage of patients that achieved and maintained optimal skin control over time, defined as a PASI90.

Results: The study included 19 psoriasis patients. Mean age was 46.4±14.4 years, and the majority were male (57.9%). Mean disease duration before treatment was 22.4±15.5 years, mean PASI at baseline was 7.84±7.97, and 73.7% had previously received oral systemic or biologic treatment. Regarding cardiovascular risk factors, 52.6% had dyslipidemia, 15.8% had hypertension, and 5.26% were active smokers. Figure 1 shows the number of doses each patient received (green bars) over 40 weeks and the number of doses they would have received if they had received standard dosing (red+green bars). All 19 patients achieved PASI90 after the first two doses, and all maintained treatment responses with as-needed dosing. 16 of 19 patients received ≤50% of bimekizumab doses over the study period without losing PASI90. No adverse events were observed, including no cases of oral candidiasis.

Conclusion: In this retrospective real-world study, as-needed dosing of bimekizumab was effective in achieving optimal skin control (PASI90) over time in patients with psoriasis, with no cases of oral candidiasis. This dosing strategy could help limit long-term healthcare costs, especially in resource-poor areas of the world, as well as limit potential adverse events. Larger and longer prospective studies comparing efficacy and safety of this regimen with standard on-label dosing are necessary to corroborate these findings.

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Abstract N°: 3780

International survey to assess options for subcutaneous injection of methotrexate (MTX) with special emphasis on a new button-free MTX autoinjector

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Introduction & Objectives: Subcutaneous injection of methotrexate (MTX) is an established option to treat patients with moderate to severe psoriasis. In addition to prefilled syringes (PFS), various pens have been developed including a new MTX pen with *button-free autoinjection technology* which succeeds a button-activated pen. The needs of users (patients and prescribers) and the relevance of features of the new MTX autoinjector were assessed in an international online survey.

Materials & Methods: This is a subgroup analysis to evaluate the responses of dermatologists and people with moderate to severe psoriasis from UK, France and Germany from a larger cohort of participants including rheumatologists, nursing staff and adults with rheumatoid arthritis (RA). All participants were invited to complete a structured online questionnaire. Satisfaction with MTX pens was assessed using a scale ranging from 1 (not at all satisfied) to 10 (very satisfied). Relevance of features of the new button-free MTX autoinjector was evaluated by distribution of a total of 100 chips per participant for all features (the more important, the more chips to be awarded for a feature).

Results: From a total of 570 respondents, 111 dermatologists and 88 people with psoriasis completed the questionnaire. Reasons advocating for the use of a MTX pen (as opposed to PFS) belonged to the categories *dosing/administration* and *ease of use* (selected by 89% and 75% of dermatologists respectively). Mean (± s.d.) satisfaction was 8.0/10 (1.4) in dermatologists, and 7.7/10 (1.9) in people with psoriasis. First impressions of the new MTX autoinjector were positive in 86% of dermatologists and 74% of people with psoriasis. The feature of the new MTX autoinjector rated as most important was the *2-step autoinjector mechanism*, scored with a mean of 15.5/100 chips by dermatologists and 17.3/100 by people with psoriasis. Importance (≥10/100 chips) was also given to *small injection volume*, the *ability to adjust the dose* and *short injection time (<5 seconds)* in the dermatologists and/or people with psoriasis subgroups. As a rule, for each feature similar numbers of chips were awarded by prescribers (dermatologists and rheumatologists) and patients (people with psoriasis and RA) (Table).

Conclusion: From the perspective of dermatologists, *dosing/administration* and *ease of use* are the key device features favouring MTX pens over PFS. Currently available MTX pens are satisfactory but there is potential for improvement. Within the subgroup analysis, dermatologists and people with psoriasis rated the *2-step mechanism for autoinjection* as the most advantageous feature of the new button-free MTX autoinjector. In addition, the features of *small injection volume*, *pens available in 10 different doses* and the *short injection time (<5 seconds)* received the highest ratings.

Table: Importance of features of the new button-free MTX autoinjector evaluated by distribution of a total of 100 chips for all features per participant[1]

Feature	Derma-tologists (n=111)	Rheuma-tologists (n=189)	People with psoriasis (n=88)	People with RA (n=92)
2-step autoinjector (1. Remove cap; 2. Place on skin and push firmly – injection starts)[2]	15.5 (15.6)	13.3 (11.4)	17.3 (16.4)	15.5 (18.4)
Small injection volume[3]	10.9 (13.8)	12.2 (11.0)	10.5 (13.3)	8.9 (9.9)
Pen is available in 10 different doses (7.5 mg – 30 mg)[4]	12.6 (9.9)	13.5 (12.3)	7.7 (9.3)	8.3 (9.2)
Injection time < 5 seconds	8.4 (7.5)	8.6 (7.5)	11.7 (10.5)	10.6 (11.5)
Audible signals at the beginning and end of injection	9.3 (7.6)	7.5 (6.4)	7.1 (7.0)	7.9 (10.7)
Hidden needle	9.1 (10.9)	8.8 (10.4)	7.3 (7.3)	8.9 (11.7)
Small viewing window for the medication	6.8 (5.2)	6.3 (5.6)	8.5 (7.9)	6.4 (6.5)
Visual control of completed injection via marker in the viewing window	7.3 (6.5)	7.1 (7.8)	6.0 (5.8)	5.8 (6.9)
Prominent colour code for different dosages	5.8 (6.2)	5.0 (5.5)	5.1 (7.8)	5.0 (5.8)
Large label containing information on substance and dosage	4.7 (5.1)	4.5 (5.1)	5.9 (7.9)	4.4 (5.2)
Announced for the future: Pen components produced in a CO_2-neutral manner[5]	4.2 (6.6)	5.7 (6.5)	4.3 (5.5)	5.5 (6.1)
Angular pen shape	3.1 (5.0)	4.4 (6.6)	4.9 (6.6)	5.2 (6.0)
Small package[6]	2.2 (5.9)	3.1 (5.0)	3.7 (5.0)	7.5 (15.6)

[1] Mean (± s.d.) number of chips; [2] no skin fold needed; [3] Injection volume ranges from 0.15 ml to 0.60 ml; [4] Availability of all dosages depends on the country; [5] This feature is currently not available; [6] Refers to single package, only

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Abstract N°: 3788

Evaluation of changes in laboratory parameters from a phase 2b trial of zasocitinib (TAK-279), an oral, selective TYK2 inhibitor, in patients with moderate-to-severe psoriasis

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Introduction & Objectives: Tyrosine kinase 2 (TYK2) mediates signalling downstream of cytokines involved in the pathogenesis of several immune-mediated inflammatory diseases, including psoriasis. TAK-279 is a highly selective, oral, allosteric TYK2 inhibitor. In a recent phase 2b trial, more patients with moderate-to-severe psoriasis treated with TAK-279 15 and 30mg once daily achieved 75% improvement in the psoriasis area and severity index 75 (PASI 75) at Week 12 (primary endpoint) than those receiving placebo (PBO; 15mg, 68%; 30mg, 67%; PBO, 6%; $p < 0.001$), with about one-third of patients in the 30mg group achieving PASI 100.1 Here we report an assessment of laboratory parameters from this study.

Materials & Methods: In this phase 2b, randomized, multicentre, double-blinded, PBO-controlled study (NCT04999839), adults with moderate-to-severe psoriasis were randomized 1:1:1:1:1 to receive oral TAK-279 (2, 5, 15 or 30mg) or PBO once daily for 12 weeks. The safety analysis set included all patients who received ≥1 dose of assigned study treatment. Laboratory parameters assessed throughout the trial included creatine kinase (CK) as well as haematologic (neutrophils, lymphocytes, haemoglobin, platelets), hepatic and renal (alanine aminotransferase, aspartate aminotransferase, bilirubin, creatinine, estimated glomerular filtration rate), and lipid (cholesterol, triglycerides) parameters.

Results: In total, 259 patients were included in the safety analysis set. Longitudinal changes in all laboratory parameters were generally similar in the PBO and TAK-279 groups with no consistent trends observed by TAK-279 dose. Mean values of most laboratory parameters remained within normal ranges during the study. There was no relationship between TAK-279 treatment and cytopenia. Some CK elevations were observed in both the PBO and TAK-279 groups, but most were transient or reversible and of Common Terminology Criteria for Adverse Events Grade 1 or 2 (Grade ≥2 events occurred in 2 [3.8%], 2 [4.0%], 6 [11.5%], 4 [7.5%] and 3 [5.8%] patients, in the PBO, and 2, 5, 15 and 30mg groups, respectively), and were not associated with rhabdomyolysis. Mean triglyceride values were slightly higher than normal ranges at Week 12 (as well as the baseline visit) in all treatment groups, including PBO, and were mainly asymptomatic, mild-to-moderate elevations. These changes were not accompanied by increases in serum cholesterol levels.

Conclusion: TAK-279 treatment did not result in adverse changes in haematologic, hepatic, renal or lipid parameters that are associated with Janus kinase (JAK) inhibition. These findings suggest that the mechanism of action of TAK-279 is distinct from that of JAK1–3 inhibition.1 Further phase 3 studies of TAK-279 in psoriasis are

ongoing to confirm these observations (NCT06088043; NCT06108544).

References

\1. Armstrong A, et al. AAD 2023.

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Abstract N°: 3798

Guselkumab improves psoriatic skin, quality of life, sexual health, and perceived stigmatization across BMI subgroups: results from the real-world G-EPOSS study

Sascha Gerdes*[1], Peter Weisenseel[2], Rolf Ostendorf[3], Sebastian Zimmer[4], Adriana Otto[5], Judita Makuc[6], Simmy Jacobsen[6], Nina Trenkler[6], Juliane Behrens[6], Dariusch Mortazawi[7]

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Introduction & Objectives:

The pathophysiological relationship between psoriasis and obesity is not fully understood. Being overweight or obese can affect the severity of psoriasis, the likelihood of having anogenital psoriasis, and treatment outcomes, and may contribute to increased risk of comorbidities. Here, we assess the impact of Body Mass Index (BMI) on outcomes regarding skin, quality of life, sexuality, and perceived stigmatization in patients with psoriasis treated with guselkumab, an IL23p19 subunit inhibitor, in the G-EPOSS study.

Materials & Methods:

G-EPOSS was a prospective, non-interventional, multicentre study of adults with moderate-to-severe plaque psoriasis in Germany. In total, 307 patients were enrolled between 2019 and 2021 and received guselkumab 100 mg at Week (W)0, W4, and every 8 weeks thereafter until study end at W76, per routine clinical practice. Assessments up to W76 included Psoriasis Area and Severity Index (PASI), anogenital PGA (aPGA), and the following patient-reported outcomes: Dermatology Life Quality Index (DLQI), Relationship and Sexuality Scale (RSS; comprising 10 questions assessing sexual function, frequency and fear), and Perceived Stigmatization Questionnaire (PSQ). Outcomes were assessed by BMI subgroup (BMI ≤25/>25–≤30/>30 kg/m2).

Results:

Overall, 295 patients were analysed. BMI data at baseline were available for 286 patients (BMI ≤25/>25–≤30/>30 kg/m2; n=77/106/103); mean weight was 69.5/84.2/105.6 kg and mean disease duration was 15.7/17.0/19.5 years, respectively. Analyses of baseline comorbidities, including arterial hypertension, depression and psoriatic arthritis, showed higher prevalence in those with a BMI >25 vs ≤25 kg/m2 (Table).

Skin and quality of life outcomes improved from baseline to W76 irrespective of BMI. At W76, mean PASI and DLQI scores were similar among BMI ≤25/>25–≤30/>30 kg/m2 subgroups (PASI 0.9/1.2/1.4; DLQI 1.4/1.9/1.3, respectively), while a higher proportion in the ≤25 kg/m2 subgroup achieved clear skin in the anogenital region (aPGA =0; 85.7%/73.7%/70.0%; Figure).

Evaluation of responses to the RSS questionnaire showed improvements for all BMI subgroups; 76.3%/74.3%/68.4% of patients with BMI ≤25/>25–≤30/>30 kg/m2, respectively, were ‘very much’, ‘much’ or ‘rather much’ satisfied with their frequency of hugs and kisses at baseline, which increased to 91.1%/85.0%/84.7% at W76. Further, 34.2%/33.3%/35.7% of patients with BMI ≤25/>25–≤30/>30 kg/m2, respectively, were ‘sometimes’, ‘often’ or ‘always’ afraid of sexual intercourse at baseline, which decreased to 3.6%/10.0%/11.1% at W76.

Perceived stigmatization outcomes improved for all BMI subgroups. Among those with BMI ≤25/>25–≤30/>30 kg/m2 at baseline, 58.4%/46.7%/39.8%, respectively, 'never' or 'almost never' perceived that people they don't know act surprised or startled when they see them, which increased to 96.4%/92.9%/96.0% at W76. Similarly, 70.1%/67.6%/56.3% responded 'never' or 'almost never' to 'People seem embarrassed by my looks' at baseline, which improved to 91.1%/94.1%/93.3%, respectively, at W76.

Conclusion:

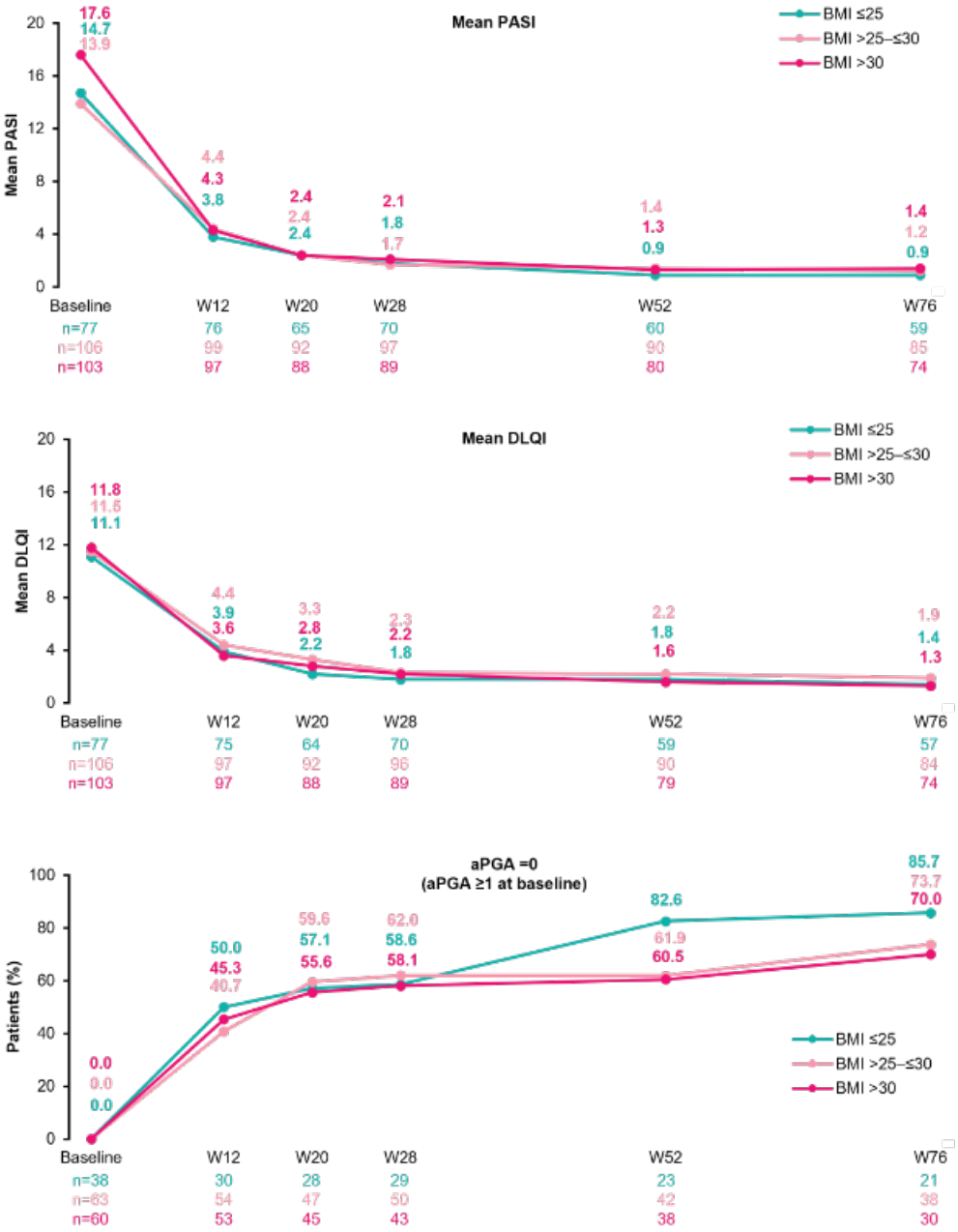
Though the risk of comorbidities and the likelihood of having anogenital psoriasis was higher with increasing BMI, guselkumab was an effective treatment irrespective of BMI for improving skin, quality of life, sexual health, and perceived stigmatization through W76 in patients with moderate-to-severe psoriasis in routine clinical practice.

Table 1. Patient comorbidities at baseline by BMI subgroup

Comorbidities, n (%)*	BMI subgroup (kg/m²)		
	≤25 (n=77)	>25–≤30 (n=106)	>30 (n=103)
Alcohol abuse	2 (2.6)	6 (5.7)	5 (4.9)
Arterial hypertension	11 (14.3)	19 (17.9)	42 (40.8)
Depression	2 (2.6)	14 (13.2)	11 (10.7)
Diabetes mellitus	3 (3.9)	8 (7.5)	15 (14.6)
Dyslipidaemia	2 (2.6)	7 (6.6)	9 (8.7)
Metabolic syndrome	0 (0.0)	2 (1.9)	14 (13.6)
Nicotine abuse	14 (18.2)	19 (17.9)	15 (14.6)
Psoriatic arthritis	13 (16.9)	25 (23.6)	34 (33.0)

*Comorbidities shown were present in ≥5.0% of patients in any BMI subgroup.
BMI, Body Mass Index.

Figure 1. Mean PASI, mean DLQI, and aPGA =0 response rate from baseline to W76, by BMI subgroup



aPGA, anogenital Physician's Global Assessment; BMI, Body Mass Index; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; W, Week.

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AMSTERDAM 25-28 SEPTEMBER 2024
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Abstract N°: 3809

Multiple switching between the biosimilar adalimumab-fkjp low concentration and reference adalimumab high concentration in patients with chronic plaque psoriasis: a phase 3, double-blind, randomised, parallel-group study

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Introduction & Objectives:

Adalimumab-fkjp, is an FDA approved biosimilar to adalimumab. This study evaluated the pharmacokinetics (PK), efficacy, safety, and immunogenicity in patients with moderate to severe chronic Plaque Psoriasis (PPs) receiving adalimumab continuously and those undergoing repeated switches between adalimumab and adalimumab-fkjp. The primary objective was to evaluate interchangeability of adalimumab-fkjp (40 mg/0.8ml) and adalimumab (40 mg/0.4ml) by comparing adalimumab steady-state PK between switching and non-switching arms. This study was conducted to fulfill FDA requirement for designation as an 'interchangeable' biosimilar.

Materials & Methods:

A total of 386 subjects (134 females, 252 males; median age: 46 years) with moderate to severe chronic PPs for ≥6 months involving body surface area ≥10% and having a Psoriasis Area and Severity Index (PASI) ≥12 and static Physicians Global Assessment (sPGA) ≥3 (moderate) were enrolled in to the run-in period to receive subcutaneous (SC) adalimumab (80 mg, Week 1; 40 mg biweekly, Weeks 2-10). At Week 12, patients with PASI ≥50 (N=374) were randomized 1:1 to continue SC adalimumab (N=193; 40 mg biweekly, Weeks 12-26) or undergo repeated switches between 40 mg SC adalimumab-fkjp and adalimumab (N=181; adalimumab-fkjp, Weeks 12 and 14; adalimumab, Weeks 16 and 18; and adalimumab-fkjp, Weeks 20, 22, 24, and 26). Assessments included PK (primary:AUCτ, 26-28 and Cmax, 26-28; secondary: Tmax, 26-28, Cmin, 26-28, and Ctrough), efficacy (Proportion of PASI 50, PASI 75, PASI 90, and PASI 100 responders and sPGA success of clear or almost clear at Week 28), safety, and immunogenicity.

Results:

The mean steady-state serum PK profiles were similar in both switching and non-switching arms. The 90% confidence intervals of LS mean ratios for AUCτ, 26-28 [104.76 (98.23%-111.74%)], Cmax, 26-28 [104.23 (95.85%-113.36%)], and Cmin, 26-28 [107.85 (99.99%-116.37%)] were within the bioequivalent range of 80.00% - 125.00% (Table 1). The overall number and proportion of patients with PASI responses and sPGA success were highly similar between the two arms at week 28. Treatment-emergent Adverse Events were comparable between switching [54 subjects (29.8%)] and non-switching arms [66 subjects (34.2%)]. The incidence of injection site reactions was lower in the switching arm (15 events) as compared to non-switching arm (30 events). Incidence of anti-drug antibodies and neutralizing antibodies were similar between the arms.

Conclusion:

This study confirmed that the subjects receiving adalimumab-fkjp low concentration and adalimumab high concentration in alternate fashion had highly similar time concentration curves compared to continuous administration of adalimumab, and demonstrated PK equivalence between switching and non-switching arms. The efficacy, safety and immunogenicity profile was similar between the arms. The overall data supports interchangeability between adalimumab and adalimumab-fkjp.

Table 1: Summary of Key Statistical Analysis

Parameter	Switching Arm LS Means (n=159)	Non-switching Arm LS Means (n=166)	LS MEANS Ratio (Switching Arm / Non-switching Arm)	90% Confidence Intervals
AUCτ, 26-28 (µg*hr/mL)	2293.38	2189.09	104.76	98.23% – 111.74%
Cmax, 26-28 (µg/mL)	8.24	7.90	104.23	95.85% – 113.36%
Cmin, 26-28 (µg/mL)	5.47	5.07	107.85	99.99% – 116.37%

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Abstract N°: 3810

Guselkumab improved psoriatic skin, quality of life, and sexual health in the real-world G-EPOSS study, regardless of biological sex

Sascha Gerdes*[1], Peter Weisenseel[2], Rolf Ostendorf[3], Sebastian Zimmer[4], Adriana Otto[5], Judita Makuc[6], Simmy Jacobsen[6], Nina Trenkler[6], Juliane Behrens[6], Dariusch Mortazawi[7]

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Introduction & Objectives:

It is unclear how biological sex impacts quality of life (QoL) and treatment outcomes in patients (pts) with psoriasis (Pso). Here, we evaluate the effectiveness of guselkumab (GUS), an IL-23p19 subunit inhibitor, on skin outcomes, QoL and sexual health by biological sex in Pso pts in the real-world G-EPOSS study.

Materials & Methods:

G-EPOSS was a prospective, non-interventional, multicentre study of adults with moderate-to-severe plaque Pso in Germany. 307 pts were enrolled at the treating physicians' discretion between 2019 and 2021 and received GUS 100 mg at Week (W)0, W4, and then every 8 weeks to study end (W76), per routine clinical practice. Assessments included PASI, anogenital PGA (aPGA), and the patient-reported outcomes DLQI and Relationship and Sexuality Scale (RSS; 10 questions assessing sexual function, frequency, and fear). All outcomes were analysed descriptively by biological sex; RSS was assessed by presence of anogenital Pso (aPso).

Results:

Of the 295 pts analysed, 41.7% (n=123) were female and 58.3% (n=172) were male. Mean age was 45.6 years and mean duration of Pso was 17.4 years.

Mean PASI scores improved substantially in females and males from baseline (BL; 15.4 and 15.3, respectively) to W12 (4.0 and 4.3), with further improvements through W76 (1.1 and 1.3). The proportions of females and males achieving PASI ≤3 (90.5% and 85.3%, respectively), PASI ≤1 (70.5% and 66.7%), and PASI =0 (47.4% and 47.3%) at W76 were similar. aPso (aPGA ≥1) was reported in 50.4% of females and 60.5% of males at BL, with mean aPGA scores of 2.8 and 2.7, respectively. Scores improved to 0.4 and 0.2, respectively, through W76, and 69.4% of females and 80.0% of males achieved aPGA =0.

The mean DLQI score was slightly higher in females than males at BL (12.1 and 10.8, respectively), but improved to similar levels by W76 (1.6 and 1.5, respectively).

Of the 120 females and 168 males who completed the RSS questionnaire, a higher proportion of females (37.5%) than males (31.0%) reported that they were 'sometimes', 'often' or 'always' afraid of sexual intercourse at BL. Values decreased to 10.2% and 7.1%, respectively, at W76 (Figure). A similar trend was reported for females (n=60) and males (n=103) with aPso at BL, albeit with higher proportions of pts at BL (45.0% and 40.0%, respectively), decreasing to 16.3% and 10.5%, respectively, at W76. At BL, a lower proportion of females (16.7%) than males (26.2%) felt their partner was 'sometimes', 'often', or 'always' afraid of sexual intercourse. This decreased to 5.7% and 10.3%, respectively, at W76. Improvements in satisfaction with the frequency of sexual

intercourse were also observed, irrespective of sex. At BL, 45.0% of females and 45.8% of males reported being ‘slightly’ or ‘not at all’ satisfied with the frequency of sexual intercourse, improving to 19.3% and 19.8%, respectively, at W76. For pts with aPso at BL, a lower proportion of females (43.3%) reported dissatisfaction than males (53.4%). This decreased to similar levels (23.3% and 19.7%, respectively) by W76.

Conclusion:

In the real-world G-EPOSS study, GUS was highly effective on the skin of patients with moderate-to-severe Pso, including the anogenital region, irrespective of biological sex. In this study, a lower proportion of females than males had aPso at BL, but were more likely to experience sexual fear. However, improvements through W76 in skin outcomes, QoL, sexual fear, and satisfaction with frequency of sexual intercourse were similar in both sexes.

Figure. Responses to Qs 5, 6, and 9 of the RSS questionnaire, by biological sex

Individual columns may not add up to 100.0% because of rounding. Proportions in the abstract were calculated using the cumulative number of patients and therefore may differ slightly compared with adding the percentages in the figures.
BL, baseline; F, female; M, male; Q, Question; RSS, Relationship and Sexuality Scale; W, Week.

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Abstract N°: 3815

Phospholipid Esters from Herring Roe have immunomodulatory anti-psoriatic effects by affecting signaling on the IL-17/23 axis in immune cells and psoriatic skin cell models in vitro.

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Introduction & Objectives:

Psoriasis is an inflammatory disease associated with elevated levels of IL-17 and IL-23. Phospholipid esters (PL) in Herring Roe Oil (HRO) (API *PEHeRo*) have immunomodulatory properties and are rich in marine omega-3 fatty acids, known for anti-inflammatory effects. HRO has previously shown effects on mild-to moderate psoriasis (NCT03359577. Tveit *et al., Acta Dermato-Venerologica* 2020). To elucidate immunomodulatory properties of HRO related to the IL-23/IL-17 axis, we investigated its effects on macrophages and T-cells, and keratinocyte and fibroblast co-culture in psoriatic skin cell models.

Materials & Methods:

HRO containing *PeHeRO* (IRIS ID: 300000046327) was supplemented in cell culture medium. Effects on IL-23 secretion from monocyte-derived macrophages (MDM) were assessed by ELISA and qrt-PCR after pretreatment with HRO and subsequent stimulation with lipopolysaccharide (LPS) and IFN-y. CD4+ T-cells were isolated by magnetic bead separation. T-cells were co-treated with HRO and IL-17 inducing stimuli (CD3/CD28 beads with IL-1β, PGE2 and IL-23) for 72 h, and IL-17 secretion analyzed by ELISA. HaCat keratinocytes were co-cultured with human dermal fibroblasts to mimic signaling *in vivo* and stimulated with and without* IL-17* and HRO for 96 h. mRNA expression of psoriasis marker psoriasine (*S100A7*)* and IL-17 responsive gene *NFKBIZ* was measured by qrt-PCR.

Results:

IL-23 from dendritic cells and macrophages promotes a shift in T-cell activation in psoriasis. Pretreatment with HRO limited expression and secretion of IL-23 in a dose-depended manner in stimulated MDM (Fig. 1A). Similarly, IL-17 secretion was reduced in stimulated CD4+ T-cells when co-treated with HRO (Fig. 1B), representing a direct effect on psoriatic T-cell responses, which impacts downstream stimulation of skin cells. In keratinocytes co-cultured with fibroblasts, HRO displayed a dampening effect on IL-17 induced, *NFKBIZ* and *S100A7* (Fig. 1 C, D). Thus, HRO dampened signaling on the IL-23/IL-17 axis through direct effects on innate and adaptive immune cells and skin cells which are involved in the inflammatory pathophysiology of psoriasis.

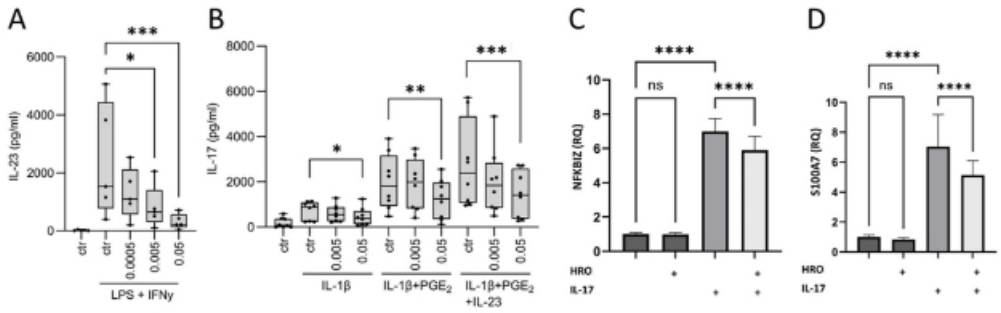

Figure 1. HRO dampens secretion of IL-23 from primary monocyte-derived macrophages (A), secretion of IL-17 from CD4+ T-cells (B), IL-17 response gene NFKBIZ (C) and psoriatic marker S100A7 (D) in keratinocyte co-culture with fibroblasts.

Conclusion:

Phospholipids from HRO display anti-inflammatory effects on psoriatic macrophages and T-cell signaling through limiting secretion of IL-23 and IL-17, respectively. Reduction of IL-17 responsive marker NFKBIZ and S100A7* of keratinocytes in co-culture supports an anti-psoriatic effect of HRO on skin cells by affecting IL-17 signaling. |||| | :- | :-: | -: |

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Abstract N°: 3823

Guselkumab improves nail psoriasis, sexual impairment and perceived stigmatization in patients with psoriasis and psoriasis-specific comorbidities: results from the real-world G-EPOSS study

Sascha Gerdes*[1], Peter Weisenseel[2], Rolf Ostendorf[3], Sebastian Zimmer[4], Adriana Otto[5], Judita Makuc[6], Simmy Jacobsen[6], Nina Trenkler[6], Juliane Behrens[6], Dariusch Mortazawi[7]

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Introduction & Objectives:

The disease burden of psoriasis extends beyond skin signs and symptoms and includes many other aspects of patients' lives, in part due to psoriasis-specific comorbidities. Here, we assess the effectiveness of guselkumab, an interleukin-23p19 subunit inhibitor, on comorbidities and their effect on patientreported outcomes in patients with moderate-to-severe psoriasis.

Materials & Methods:

G-EPOSS was a prospective, non-interventional, multicentre study of adults with moderate-to-severe psoriasis in Germany. In total, 307 patients were enrolled between 2019 and 2021 and received guselkumab 100 mg at Week (W)0, W4, and every 8 weeks thereafter until study end at W76, per routine clinical practice. Psoriasis-specific comorbidities were self-reported by the patient and monitored from baseline through W76. Patients' sexual health and perceived stigmatization were assessed using the Relationship and Sexuality Scale (RSS) questionnaire, which comprises 10 questions (Qs) assessing sexual function, frequency and fear, and the Perceived Stigmatization Questionnaire (PSQ), respectively. A descriptive analysis of W76 (as observed) data is presented.

Results:

In total, 295 patients were analysed. Mean psoriasis duration was 17.4 years; psoriasis-specific comorbidities that affected ≥7.0% of patients at baseline were psoriatic arthritis (PsA; 25.4%), arterial hypertension (24.7%), nicotine abuse (16.6%), obesity (13.2%), depression (9.2%), and diabetes (8.8%). Through W76, the numbers of self-reported new and resolved cases were: PsA, two and one*; arterial hypertension, three and one; and nicotine abuse, three and three, respectively. There were no new cases of inflammatory bowel disease or malignant lymphoma through W76.

Among patients with baseline NAPSI ≥1, mean NAPSI score decreased from 4.7 at baseline to 1.3 by W76; 52.2% achieved NAPSI =0. For patients with PsA and baseline NAPSI ≥1, mean NAPSI score decreased from 5.7 at baseline to 1.7 by W76, and 53.3% had NAPSI =0 at W76.

Among patients with/without PsA, 54.2%/52.8% answered RSS questionnaire Q9 ('I am satisfied with my present frequency of sexual intercourse') positively, with 'very much', 'much' or 'rather much' at baseline, increasing to 71.7%/82.0% by W76. Among patients with/without diabetes, response rates increased from 56.5%/52.8% at baseline to 63.2%/81.0% by W76 (Figure 1).

Among patients with/without depression, 34.6%/55.0% answered RSS Q9 positively at baseline, increasing to 45.5%/83.3% by W76 (Figure 1), and 59.3%/37.1% answered PSQ Q1 ('People avoid looking at me') with 'always',

'often' or 'sometimes' at baseline, decreasing to 13.0%/2.5% by W76 (Figure 2).

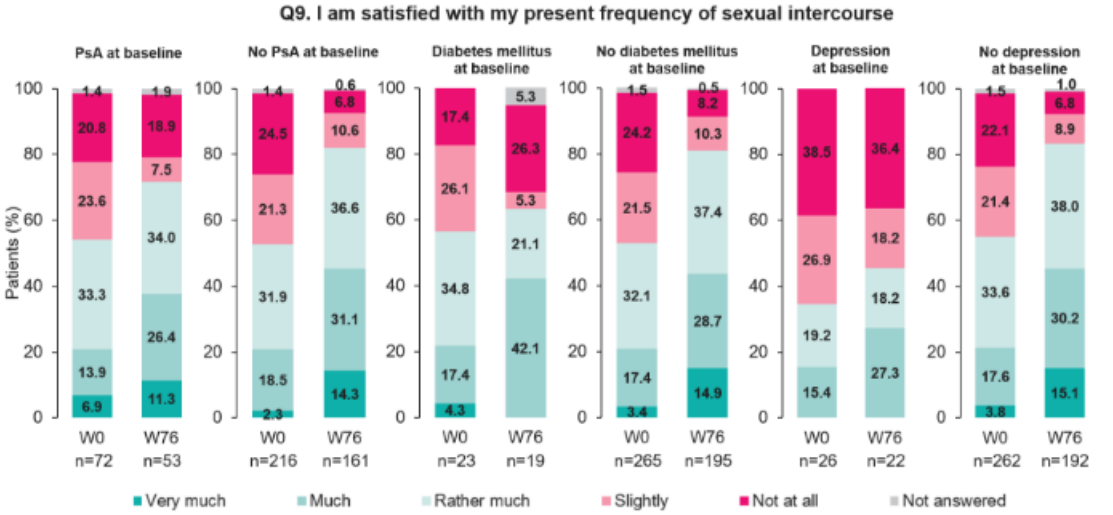
Conclusion:

In patients with moderate-to-severe psoriasis treated with guselkumab, prevalence of psoriasis-specific comorbidities remained mostly consistent through W76, with generally few and balanced numbers of new and resolved cases. Mean baseline NAPSI score was higher for patients with PsA than the overall population, but mean NAPSI scores and proportions of patients with NAPSI =0 were similar at W76.

These data show that the psoriasis-specific comorbidities of PsA, diabetes and depression substantially impacted the lives of patients with psoriasis. Furthermore, the data show that guselkumab treatment improved sexual health and perceived stigmatization in affected patients.

*Further disease activity parameters for PsA were not measured.

Figure 1. RSS Q9 responses over time by baseline comorbidity status



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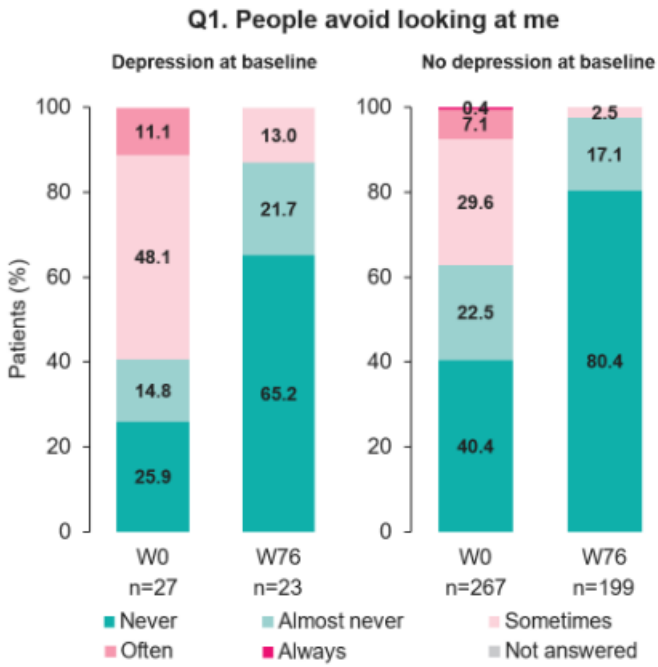
PsA, psoriatic arthritis; Q, Question; RSS, Relationship and Sexuality Scale; W, Week.

Figure 2. PSQ Q1 response over time by baseline depression status



Individual columns may not add to 100.0% because of rounding. Numbers in the abstract were calculated using the cumulative number of patients and therefore may differ slightly compared with adding the values in the figures.
PSQ, Perceived Stigmatization Questionnaire; Q, Question; W, Week.

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Abstract N°: 3844

FK-adalimumab MSB11022 showed similar efficacy on PASI 90 and PASI 100 when compared to the adalimumab originator in different subgroups of subjects suffering from moderate to severe chronic plaque psoriasis (results from the AURIEL-Pso study)

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Introduction & Objectives:

Biosimilars offer similar efficacy, safety, quality, and favorable economic impact when compared to originators, therefore increasing patient access to treatment. MSB11022 (FK-ada) is an adalimumab biosimilar approved for the treatment of autoimmune and chronic inflammatory diseases, including psoriasis and hidradenitis suppurativa. FK-ada approval, based on the totality of evidence, was comprehensive of a robust clinical program including 1234 subjects, 465 of which treated up to 52 weeks (total 420 patients-year). Therapeutic equivalence of FK-ada to reference adalimumab was shown in subjects with moderate to severe chronic plaque psoriasis in AURIEL-Pso a randomized, double blind efficacy study. Since first approval of FK-ada more than 115.000 patient-year of exposure have been reached without unexpected safety signals. Objective of the present analysis was to assess the achievement of almost clear (PASI 90) and clear skin (PASI 100) in subjects treated with FK-ada or the originator.

Materials & Methods:

Subjects (M/F) aged ≥18 years with moderate to severe chronic plaque psoriasis received FK-ada or adalimumab originator 80 mg sc then 40 mg sc every other week.Subjects were stratified by previous systemic treatment and by type of systemic therapy. A cohort of patients were switched to FK-ada from the originator at week 16. The primary objective of the trial was to demonstrate equivalence in efficacy (PASI 75 at Week 16). PASI 90 and PASI 100 responses at Week 16 were secondary endpoints. Difference in response rate were calculated at Week 16 for relevant subgroups including age, gender, weight, and previous systemic therapeutic use.

Results: 222 subjects on FK-ada and 221 on the originator were randomized; 213 on FK-ada and 202 on the originator were still on treatment at Week 16. Gender, race, ethnicity, and age were all well balanced between treatment groups. Median age: 44.2 and 41.3 years in FK-ada or originator, respectively. Baseline characteristics were consistent across treatment groups. Therapeutic equivalence was demonstrated between treatments for the primary endpoint: the 95% stratified Newcombe CIs (PP: -7.82%, 4.07%; ITT: -4.00%, 9.57%) for the difference in PASI 75 response rates were well within the prespecified equivalence margin [-18%, 18%]. No clinically meaningful differences in safety or immunogenicity were observed. The percentage of subjects achieving PASI 90 and PASI 100 were similar between the treatment groups (PASI90: 64% vs 66%; PASI100: 33% vs 37%); no differences were observed across the subgroups analyzed (see table).

Conclusion: Response rates were similar for PASI 90 and PASI 100 in different subgroups of subjects treated with FK-ada or the originator.

PASI 90 and PASI 100 DIRR (95% CI) – PP population (FK-ada vs originator)				
Category	Subgroup	N FK-ada/originator	PASI 90 DIRR (95% CI)	PASI 100 DIRR (95% CI)
Overall		203/191	-1.764 (-11.08, 7.63)	-4.32 (.13.35, 5.35)
Age	<65 years	192/184	-1.229 (.10.75, 8.36)	-4.346 (-13.88, 5.27)
	≥65 years	11/7	12.5 (-31.16, 54.59)	17E-16 (-39.40, 42.55)
Gender	Male	136/130	-8.487 (-19.81, 3.20)	-11.05 (-22.00, 0.22)
	Female	67/61	11.611 (-4.02, 27.61)	9.8586 (-7.00, 25.87)
Weight	< 90 kg	143/145	1.8093 (-8.87, 12.42)	-3.401 (-14.48, 7.81)
	≥90 kg	60/46	-10.29 (-28.19, 8.83)	-3.328 (-20.06, 12.77)
Previous systemic therapy	Naive	104/99	-5.128 (-17.96, 8.00)	-4.584 (-17.27, 8.25)
	Biologics: NO	74/67	-0.383 (-16.05, 15.42)	-3.247 (-18.44, 11.97)
	Biologics: YES	25/25	8 (-14.46, 29.67)	-4 (-29.41, 22.17)

Note: The 2 treatment groups were compared using the 2-sided 95% stratified Newcombe CI for the difference in PASI xx response rate (except for the previous systemic therapy use subgroups, for which the unstratified Newcombe version is used). Weighted Difference in Response date (DiRR) is calculated except for previous systemic therapy use subgroups.

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Abstract N°: 3860

Modulation of disease-central cytokine pathways with zasocitinib (TAK-279), a highly selective oral TYK2 inhibitor, defines clinical response in patients with psoriasis

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Introduction & Objectives:

A phase 2b study (NCT04999839) demonstrated promising efficacy and acceptable safety of TAK-279 in patients with moderate-to-severe psoriasis.1 This study also investigated associations between TAK-279 treatment, psoriasis/TYK2 biomarkers and clinical or histologic response using serum samples and lesional and non-lesional skin biopsies from patients included in the trial.

Materials & Methods:

Lesion and non-lesion skin biopsies and serum samples were obtained at Day 1 (pre-dose) and Weeks 4 and 12 from patients receiving TAK-279 (2mg, 5mg, 15mg, 30mg) or placebo orally once daily. RT-qPCR, RNA-Seq, and immunohistochemistry were used to assess changes in lesion keratinocyte proliferation (*KRT16* expression), psoriasis/TYK2 biomarkers, lesion gene signatures and plaque resolution (histological), and their associations with response (clinical [PASI 75] and histologic2).

Results:

Biopsies from 63 consenting patients and serum from 252 patients were analyzed. At Week 12, most clinical responders (n=21/24, 88%) had reductions in *KRT16* expression of >87% versus baseline lesion levels. Pooled analysis showed that in most histologic responders (18/25, 72%), *IL-17A* and *IL-17F* expression reduced by >80% versus baseline lesion levels. Reductions in lesional type I IFN, IL-12, and IL-23 pathway gene expression occurred at 15mg and 30mg doses compared with baseline levels ($p<0.05$). Dose- and time-dependent reductions in serum IL-17A, IL-17C, and IL-17F were observed in all TAK-279 groups versus placebo. In the 15 mg and 30 mg groups (n=23), expression of key psoriasis/TYK2 biomarkers (e.g. *DEFB4A*, *IL-36G*, *IL-19*, *IL-23A*) reverted to non-lesion levels. Additionally, of PASI90 responders at Week 12 (n=12), 48/50 of the top upregulated genes in lesions reverted to non-lesion expression levels. Laboratory parameters were similar between groups. In all dose groups, patients had reduced lesion epidermal thickness, CD3+ T-cell and CD11c+ myeloid dendritic cell counts with TAK-279 versus baseline and placebo.

Conclusion:

TAK-279 modulated psoriasis/TYK2 biomarkers, and this modulation was associated with clinical and histologic response in patients with moderate-to-severe psoriasis.

References:

1. Armstrong A *et al.* Oral presentation presented at the Annual Meeting of the American Academy of Dermatology, March 17–21, 2023, New Orleans, LA, USA.

2. Krueger JG *et al. J Allergy Clin Immunol* 2019;144:750–63.

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Abstract N°: 3881

FK-adalimumab MSB11022 showed similar efficacy on joints when compared to the adalimumab originator in the subgroup of chronic plaque psoriasis subjects suffering from concomitant PSA (results from the AURIEL-Pso study)

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Introduction & Objectives: Biosimilars offer similar efficacy, safety, quality, and favorable economic impact when compared to originators, therefore increasing patient access to treatment. MSB11022 (FK-ada) is an adalimumab biosimilar approved for the treatment of autoimmune diseases, including psoriasis and psoriatic arthritis. FK-ada approval, based on the totality of evidence, was comprehensive of a robust clinical program including 1234 subjects, 465 of which treated up to 52 weeks (total 420 patients-year). Therapeutic equivalence of FK-ada to reference adalimumab was shown in subjects with moderate to severe chronic plaque psoriasis in AURIEL-Pso a randomized, double blind efficacy study (Br J Dermatol 2020, 182:316). Since first approval of FK-ada more than 115000 patient-year of exposure have been reached without the emergence of unexpected safety signals (data on file). Objective of the present analysis was to assess the effect on joints of FK-ada vs originators in the subgroup of patients with concomitant PSA using HAQ and Patient Global Assessment for Joint on a Visual analogue scale (PJA-VAS).

Materials & Methods: Subjects (M/F) aged ≥18 years with moderate to severe chronic plaque psoriasis received FK-ada or adalimumab originator 80 mg sc then 40 mg sc q15d. The primary objective of the trial was to demonstrate equivalence in efficacy (PASI 75 at Week 16). PASI 90 and PASI 100 responses at Week 16 were secondary endpoints. HAQ and PJA-VAS on a 0 to 100 scale were collected and reported in subjects with history of PSA as secondary endpoints.

Results: 222 subjects on FK-ada and 221 on the originator were randomized; 26 and 25 had diagnosis of PSA, respectively. Gender, race, ethnicity, age and disease characteristics were all well balanced at baseline. Therapeutic equivalence was demonstrated for the primary endpoint: the 95% stratified Newcombe CIs (PP: [-7.82%, 4.07%]; ITT: [-4.00%, 9.57%]) for the difference in PASI 75 response rates were well within the prespecified equivalence margin. PASI 75 response rates score was similar in the PSA subgroup: 76.9% for FK-ada and 76.0% for originator. HAQ improvement was 51.9% for FK-ada and 52.3% for the originator. Differences on the PJA-VAS at Week 16 are reported in the table below (ITT population).

		FK-adalimumab		Originator adalimumab	
Visit		Value	Change from BL	Value	Change from BL
Baseline	n/N	25/26		24/25	
	Mean ± SD	43.3 ± 24.71		45.4 ± 27.53	
	Median	39.0		40.0	
	Q1; Q3	28.0; 58.0		23.0; 69.0	
	Min; Max	0; 93		1; 99	
Week 16	n/N	21/23		21/22	
	Mean ± SD	26.0 ± 27.30	-15.4 ± 20.84	24.6 ± 24.33	-17.9 ± 26.16
	Median	14.0	-16.0	17.0	-12.0
	Q1; Q3	10.0; 30.0	-24.0; -5.0	3.0; 49.0	-30.0; -7.0
	Min; Max	0; 100	-62; 44	0; 77	-76; 55

Notes: n number of subjects with history of PSA evaluated with PJA-VAS; N: number of subjects with history at PSA at Screening; Patient Global Assessment for Joints was assessed on a 100 mm Visual Analog Scale (PJA-VAS) with 0= best answer and 100=worst

Conclusion: Effect on joint measure with HAQ and PJA-VAS was similar in patients treated with FK-ada and originator at Week 16. Effects on patient's quality of life support confidence in the use of FK-ada.

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Abstract N°: 3905

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in plaque psoriasis: Psoriasis Area and Severity Index (PASI) outcomes over 4 years in patients receiving continuous deucravacitinib in the phase 3 POETYK PSO-1, PSO-2, and LTE trials

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was efficacious versus placebo and apremilast and was well tolerated in two global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) parent trials. At Week 52, patients could enroll in the POETYK long-term extension (LTE) (NCT04036435) trial and receive open-label deucravacitinib. This analysis evaluated PASI outcomes in the PSO-1, PSO-2, and LTE trials over 4 years (Week 208; data cutoff, November 1, 2023).

Materials & Methods: Efficacy was evaluated in the pooled population of patients from the parent trials who received continuous deucravacitinib treatment from Day 1 through 4 years (n=513). Outcomes included adjusted mean change from baseline in PASI score analyzed using modified baseline imputation, where baseline value was imputed for patients who discontinued due to worsening psoriasis and by multiple imputation for patients with missing data due to other reasons. In addition, modified nonresponder imputation was used to analyze the proportions of patients achieving treat-to-target absolute PASI thresholds ≤1, ≤2, ≤3, ≤4, ≤5, and ≤6, and PASI responses at Week 52 and Week 208 in patients who achieved PASI ≤3 at Week 16.

Results: The mean (standard deviation) baseline PASI score was 21.2 (7.9). Improvements were observed beginning at Week 1 (adjusted mean % change [standard error], −14.8% [1.0]), improving through Week 16 (−72.1% [1.9]), further improving through Week 52 (−82.4% [1.0]), and were maintained through Week 208 (−81.1% [1.4]). Proportions of patients achieving treat-to-target absolute PASI thresholds ≤1, ≤2, ≤3, ≤4, ≤5, and ≤6 were increased or maintained from Week 16 through Week 52 and subsequently through Week 208. The majority of patients who achieved PASI ≤3 at Week 16 (n=228) maintained this response through Week 52 (78.9% [95% CI, 73.6%-84.2%), and subsequently through Week 208 (74.5% [95% CI, 68.2%-80.9%]).

Conclusion: Patients with moderate to severe plaque psoriasis treated continuously with deucravacitinib demonstrated clinically meaningful PASI outcomes, including improvement in PASI scores within 1 week and achievement of treat-to-target PASI outcomes through Week 52, that were maintained through 4 years of treatment. These findings suggest deucravacitinib, a once-daily oral drug, has the potential to become a treatment of choice for patients with moderate to severe plaque psoriasis, with the ability to achieve treatment targets in a large proportion of patients through 4 years of continuous treatment.

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Abstract N°: 3943

Cost per responder, an approach for psoriasis treatment in Colombia

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Cost per responder, an approach for psoriasis treatment in Colombia

Introduction & Objectives:

Advances in treating moderate-to-severe plaque psoriasis have greatly improved the outcomes for patients suffering from the disease. Despite that improvement, the cost of the disease has increased exponentially with a significant impact on health budgets.

Our objective was to get an indirect comparison of the cost-effectiveness of psoriasis treatments available in Colombia based on the number needed to treat and the cost of achieving a response.

Materials & Methods:

A cost-per-responder model of psoriasis treatments was developed to support clinicians' and administrators' decisions related to drug choice and treatment sequence. We conducted a systematic review of the literature to identify the placebo-controlled phase 3 trials of the psoriasis treatment drugs (conventional synthetic and biological). PASI75 was selected as the target result to compare all products. The number needed to treat (NNT) was calculated for each product based on pivotal studies, by applying the inverse of the average risk reduction. The treatment costs for 16 weeks were obtained from the SISMED report (Q2, 2023) for the selected medications and based on the recommended dosing from the locally approved prescribing information in Colombia. The cost per responder (CPR) was calculated by multiplying the NNT by the acquisition cost for 16 weeks.

Results:

We found that subcutaneous methotrexate and adalimumab had the best CPR results (USD 814,68 and USD 1.376,85 respectively) for PASI 75 response. Interleukin inhibitors, as it has been demonstrated previously, have better PASI responses, but are priced higher, resulting in CPR ranging from 6 to 9 times the CPR of MTX (table 1). Finally, ustekinumab had a higher CPR result (11 times than MTX).

Conclusion:

This study supports the preferential use of SC MTX and adalimumab as starting treatments for psoriasis. The optimal treatment for psoriasis patients in different clinical settings may consider CPR analysis in addition to the clinical guidelines to help optimize the use of resources in the healthcare system and define the optimal treatment sequence for social security as well as out-of-pocket patients.

It should be taken into consideration that the current analysis is based on prices resulting from local regulations in Colombia and could have different results when adapted to other markets.

Table 1. Cost per responder results at 16 week for PASI75 in the Colombian Market

Treatment	PASI 75 CPR at 16 wk (USD)	IC 95 low	IC 95 high	CPR index
SC MTX	$ 814,68	$ 545,18	$ 1.612,05	1,0
Adalimumab	$ 1.376,85	$ 1.297,96	$ 1.467,39	1,7
Infliximab	$ 2.665,18	$ 2.493,42	$ 2.866,12	3,3
Certolizumab	$ 4.093,17	$ 3.585,42	$ 4.671,28	5,0
Apremilast	$ 4.796,67	$ 4.106,79	$ 5.775,12	5,9
Secukinumab	$ 4.943,22	$ 4.537,68	$ 5.440,87	6,1
Etanercept	$ 5.074,85	$ 4.442,98	$ 5.922,75	6,2
Guselkumab	$ 5.405,61	$ 5.107,15	$ 5.737,23	6,6
Ixekizumab	$ 5.769,81	$ 5.490,08	$ 6.080,40	7,1
Risankizumab	$ 7.284,19	$ 6.681,16	$ 7.997,76	8,9
Ustekinumab	$ 9.097,25	$ 8.445,37	$ 9.845,94	11,2

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Abstract N°: 3958

Deucravacitinib in plaque psoriasis: maintenance of response over 4 years in the phase 3 POETYK PSO-1, PSO-2, and LTE trials

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, was superior to placebo and apremilast in two global, phase 3 trials (POETYK PSO-1 and PSO-2) in moderate to severe plaque psoriasis. At Week 52, patients could enter the POETYK long-term extension (LTE) trial and receive open-label deucravacitinib. Long-term efficacy was maintained through 3 total years of continuous treatment with no new safety signals in the ongoing LTE trial.

Materials & Methods: Efficacy was further evaluated through Week 208 (4 years; data cutoff, November 1, 2023) in patients from the pooled PSO-1/PSO-2 populations who received continuous deucravacitinib from Day 1, achieved ≥75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75) at Week 16 (primary endpoint) or Week 24 (peak response), and entered the LTE trial. Maintenance of response assessments included ≥75% reduction from baseline in Psoriasis Area and Severity Index (PASI 75), ≥90% reduction from baseline in PASI (PASI 90), and static Physician Global Assessment score of 0 (clear)/1 (almost clear) (sPGA 0/1). Efficacy is reported using modified nonresponder imputation in patients who reached or discontinued before Week 208.

Results: Of 513 patients who received continuous deucravacitinib from Day 1 and entered the LTE trial, PASI 75 was achieved by 313 (61.0%) and 336 (65.5%) patients at Week 16 and Week 24. Among Week 16 PASI 75 responders, response rates were maintained well from Week 16 to Week 208 (PASI 75: 100%, 84.4%; PASI 90: 55.7%, 57.4%; sPGA 0/1: 82.8%, 65.4%). Among Week 24 PASI 75 responders, response rates were also maintained from Week 24 to Week 208 (PASI 75: 100%, 84.6%; PASI 90: 62.7%, 58.2%; sPGA 0/1: 82.5%, 66.0%).

Conclusion: Clinical efficacy was generally maintained with continuous deucravacitinib in the vast majority of Week 16 and Week 24 PASI 75 responders from the parent trials through 4 years, supporting the long-term effectiveness and treatment durability of once-daily oral deucravacitinib for moderate to severe plaque psoriasis.

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Abstract N°: 3990

Deucravacitinib long-term efficacy through 4 years in Week 16 placebo crossover patients in the phase 3 POETYK PSO-1, PSO-2, and LTE program

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was efficacious and well tolerated in the two global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) parent trials, and through 2 additional years in the POETYK long-term extension (LTE) (NCT04036435) trial in patients treated with deucravacitinib from Day 1 of PSO-1/PSO-2. Here, long-term efficacy was assessed through 4 years in patients who crossed over from placebo to deucravacitinib at Week 16 in PSO-1 or PSO-2 and entered the LTE trial.

Materials & Methods: PSO-1 and PSO-2 randomized patients 1:2:1 to oral placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily. At Week 16, patients randomized to placebo crossed over to deucravacitinib. At Week 52, patients could enroll in the LTE trial and receive open-label deucravacitinib. Efficacy was evaluated in patients who crossed over from placebo to deucravacitinib at Week 16 of the parent trial and received continuous deucravacitinib through 4 years (Week 208; data cutoff, November 1, 2023). Outcomes included ≥75%/≥90% reduction from baseline in Psoriasis Area and Severity Index (PASI 75/90) and static Physician Global Assessment score of 0 (clear) or 1 (almost clear) (sPGA 0/1). Efficacy is reported using modified nonresponder imputation (mNRI) in patients who reached the Week 208 assessment or discontinued before Week 208.

Results: Of 421 patients originally randomized to placebo, 348 crossed over to deucravacitinib at Week 16; 298 completed the parent trials and entered the LTE trial, with 291 meeting mNRI criteria. Efficacy response rates improved from Week 16 on placebo (PASI 75, 12.0% [95% CI, 8.5%-16.3%]; PASI 90, 3.4% [1.7%-6.2%]; sPGA 0/1, 10.0% [6.8%-14.0%]) through Week 52 on deucravacitinib (PASI 75, 75.2% [70.2%-80.2%]; PASI 90, 47.4% [41.6%-53.1%]; sPGA 0/1, 60.1% [54.5%-65.7%]). Response rates were maintained well through Week 208 (PASI 75, 75.6% [70.0%-81.2%]; PASI 90, 46.6% [40.4%-52.7%]; sPGA 0/1, 55.1% [48.8%-61.4%]).

Conclusions: These findings support the long-term efficacy profile of once-daily oral deucravacitinib for treatment of patients with moderate to severe plaque psoriasis.

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Abstract N°: 4096

Therapeutic challenge in managing a patient with HIV-associated psoriasis vulgaris

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Introduction & Objectives: Psoriasis is a chronic, immune-mediated, inflammatory disorder, associated with both physical and psychological burden. An estimated of 2-4% of people with HIV can have psoriasis. Psoriasis can appear for the first time or worsen after a person contracts HIV. The symptoms can present in the early or late stages of HIV infection. Both HIV and psoriasis respond to medications, although having both conditions can lead to a more severe form of psoriasis and make it more difficult to treat. Multiple therapeutic options routinely used to treat psoriasis cause immunosuppression, which should be avoided in these patients. In the following section, we would like to present how a patient with psoriasis associated with HIV infection was treated.

Materials & Methods: We present the case of a 61-year-old patient, who was referred to our department in September 2022 by our colleagues from infectious disease service. The patient is known to have HIV infection for 22 years, for which she is receiving HAART, and reports an intensely pruritic eruption consisting of erythematous, well-demarcated plaques with white, easily detachable scales spread over the entire body as well as the scalp that appeared about 6 months ago. Based on the clinical examination and the patient's history, the presumptive diagnosis of HIV-associated psoriasis is raised.

Results: The diagnosis of psoriasis vulgaris was confirmed following a skin biopsy. As an immunosuppressed patient with a severe form of psoriasis vulgaris, choosing an appropriate systemic therapy was a challenge. Acitretin along with UVB-NB phototherapy 3 sessions per week was the chosen treatment regime. At the start of systemic therapy PASI score was 21.4 and DLQI 15. After the first 4 weeks of Acitretin 20mg/daily PASI score decreased minimally and DLQI decreased significantly to 8. It was decided to increase the dose of Acitretin to 30mg/daily for another 8 weeks, without seeing any improvement in the PASI score, on the contrary rather an increase in the DLQI score. In February 2023 it was decided to change the conventional systemic therapy to a biologic therapy. A drug from the IL23 inhibitor class, Tildrakizumab, is chosen. At the start of biologic therapy PASI score was 17.4 and the DLQI score was 12. After the first 3 months of biologic therapy the PASI score decreased to 6, with a significant improvement in the DLQI score of just 2. The PASI and DLQI scores continued to have values close to those mentioned above at the following examinations. At the 1-year evaluation of the efficacy of the biologic therapy, the patient states an increased degree of satisfaction following the start of the biologic therapy, presenting a DLQI score of 2 and a PASI score of 4.

Conclusion: In the presented case, HIV infection led to an extensive and severe form of psoriasis vulgaris, unresponsive to conventional systemic therapies. The choice of biologic therapy took into account the fact that the patient is immunosuppressed and her desire to do injections as seldom as possible. Because few studies enroll patients with associated HIV psoriasis, the decision was a difficult one. A drug from the IL23 inhibitor class, a regulatory cytokine of the inflammatory process involved in psoriasis, was chosen that should not interfere in any way with the host immune system. One year after the start of biologic therapy, the treatment is effective, with a high patient satisfaction and no change in CD4 cell count compared to the period before the start of therapy.

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Abstract N°: 4112

Cardiovascular risk factors in patients with psoriasis

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Introduction & Objectives:

Psoriasis is a chronic inflammatory disease that not only affects the skin, but is also associated with multiple comorbidities, the most common of which are cardiovascular risk factors. The objective of this study is

to analyze cardiovascular risk factors and comorbidities in patients with psoriasis referred to the Dermatology-Internal Medicine Unit and to compare them with a group of patients with the same disease from the General Dermatology Clinic.

Materials & Methods:

Observational, prospective, case-control, prospective study. The variables studied were obtained from the clinical history and the patients signed the informed consent form. A statistical analysis was performed including descriptive statistics, comparison of case-control variables, intra- and inter-group comparison over time (t1, t2 and t3) and multivariate analysis, using the SPSS version 20 statistical program.

Results:

In the case group, 27 patients were included, 22 men (81.5%) and 5 women (18.5%) with a mean age of 54.19 years. In the control group, 25 patients were included, 18 men (72%) and 7 women (28%), with a mean age of 56.76 years. In the case group 88.9% (n=24) had dyslipidemia, 55.6% (n=15) were hypertensive and 25.9% (n=7) diabetic. In control patients, 44% (n=11) were dyslipidemic and hypertensive and 5 were diabetic (20%), and the time course of HT and diabetes were significantly longer in controls.

The mean BMI of the controls was significantly lower at the 2 follow-up times (t2 and t3). The SCORE value in cases decreased over time. The mean SCORE_t1 was 2.62 (SD=1.96), dropping to 1.89 (SD=1.05) at t3. However, this decrease was less in the control group, with the mean SCORE_t2 being 2.88 (SD=3.30) and SCORE_t3 being 2.83 (SD=3.34).

Conclusion:

The patients seen in the joint consultation are patients with long-standing psoriasis and comorbidities such as metabolic syndrome (62.9%), obesity (67%), dyslipidemia (88.9%), diabetes (25.9%), and moderate cardiovascular risk measured by the SCORE scale (2.62, SD=1.96).

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Abstract N°: 4120

Enhanced psoriasis trial screening using an Artificial Intelligence (AI) model to remotely assess digital skin images

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[1]Johnson & Johnson Innovative Medicine

Introduction & Objectives: Inclusion criteria in psoriasis (PsO) clinical trials often requires in-person assessments, including Psoriasis Area and Severity Index (PASI), Investigator Global Assessment (IGA), and Body Surface Area (BSA). Such assessments can be burdensome and may hinder trial screening efficiency. Thus, we developed an AI framework for patient classification using remotely collected images from mobile devices in a decentralized observational study.

Materials & Methods: PsO patients participated in a non-interventional observational study, where they uploaded images spanning the body to a mobile application. A US board-certified dermatologist evaluated the image sets for PASI, IGA, and BSA. Patients were stratified by disease severity and skin tone, with ≈70% used for training, ≈10% for validation, and ≈20% for the hold-out test set. Weakly-supervised ResNET-50, ConvNeXt, and NextViT AI models were trained to identify if a patient image set met the Inclusion Criteria (IC+: BSA≥10%, PASI≥12, and IGA≥3), using standards commonly used in moderate-to-severe PsO trials. The best-performing model was selected based on validation Area Under the Curve (AUCval). Test AUC (AUCtest) was calculated on the best model. To explore the potential of AI as a screening tool, the model output probability threshold (β) was chosen on the validation set to achieve equal sensitivity and specificity. This β was applied to the test set to calculate sensitivity, specificity, accuracy, and positive and negative predictive value (PPV and NPV).

Results: 533 PsO patients provided 1-4 skin image sets (46 images/set) taken at different time points, totaling 1061 image sets. Following quality control, 38,824 images from 344 patients (844 image sets) were used for analysis. 56% of image sets (473/844 image sets) were classified as IC+. ConvNeXt (AUCval=85%) and ResNet-50 (AUCval=84%) showed higher classification performance than NextViT (AUCval=76%). ConvNeXt had an AUCtest of 83%. The choice of βs influenced the trade-off between sensitivity and specificity. At β=0.80, sensitivity and specificity were >75% in the validation set. At this β, the test set showed sensitivity >75%, positive predictive value (PPV) >75%, accuracy >75%, specificity ≈74%, and negative predictive value (NPV) ≈71%. Alternatively, using a ConvNeXT β of 0.5 resulted in sensitivity ≈87% but only specificity ≈56%.

Conclusion: The ConvNeXT model accurately classified IC+ patients using decentralized images, demonstrating the potential of AI in patient screening. With high sensitivity and PPV, the model can identify IC+ patients in a high-throughput way. AI can be tailored to specific trial needs, offering high sensitivity, high specificity, or a balance of both for identifying eligible patients. This study provides an AI-based approach towards remote and efficient screening, potentially enhancing recruitment of patients for PsO clinical trials.

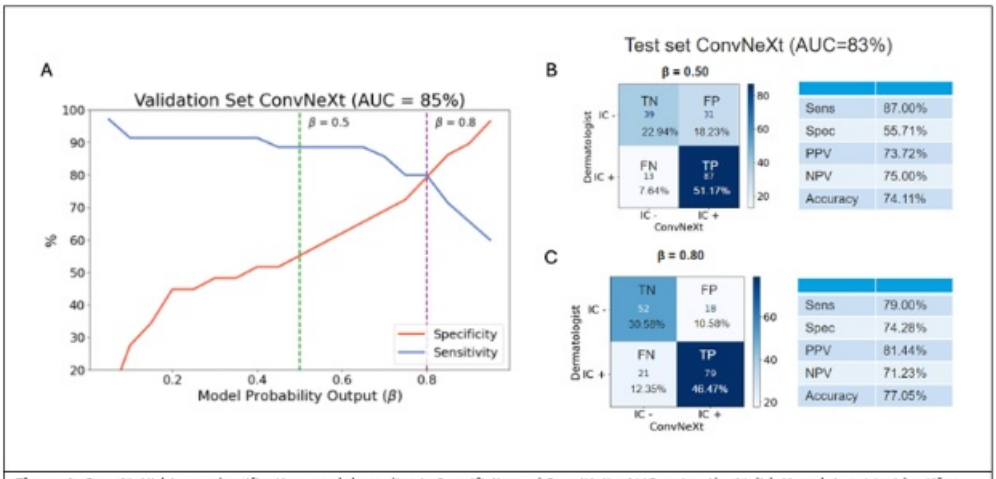

Figure 1. ConvNeXt binary classification model results. A. Specificity and Sensitivity AUC, using the Validation dataset to identify model output probability thresholds: β = 0.5 and β = 0.8. B and C. Test dataset confusion matrices and metrics for β = 0.5 and β = 0.8, respectively. Metrics include sensitivity (Sens), specificity (Spec), positive and negative predictive value (PPV and NPV), and Accuracy.

EA DV CONGRESS
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EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 4193

A Decentralized Clinical Study for Remote Assessment of Psoriasis Severity with Deep Learning-based Automated Classification

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[1]Johnson & Johnson Innovative Medicine

Introduction & Objectives:

Psoriasis (PsO) clinical trials require patients to make in-person site visits to assess disease severity and response to treatment. Frequent visits can be burdensome and discourage participation. We conducted a decentralized non-interventional observational study using patient-acquired digital images with mobile devices to investigate the feasibility of remote assessment of PsO severity. A deep learning model was built to automate PsO classification (Clf) using images.

Materials & Methods:

PsO patients were recruited to participate in the study. Patients used a mobile application to acquire and upload full-body image sets at 1-4 different time points. A US board-certified dermatologist remotely assessed Psoriasis Area and Severity Index (PASI) using the images. PASI<5, 5≤PASI≤10, and PASI>10 were classified as mild, moderate, and severe PsO, respectively. To evaluate inter-assessor consistency, image sets from 27% of patients were randomly chosen to be re-scored by a second dermatologist to determine intraclass correlation (ICC). To develop Clf models, the data were partitioned into training and hold-out test sets (stratified by disease severity and skin tone). Weakly supervised ResNet-50, ConvNeXt, and NextViT models were trained and data-driven model hyperparameters were selected. Area Under the Curve (AUC) was used to assess model performance.

Results:

533 PsO patients participated in the study. Each patient provided 1-4 skin image sets (46 images/set) taken at home across different time points, totaling 1061 image sets. Image sets without active disease, incomplete sets, and poor quality images were removed after a quality control evaluation. After removal, 344 patients with 844 image sets, totalling 38,824 skin images were used for analysis. 35% of patients had Fitzpatrick Skin Tone Type III-VI. The average PASI score was 5.03±4.68 (range: 0—25.8). There were 550 mild, 183 moderate, and 111 severe image sets. 92 patients with a total of 165 image sets were selected for rescoring. Independent dermatologists showed high consistency for image-based PASI scoring with ICC of 93.4 (range: 83.8—88.7 across body regions). Our model development data partition yielded training (275 pts, 674 image sets, and 31,004 total images) and test (69 pts, 170 image sets, 7,800 total images) datasets. The test set for WSL ResNet50, ConvNeXt, and NextViT all had AUC > 85%, and all models significantly differentiated PsO severity levels (t-test p-value < 0.001).

Conclusion:

A decentralized study using images collected through mobile devices by patients was successfully conducted. From this data, we developed a classification tool for remote assessment of PsO severity using deep learning. High consistency in PASI scoring among dermatologists validated the reliability of remote PsO assessments. This study supports the potential for conducting decentralized interventional PsO trials and increasing participant inclusion.

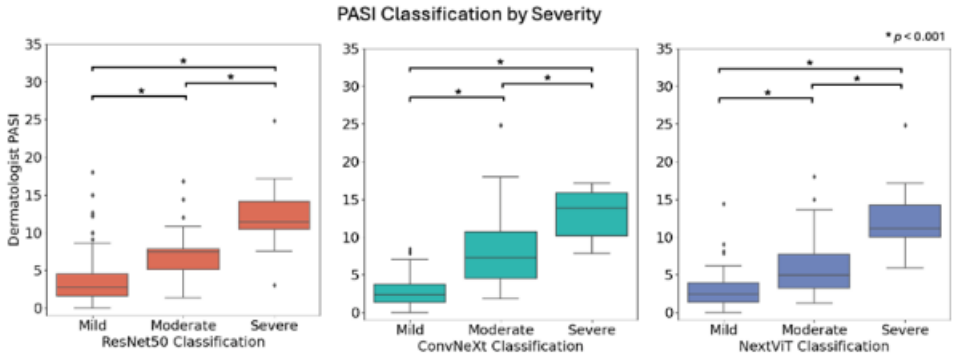

Figure 1. PASI Classification by Severity across 3 Clf models: ResNet-50, ConvNeXt, and NextViT. Accuracy was evaluated using the Test dataset. Pairwise comparisons were calculated using unpaired t-tests.

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Abstract N°: 4208

Serum IL-6 and IL-10 levels in patients with psoriasis: correlation with clinical type and disease severity

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Introduction & Objectives:

Psoriasis is a chronic, immune-mediated disease with genetic predisposition. Althought the etiopathogenesis of the disease is not clear, many studies have shown that levels of cytokines released by keratinocytes and inflammatory leukocytes contribute to the induction or persistence of the inflammatory process in psoriasis. The purpose of the study was to evaluate serum levels of IL-6 and IL-10 cytokines in patients with psoriasis and the healthy subjects and also to assess a possible association between IL-6 and IL-10 with clinical type and severity of disease.

Materials & Methods:

The study included a total of 60 patients with psoriasis, both genders and all of ages and 20 healthy subjects in the control group. According to the clinical type of disease, patients with psoriasis were divided into four groups: psoriasis vulgaris, psoriasis pustulosa, psoriasis erythrodermica and psoriasis arthropatica. Blood samples were collected from all psoriasis patients and from healthy control subjects. Serum IL-6 and IL-10 levels were measured by an enzyme-linked immunosorbent assay (ELISA) technique. The severity of psoriasis vulgaris was assessed by Psoriasis Area and Severity Index (PASI) score.

Results:

The serum level of IL-6 in patients with psoriasis was significantly higher than that in the control group (6.23±5.29 pg/ml vs 0.16±0.07 pg/ml, respectively). There was a statistically significant difference between the mean values of IL-6 in relation to the clinical type of psoriasis. The highest serum IL-6 level was in the psoriasis erythrodermica group (9,37 pg/ml). Serum level of IL-10 in psoriatic patients was also higher than that in the control group but without statistical significance ($p > 0.05$). Analysis of cytokine values indicated statistically significant difference of IL-10 compared to the clinical form of psoriasis.

Conclusion:

The results of this study have been shown that psoriasis is associated with significant changes in serum level of IL-6. There was a statistically significant correlation between serum IL-6 levels, clinical type of psoriasis, and severity of psoriasis vulgaris evaluated by PASI score. Serum IL-10 levels in patients with psoriasis are higher than in the control healthy group, but without statistical significance. Also, the values of IL-10 are not correlated with PASI score in group of patients with psoriasis vulgaris.

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Abstract N°: 4227

Deucravacitinib in plaque psoriasis: laboratory parameters through 4 years of treatment in the phase 3 POETYK PSO-1, PSO-2, and LTE trials

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[1]Case Western Reserve University, University Hospitals of Cleveland, Cleveland, United States,[2]Université Côte d'Azur, University Hospital of Nice, Nice, France, [3]Tokyo Medical University, Tokyo, Japan, [4]Psoriasis Treatment Center of New Jersey, East Windsor, United States, [5]Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Manchester, United Kingdom, [6]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, United Kingdom, [7]Veracity Clinical Research, Brisbane, Australia, [8]Oregon Health & Science University, Portland, United States,[9]Bristol Myers Squibb, Princeton, United States, [10]University of Lübeck, Lübeck, Germany,[11]Yale University School of Medicine and Central Connecticut Dermatology, Cromwell, United States, [12]Henry Ford Health System, West Bloomfield, United States

Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in multiple countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was efficacious versus placebo and apremilast and was well tolerated in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) parent trials. At Week 52, patients could enroll in the ongoing POETYK long-term extension (LTE; NCT04036435) trial and receive open-label deucravacitinib. Changes in laboratory parameters in the blood known to be associated with Janus kinase (JAK) 1,2,3 inhibitors were evaluated through 4 years of deucravacitinib treatment.

Materials & Methods: Changes from baseline in lipid (cholesterol, triglycerides), chemistry (alanine aminotransferase [ALT], aspartate aminotransferase [AST], creatinine, creatine phosphokinase [CPK]), and hematology (hemoglobin, lymphocytes, neutrophils, platelets) parameters in the blood known to be affected by JAK1,2,3 inhibitors in clinical trials were evaluated through Week 208 (4 years; data cutoff, November 1, 2023). Treatment discontinuations due to laboratory abnormalities were assessed.

Results: A total of 1519 patients received ≥1 deucravacitinib dose (total exposure, 4392.8 person-years); 1203 (79.2%) had ≥52 weeks and 542 (35.7%) had ≥208 weeks of continuous deucravacitinib exposure (median, 185 weeks). No trends or clinically meaningful mean changes from baseline were observed in any of the above laboratory parameters. A total of 3 patients discontinued treatment due to increased CPK, and 1 patient each discontinued due to lymphopenia, abnormal hepatic function, increased ALT, and increased AST. Discontinuations due to triglyceride elevations were not observed.

Conclusion: In PSO-1/PSO-2/LTE, no trends or clinically meaningful mean changes from baseline were observed in lipid, chemistry, or hematology parameters, in contrast to signature changes (eg, increased cholesterol, creatinine, serum transaminases, CPK, cytopenias) that have been observed with JAK1,2,3 inhibitors. Discontinuations due to laboratory abnormalities noted above were rare (n=7 events) through 4 years of deucravacitinib treatment. Results suggest deucravacitinib treatment does not warrant routine laboratory testing for all patients, in contrast with the requirements for JAK1,2,3 inhibitors, reflecting its selectivity for TYK2.

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Abstract N°: 4241

Therapeutic challenge in psoriasis: a case report of brodalumab treatment in a patient with psoriasis and obesity

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Introduction. Moderate-to-severe plaque psoriasis depends on IL23/IL17 cytokine pathway, and most patients are managed with biologic drugs targeting either of these pathways. However, not all biologics offer the same efficacy in achieving therapeutic goals (PASI 90; PASI <3). For instance, it is well known that patients with BMI >35, female gender or prior biological failure (primary or secondary) represent clinically challenging scenarios with high therapeutic need.

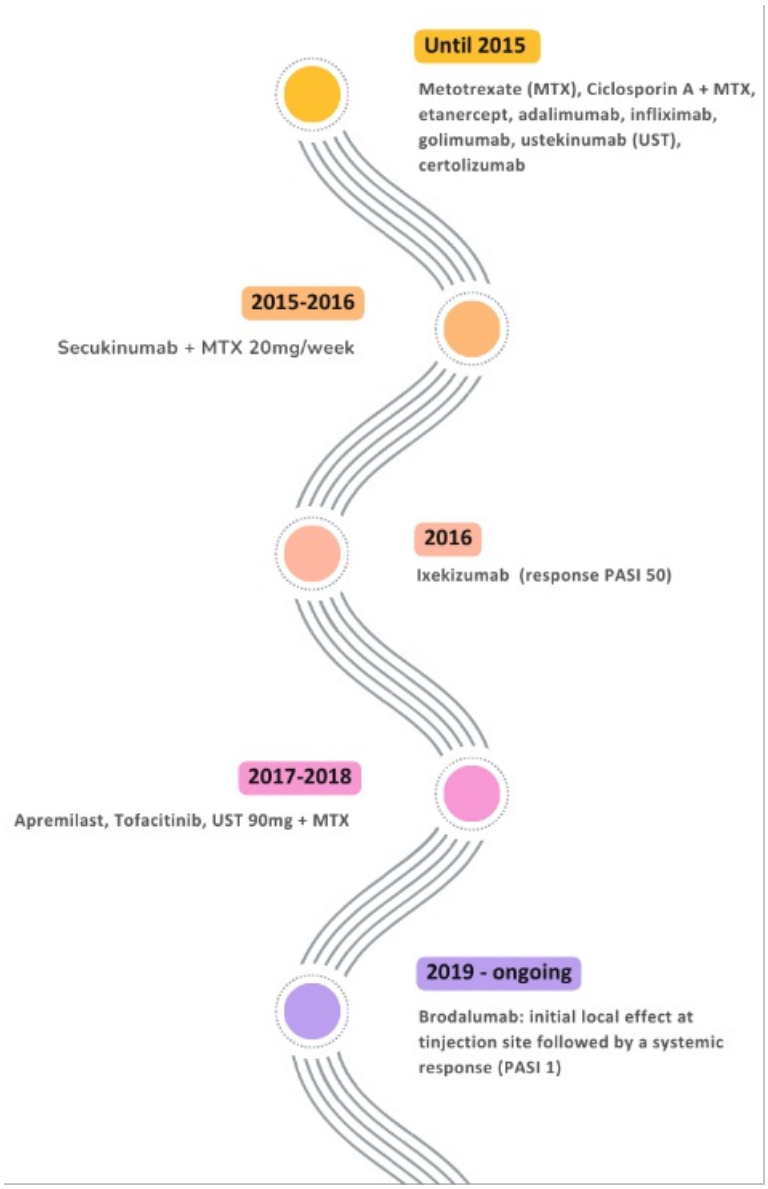
Clinical case: We present the case of a 37-year-old woman, non-smoker, with history of morbid obesity since the age of 8 (currently with a BMI of 59.5) and metabolic syndrome. She has had plaque psoriasis since childhood and peripheral psoriatic arthritis with onset at the age of 20 as dactylitis. She presented to our clinic with a baseline PASI of 36 and BSA of 75% after multiple systemic and biologic treatments with variable efficacy (Figure 1).

Because of her clinical features and the lack of evidence of arthritis at the time, brodalumab was prescribed. The first subcutaneous administration produced a local response at the injection site, where psoriasis had previously existed. As a result, it was agreed to inject the drug into areas with active skin disease. Subsequent administrations revealed the same local reaction phenomenon, along with an ulterior systemic response with almost complete whitening (PASI 1), which has remained consistent to this day. During the COVID-19 pandemic, the patient discontinued treatment for 2 months and it was observed a complete response after resuming brodalumab.

Discussion and Conclusion: The illustrated case depicts the most difficult clinical situation in psoriasis management: a patient with substantial biologic experience (including IL-17A inhibitors) with arthritis and morbid obesity. In this context, achieving positive outcomes is challenging for any biologic drug. However, brodalumab has not only demonstrated clinical efficacy but also achieved long-term response maintenance (>4 years, ongoing). Additionally, in this scenario, it has proved several distinguishing qualities, including a lack of weight impact on efficacy, a rapid onset of action, efficacy in retreatment, and an excellent safety profile.

Furthermore, this case raises interesting new ideas for debate in the field of psoriasis treatment. We observed an initial drug effect in the form of local whitening at the injection site, which could be a marker of subsequent systemic response, as was the case with our patient. The mechanism of action is unknown, however it could be explained by an influence on immunological memory or the drug's local bioavailability or distribution. Therefore, future research is required to confirm this hypothesis. Nonetheless, it suggests that delivering the medication directly to psoriatic plaques, even if they are extremely resistant to previous treatments, may be very useful for the patients.

Figure 1. Chronology timeline of multiple systemic and biologic treatments previously administered to the patient.


Until 2015
Metotrexate (MTX), Ciclosporin A + MTX, etanercept, adalimumab, infliximab, golimumab, ustekinumab (UST), certolizumab
2015-2016
Secukinumab + MTX 20mg/week
2016
Ixekizumab (response PASI 50)
2017-2018
Apremilast, Tofacitinib, UST 90mg + MTX
2019 - ongoing
Brodalumab: initial local effect at tinjection site followed by a systemic response (PASI 1)

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Abstract N°: 4255

Deucravacitinib efficacy at 4 years with continuous treatment in Week 52 PASI 90 responders in the phase 3 POETYK PSO-1 and PSO-2 trials in psoriasis

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was efficacious versus placebo and apremilast and was well tolerated in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) trials. At Week 52, patients in the parent PSO-1 and PSO-2 trials could enroll in the POETYK long-term extension (LTE) (NCT04036435) trial and receive open-label deucravacitinib 6 mg once daily. This analysis evaluated the maintenance of high clinical responses among patients treated with continuous deucravacitinib through 4 years of therapy.

Materials & Methods: Efficacy through 4 years (Week 208; data cutoff, November 1, 2023) was evaluated in patients (n = 513) who received continuous deucravacitinib treatment from Day 1 and who achieved a high clinical response (≥90% reduction from baseline in Psoriasis Area and Severity Index [PASI 90] at Week 52) in the parent trials. Outcomes included ≥90%/100% reduction from baseline in PASI (PASI 90/100) and sPGA score of 0 (clear) or 0/1 (clear/almost clear) with a ≥2-point improvement from baseline. Data were analyzed as observed, by modified nonresponder imputation (mNRI), and by treatment failure rule (TFR).

Results: A total of 234 of 513 (45.6%) patients dosed with deucravacitinib from Day 1 achieved PASI 90 at Week 52. In the stringent mNRI analysis (n = 231), the proportions of patients achieving PASI 90, PASI 100, sPGA 0, and sPGA 0/1 at Week 52 were 100.0%, 44.2%, 53.2%, and 91.3%. The proportions at Week 208 were 72.8%, 35.2%, 40.1%, and 79.4%, respectively. Results were similar by TFR methodology.

Conclusion: Clinical efficacy response rates for PASI and sPGA thresholds were generally maintained through 4 years in Week 52 PASI 90 responders. These results further support the long-term maintenance of efficacy of deucravacitinib in PASI 90 responders with moderate to severe plaque psoriasis.

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Abstract N°: 4283

Patients with a history of neoplasia and psoriasis under treatment with Tildrakizumab: series of 48 cases

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Introduction & Objectives: Patients with psoriasis appear to have a higher risk of developing cancer over their lifetime. Tildrakizumab, a selective inhibitor of IL23p19 in the treatment of moderate to severe psoriasis, has been associated with high efficacy and a good long-term safety profile. We present a series of 48 cases from 28 Spanish hospitals involving patients with a history of neoplasia who were treated for their psoriasis with Tildrakizumab.

Materials & Methods: We present 48 patients, 34 males and 14 females, aged between 33 and 88 years, with moderate to severe plaque psoriasis. Following the diagnosis of neoplasms (4 skin cancers, 2 blood cancers and 42 solid organ), most patients discontinued the treatments they were receiving for psoriasis. Subsequently, they initiated systemic treatments (acitretin, methotrexate, apremilast, dimethyl fumarate), phototherapy, and/or biologics (ustekinumab, etanercept) without disease control. At the start of Tildrakizumab, they presented with an average PASI of 12.15, BSA 18,45%, PGA 3.45 and DLQI 11.92. The follow-up ranged from 4 weeks to 3 years. During this period, Tildrakizumab was discontinued in 10 cases: 2 due to death from causes unrelated to psoriasis and the drug; 2 due to cancer progression; the other 2, due to early drug failure, were switched to guselkumab and risankizumab. In other four cases it was stopped, without initiating a new drug. Of the remaining 38, they continued with the drug, achieving absolute PASI ≤2 in 31 of them (81,5%), with a good safety profile. In 2

patients, Tildrakizumab was combined with UVB phototherapy and 20 mg/d acitretin, respectively.

Results:

Conclusion: There is still little evidence in literature of psoriatic patients undergoing biologic treatment after or simultaneously with a history of cancer. Tildrakizumab has been associated with high efficacy and a good long-term safety profile, with low sustained rates of malignant tumors, in clinical trials with extension phases up to 5 years. However, real-world data are needed to understand the safety of biologic treatments in patients with a history of malignant disease. We hope that this series of 48 cases of patients with preexisting cancer treated with Tildrakizumab contributes to expanding the experience in managing them.

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Abstract N°: 4360

Factors associated with the time to first response to vunakizumab in patients with moderate-to-severe plaque psoriasis: a post hoc analysis

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Introduction & Objectives:

As therapeutic goals for lesion clearance in psoriasis treatment advance, the speed of lesion improvement has become a critical outcome of interest for both clinicians and patients. Vunakizumab, a novel IL-17A inhibitor, has demonstrated efficacy and safety in the treatment of moderate-to-severe plaque psoriasis. We conducted a post-hoc analysis to evaluate the impact of various factors on the time taken to achieve psoriasis area and severity index (PASI) 75, 90, and 100 responses.

Materials & Methods:

The Phase III trial of vunakizumab (NCT04839016) was a multicenter, double-blind, randomized control trial that enrolled 690 patients with moderate-to-severe plaque psoriasis. Patients were randomized in a 2:1 ratio into the vunakizumab group (n=461) and the placebo group (n=229). During the first 12 weeks, patients received vunakizumab 240 mg or placebo at weeks 0, 2, 4, and every 4 weeks thereafter. At week 12, patients in the vunakizumab group continued to receive vunakizumab 240 mg every 4 weeks until the final injection at week 48, while patients initially in the placebo group were switched to receive vunakizumab 240 mg. This post-hoc analysis focused on factors such as age, sex, body mass index (BMI), baseline severity of psoriasis (body surface area, PASI score, static physician's global assessment score), disease duration, and common comorbidities. Univariate and multivariate Cox regression analyses were performed to evaluate the influence of these factors on the time to achieve PASI 75, 90, and 100 responses.

Results:

Univariate and multivariate Cox regression analyses were conducted to assess the risk factors associated with the time to achieve PASI 75, 90, and 100 responses. Among the 461 patients in the vunakizumab group analyzed, both univariate and multivariate analysis showed no significant effect of age on the time to achieve PASI 75, 90, or 100 responses, with HRs of 0.93 (95% CI: 0.86, 1.01, p=0.1074), 1.01 (95% CI: 0.98, 1.03, p=0.6229), and 1.01 (95% CI: 1.00, 1.02, p=0.0990), respectively. Similarly, no significant effects of sex and BMI on the time to achieve PASI 75, 90, or 100 responses were found. Furthermore, the baseline severity of psoriasis, disease duration, and common comorbidities including diabetes, hypertension, dyslipidemia, and hyperuricemia were also not associated with the time to achieve PASI 75, 90, and 100 responses (Tables 1-3).

Conclusion:

In this post hoc analysis, factors including age, sex, BMI, psoriasis severity, disease duration, and common comorbidities did not appear to affect the time to onset of action of vunakizumab in patients with moderate-to-severe plaque psoriasis. Patients with different demographic and clinical characteristics had consistently rapid onset of response to vunakizumab.

Table 1. Predictive factors for the time to achieve PASI 75 response

	Univariate Cox analyses		Multivariate Cox analyses	
Variables	HR (95% CI)	p value	HR (95% CI)	p value
Age	0.98 (0.94, 1.01)	0.1369	0.93 (0.86, 1.01)	0.1074
Sex				
Female vs. Male	1.27 (0.48, 3.38)	0.6285	4.52 (0.43, 48.05)	0.2110
Baseline BMI (kg/m²)	1.07 (0.99, 1.15)	0.0750	1.06 (0.90, 1.26)	0.4767
Baseline BSA	1.00 (0.98, 1.03)	0.6952	0.95 (0.87, 1.04)	0.2465
Baseline PASI Score	1.02 (0.98, 1.06)	0.3499	1.22 (0.99, 1.49)	0.0622
Baseline sPGA Score				
4 vs. 3	1.63 (0.73, 3.63)	0.2326	3.66 (0.60, 22.30)	0.1588
5 vs. 3	2.10 (0.58, 7.68)	0.2606	2.69 (0.13, 56.75)	0.5255
Psoriasis Duration	0.98 (0.93, 1.03)	0.3673	0.99 (0.84, 1.17)	0.9307
History of Diabetes				
Yes vs. No	0.60 (0.22, 1.59)	0.3020	0.05 (0.00, 1.20)	0.0644
History of Hypertension				
Yes vs. No	0.76 (0.28, 2.02)	0.5771	3.53 (0.39, 32.04)	0.2627
History of Hyperlipidemia				
Yes vs. No	0.93 (0.41, 2.12)	0.8682	8.19 (0.46, 144.40)	0.1510
History of Hyperuricemia				
Yes vs. No	1.10 (0.45, 2.73)	0.8310	0.11 (0.01, 1.71)	0.1139

BMI, body mass index; BSA, body surface area; PASI, psoriasis area and severity index; sPGA, static physician's global assessment.

Table 2. Predictive factors for the time to achieve PASI 90 response

	Univariate Cox analyses		Multivariate Cox analyses	
Variables	HR (95% CI)	p value	HR (95% CI)	p value
Age	1.01 (0.99, 1.02)	0.3974	1.01 (0.98, 1.03)	0.6229
Sex				
Female vs. Male	1.24 (0.72, 2.12)	0.4412	1.28 (0.64, 2.58)	0.4874
Baseline BMI (kg/m^2)	1.03 (0.98, 1.08)	0.2020	1.03 (0.97, 1.09)	0.3689
Baseline BSA	1.00 (0.99, 1.01)	0.9017	1.00 (0.98, 1.03)	0.7621
Baseline PASI Score	1.00 (0.97, 1.02)	0.8871	0.97 (0.91, 1.04)	0.3513
Baseline sPGA Score				
4 vs. 3	1.21 (0.81, 1.81)	0.3573	1.26 (0.72, 2.19)	0.4242
5 vs. 3	1.33 (0.52, 3.37)	0.5502	1.40 (0.41, 4.81)	0.5912
Psoriasis Duration	1.01 (0.99, 1.03)	0.5801	1.00 (0.97, 1.04)	0.8364
History of Diabetes				
Yes vs. No	1.09 (0.59, 2.00)	0.7820	1.13 (0.44, 2.90)	0.7947
History of Hypertension				
Yes vs. No	0.83 (0.47, 1.47)	0.5251	0.86 (0.43, 1.72)	0.6626
History of Hyperlipidemia				
Yes vs. No	1.04 (0.65, 1.66)	0.8616	1.07 (0.44, 2.60)	0.8833
History of Hyperuricemia				
Yes vs. No	0.91 (0.49, 1.66)	0.7469	0.76 (0.30, 1.95)	0.5688

BMI, body mass index; BSA, body surface area; PASI, psoriasis area and severity index; sPGA, static physician's global assessment.

Table 3. Predictive factors for the time to achieve PASI 100 response

	Univariate Cox analyses		Multivariate Cox analyses	
Variables	HR (95% CI)	p value	HR (95% CI)	p value
Age	1.01 (1.00, 1.02)	0.1382	1.01 (1.00, 1.02)	0.0990
Sex				
Female vs. Male	1.01 (0.74, 1.37)	0.9446	1.14 (0.79, 1.63)	0.4881
Baseline BMI (kg/m²)	1.01 (0.98, 1.04)	0.6577	1.00 (0.97, 1.04)	0.9206
Baseline BSA	1.00 (0.99, 1.01)	0.9449	0.99 (0.98, 1.01)	0.5313
Baseline PASI Score	1.00 (0.99, 1.02)	0.6055	1.00 (0.97, 1.04)	0.9620
Baseline sPGA Score				
4 vs. 3	1.18 (0.92, 1.51)	0.1928	1.18 (0.87, 1.61)	0.2767
5 vs. 3	1.27 (0.84, 1.92)	0.2504	1.31 (0.72, 2.39)	0.3687
Psoriasis Duration	1.00 (0.99, 1.01)	0.9688	1.00 (0.98, 1.02)	0.8890
History of Diabetes				
Yes vs. No	0.97 (0.64, 1.46)	0.8870	0.83 (0.47, 1.47)	0.5195
History of Hypertension				
Yes vs. No	1.08 (0.79, 1.47)	0.6307	1.12 (0.77, 1.64)	0.5443
History of Hyperlipidemia				
Yes vs. No	0.92 (0.69, 1.24)	0.6019	0.86 (0.52, 1.42)	0.5607
History of Hyperuricemia				
Yes vs. No	0.94 (0.66, 1.33)	0.7256	1.04 (0.64, 1.68)	0.8767

BMI, body mass index; BSA, body surface area; PASI, psoriasis area and severity index; sPGA, static physician's global assessment.

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Abstract N°: 4367

Care and psychological impact of patients with chronic skin conditions compared to other chronic and non-chronic conditions treated by general practitioners

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Introduction & Objectives: The WHO underscores the essential role of general practitioners (GPs) in managing chronic diseases, with skin conditions being a common reason for seeking their expertise. Despite this, GPs encounter significant barriers in addressing chronic skin conditions, with limited comparative data available across other diseases. Many chronic illnesses are associated with psychosocial burdens and diminished quality of life, including an increased prevalence of depression, anxiety disorders, and addictions. This study aims to investigate the provision of GP care for individuals with chronic skin conditions, compare it to care for other chronic and non-chronic diseases, and evaluate the prevalence of comorbidities such as distress and addiction while considering perspectives from both patients and GPs.

Materials & Methods: This cross-sectional study was carried out among patients and GPs in Germany from January to December 2023, utilizing paper-based questionnaires. GPs were invited to participate and recruit patients aged ≥18 years, including those with chronic dermatological (e.g., psoriasis), chronic non-dermatological (e.g., migraine), and non-chronic (e.g., sinusitis) conditions. Qualitative interviews were conducted in advance to formulate questions on aspects lacking validated questionnaires in the literature. The patient questionnaire encompassed questions regarding their satisfaction with their GP and disease management, alongside validated assessments of well-being, life satisfaction, anxiety, and addictions. Established questions about guideline adherence were incorporated for the GPs. Descriptive analyses were carried out.

Results: 298 patients (64.7% women; mean age: 51±15 years) and 32 GPs (37.5% women; mean age: 52±9 years) were analyzed. 75% of patients see their GP as the main point of contact for questions relating to the disease (57% of patients with chronic dermatological diseases). Patients were overall satisfied with the GP and disease management. In terms of psychosocial distress, the results suggested that patients with chronic skin and non-skin conditions are equally affected and, on average, showed no signs of addiction. Most GPs reported that the diagnosis, care, and treatment of chronic dermatological diseases were more difficult than other conditions. Moreover, while most GPs reported at least good knowledge of current guidelines for non-chronic and chronic non-dermatological diseases, most reported moderate knowledge of current guidelines on dermatological diseases. 75% of GPs at least sometimes refer to guidelines for diagnosing and managing chronic non-skin diseases, whereas only 51% use guidelines for chronic skin diseases.

Conclusion: The results highlight the GP's central role in caring for people with chronic (dermatological) diseases. Patients see GPs as their first point of contact for questions about their condition, and patient satisfaction with GP care is high. However, patients with chronic diseases tend to receive a lower quality of care in GP practices than patients with non-chronic diseases. Knowledge about managing chronic skin diseases could be improved through increased GP training through the cooperation between dermatologists, GPs, and GP educators. Close interaction between GPs, dermatologists, and other specialists could ensure comprehensive, holistic, person-centered, and guideline-based care and improve the quality of life of affected patients.**

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Abstract N°: 4372

TET2 Deficiency Promotes Psoriatic Keratinocyte Inflammatory Response by activating the JAK2/STAT3 Pathway

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Introduction & Objectives:

TET2 is a protein with dioxygenase activity that catalyzes the conversion of 5mC to 5hmC. TET2 is involved in regulating immune cell proliferation and differentiation and maintaining epidermal barrier function; however, the role of TET2 in mediating keratinocyte inflammation has not been elucidated, and further studies are needed.

Materials & Methods:

We applied IMQ to C57BL/6 wild-type (WT) and epidermal TET2 knockout mice (TET2eKO) to observe inflammatory responses and detect cytokine and chemokine secretion in psoriasis-like mice. We detected the expression of JAK2/STAT3 signaling pathway molecules in TET2 knockdown keratinocytes by immunoblotting and assessed the effect of epidermal TET2 on downstream pathways.

Results:

IMQ-treated TET2eKO mice had exacerbated dermatitis, increased release of inflammatory factors, and enhanced neutrophil chemotaxis. RNA sequencing showed that upregulated genes in IMQ-induced epidermal TET2 deficiency mice were associated with the JAK/STAT signaling pathway. Knockdown TET2 expression promoted keratinocyte proliferation by activating the JAK2/STAT3 signaling pathway. We observed elevated P-STAT3 expression in NHEK. In addition, Keratinocyte activation releases more inflammatory factors (IL-17A,IL-1β□TNF-α□IL-22□ and chemokines(CXCL1,CXCL8), as well as elevated ICAM-1 expression recruiting neutrophils, exacerbating the inflammatory response in psoriasis.

Conclusion:

This study identified a key role of TET2 for epidermal activation in the pathogenesis of the inflammatory response in psoriasis, and TET2 could be a potential target for local treatment of psoriasis.

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Abstract N°: 4382

A Randomized, Double-blind, Parallel Group, Multicenter, Phase 3 Study to Compare the Efficacy and Safety of Bmab 1200 and Reference Biologic-Ustekinumab in Patients with Moderate to Severe Chronic Plaque Psoriasis 28-week Results

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Introduction & Objectives: Bmab 1200 (reference biologic-ustekinumab), a recombinant, fully human IgG1κ monoclonal antibody, inhibits the bioactivity of human interleukin (IL)-12 and IL-23. The reference product is approved for plaque psoriasis (Pso), psoriatic arthritis, Crohn's disease and ulcerative colitis. This Phase 3, randomized, double-blind, active-controlled, parallel-group, multicenter study compared the efficacy, safety, immunogenicity, and pharmacokinetics (PK) of Bmab 1200 with reference ustekinumab in adult patients with moderate to severe chronic plaque Pso.

Materials & Methods: A total of 384 patients (257 male, 127 female; median age: 42 years) with a confirmed diagnosis of chronic plaque Pso for ³6 months involving ≥10% body surface area (BSA), Psoriasis Area and Severity Index (PASI) ≥12, and static Physician's Global Assessment (sPGA) ≥3 at screening and baseline were enrolled. The study comprised a 4-week screening period and a 52-week double-blind, active-controlled treatment period (TP) with rerandomization at Week 16 for switching therapy from ustekinumab to Bmab 1200. In TP1 (baseline to predose Week 16), patients were randomized 1:1 to subcutaneous Bmab 1200 or ustekinumab (dose: ≤100 kg, 45 mg; >100 kg, 90 mg). In TP2 (Week 16 dosing to predose Week 28), patients receiving ustekinumab treatment in TP1 and achieving ³PASI 50 response by Week 12 were rerandomized 1:1 to either Bmab 1200 or ustekinumab. Patients receiving Bmab 1200 in TP1 continued the same in TP2. All continuing patients who completed TP2 and achieved ³PASI 75 response at Week 28 were offered to enter TP3 (Week 28 dosing to Week 52). The primary efficacy endpoint was percentage change from baseline (%CFB) in PASI at Week 12. The prespecified equivalence margins based on percentage improvement (least squares mean difference) in PASI from baseline to Week 12 between Bmab 1200 and ustekinumab was ±10% for the 90% confidence interval (CI) and ±13% for the 95% CI. Secondary endpoints included additional efficacy endpoints (%CFB in PASI; PASI 50, PASI 75, and PASI 90; raw PASI; sPGA response; and CFB in affected BSA), safety, immunogenicity, and PK at various timepoints from Week 4 through Week 52. The results up to Week 28 (TP2) are reported here.

Results: In the primary efficacy analysis, Bmab 1200 and ustekinumab were equivalent (Table 1). All secondary efficacy analyses supported the therapeutic equivalence of Bmab 1200 and ustekinumab. Bmab 1200 was safe and well tolerated compared with ustekinumab and data support biosimilarity. The serum concentration and immunogenicity profile did not result in any treatment-related differences in efficacy and safety.

Conclusion: This study established equivalent efficacy and comparable safety of Bmab 1200 with ustekinumab in patients with moderate to severe chronic plaque Pso.

Table 1. Percentage Change from Baseline in Psoriasis Area and Severity Index Score at Week 12 (Full Analysis Set)

	Bmab 1200 (N=191)	Ustekinumab (N=193)	Difference between Treatments
Primary estimand			
n	191	193	-
LSM (SE)	-79.87 (2.818)	-80.55 (2.783)	-
95% CI	-85.40, -74.35	-86.01, -75.10	-
LSM	-	-	0.6800
90% CI	-	-	-1.27, 2.63
95% CI	-	-	-1.64, 3.00
Secondary estimand			
n	191	193	-
LSM (SE)	-80.15 (2.841)	-80.76 (2.801)	-
95% CI	-85.72, -74.58	-86.25, -75.27	-
LSM difference	-	-	0.6067
90% CI	-	-	-1.36, 2.57
95% CI	-	-	-1.73, 2.95
CI, confidence interval; LSM, least squares mean; N, Total number of patients; n, patients with available data; SE, standard error			

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Abstract N°: 4395

Efficacy and safety of vunakizumab in patients with moderate-to-severe plaque psoriasis with different disease durations: a post-hoc analysis of a phase III, randomized controlled trial

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Introduction & Objectives:

The psoriasis treatment landscape has evolved with the advent of targeted biologic therapies and a proactive treatment approach. Vunakizumab, a novel interleukin 17A inhibitor, has shown promising results in both efficacy and safety in preliminary data from phase III studies. This study aims to conduct a post-hoc analysis to evaluate the efficacy and safety of vunakizumab in patients with moderate-to-severe plaque psoriasis with different disease durations.

Materials & Methods:

Post-hoc analysis was conducted on data from a phase 3, randomized, double-blind, multicenter clinical study (NCT04839016). Patients treated with vunakizumab were divided into short disease duration (SDD, ≤ 2 years) or long disease duration (LDD, > 2 years) groups. Efficacy analysis included Psoriasis Area and Severity Index (PASI) 75, PASI90, and PASI100 response rates in both groups of intention-to-treat (ITT) population, with 95% confidence intervals (CI) estimated by Clopper-Pearson method. Safety analysis involved summarization by system organ class and preferred term, along with severity grading.

Results:

A total of 461 patients were included (SDD:67; LDD: 394). Baseline characteristics were shown in Table 1. From w0 to w12, the total response rates of PASI 75 were 97.0% (95% CI: 89.6-99.6), 93.4% (95% CI: 90.5-95.6); PASI 90 were 85.1% (95% CI: 74.3-92.6), 76.9% (95% CI: 72.4-81.0); PASI 100 were 40.3% (95% CI: 28.5-53.0), 38.3% (95% CI: 33.5-43.3) in the SDD and LDD groups, respectively (Table 2). From w0 to w52, the total response rates of PASI 75 were 100.0% (95% CI: 94.6-100.0), 99.2% (95% CI: 97.8-99.8); PASI 90 were 97.0% (95% CI: 89.6-99.6), 97.0% (95% CI: 94.7-98.4); PASI 100 were 86.6% (95% CI: 76.0-93.7), 81.9% (95% CI: 77.8-85.6) in the SDD and LDD groups, respectively (Table 3). Regarding safety, the incidence of treatment related adverse events within w52 was 62.7% (serious in 1.5%) in the SDD group; 64.1% (serious in 0.8%) in the LDD group, with an overall incidence of 63.9% (serious in 0.9%).

Conclusion:

Vunakizumab demonstrates favorable efficacy and safety for moderate-to-severe plaque psoriasis patients with different disease durations. Compared to patients with longer disease duration, those with shorter disease duration showed higher PASI75, 90, and 100 response rates within both w12 and w52.

Table 1. Baseline characteristics

Characteristic	SDD (N=67)	LDD (N=394)	Overall (N=461)
Age (years)			
< 65	65 (97.0)	367 (93.1)	432 (93.7)
≥ 65	2 (3.0)	27 (6.9)	29 (6.3)
Sex, n (%)			
Male	51 (76.1)	301 (76.4)	352 (76.4)
Female	16 (23.9)	93 (23.6)	109 (23.6)
Weight (kg)			
< 90kg	59 (88.1)	342 (86.8)	401 (87.0)
≥ 90kg	8 (11.9)	52 (13.2)	60 (13.0)
BMI (kg/m^2)			
< 24kg/m^2	27 (40.3)	152 (38.6)	179 (38.8)
≥ 24kg/m^2	40 (59.7)	242 (61.4)	282 (61.2)
Baseline BSA (%)			
Mean (SD)	29.0 (15.9)	35.4 (17.4)	34.5 (17.3)
Median	26.5	32.0	31.0
Min, max	10.1, 74.4	10.1, 89.5	10.1, 89.5
Baseline PASI			
Mean (SD)	19.6 (6.9)	22.7 (9.161)	22.2 (8.9)
Median	17.4	21.0	20.1
Min, max	12.0, 40.0	12.0, 60.0	12.0, 60.0
Baseline sPGA, n (%)			
3	31 (46.3)	157 (39.8)	188 (40.8)
4	33 (49.3)	198 (50.3)	231 (50.1)
5	3 (4.5)	39 (9.9)	42 (9.1)

SDD: short disease duration; LDD: long disease duration; SD: Standard Deviation; BSA: Body Surface Area; PASI: Psoriasis Area and Severity Index; sPGA: static Physician's Global Assessment

Table 2. PASI response from week0 to week12

Characteristic	SDD (N=67)	LDD (N=394)
PASI 75		
Response, n (%) [1]	65 (97.0)	368 (93.4)
Response rate (95% CI) [2]	97.0 (89.6-99.6)	93.4 (90.5-95.6)
PASI 90		
Response, n (%)	57 (85.1)	303 (76.9)
Response rate (95% CI)	85.1 (74.3-92.6)	76.9 (72.4-81.0)
PASI 100		
Response, n (%)	27 (40.3)	151 (38.3)
Response rate (95% CI)	40.3 (28.5-53.0)	38.3 (33.5-43.3)

N: number of patients in treatment group of ITT; n: number of subjects in specific category;

[1] Percentage are calculated using the subjects in ITT count as denominator.

[2] Clopper-Pearson method used.

Table 3. PASI response from week0 to week52

Characteristic	SDD (N=67)	LDD (N=394)
PASI 75		
Response, n (%) [1]	67 (100.0)	390 (99.2)
Response rate (95% CI) [2]	100.0 (94.6-100.0)	99.2 (97.8-99.8)
PASI 90		
Response, n (%)	65 (97.0)	381 (97.0)
Response rate (95% CI)	97.0 (89.6-99.6)	96.95 (94.7-98.4)
PASI 100		
Response, n (%)	58 (86.6)	322 (81.9)
Response rate (95% CI)	86.6 (76.0-93.7)	81.9 (77.8-85.6)

N: number of patients in treatment group of ITT; n: number of subjects in specific category;

[1] Percentage are calculated using the subjects in ITT count as denominator.

[2] Clopper-Pearson method used.

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Abstract N°: 4400

Prognostic Factors Associated with Complete Clearance of Skin Lesions in Patients with Moderate to Severe Psoriasis Treated with Vunakizumab

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Introduction & Objectives:

Psoriasis is a chronic, relapsing, inflammatory systemic disorder that substantially affects patients' quality of life and occupational capabilities. Greater clearance of skin lesions is associated with improved patient-reported outcomes (PROs). The phase III study of vunakizumab in moderate to severe plaque psoriasis demonstrated favorable Psoriasis Area and Severity Index (PASI) 100 response rates at both week 12 and week 52. This post-hoc analysis aims to evaluate the factors influencing the achievement of PASI 100 at week 12.

Materials & Methods:

The phase III study of vunakizumab (NCT04839016) was a multicenter, double-blind, randomized controlled trial that enrolled 690 patients with moderate to severe plaque psoriasis. Participants were randomized in a 2:1 ratio, with 461 in the treatment group and 229 in the control group. Patients received either vunakizumab or placebo at a dose of 240 mg at weeks 0, 2, 4 and 8. At week 12, the vunakizumab group continued with 240 mg every 4 weeks through week 52, while the placebo group was switched to the vunakizumab 240 mg treatment. Within the subgroup of patients achieving a PASI 75 response at week 12, distinctions were made between those reaching PASI 100 (considered "super responders") and others (considered "regular responders"). Factors associated with super responder status were evaluated using univariate and multivariate logistic regression analyses, with analyzed factors including demographic characteristics, medical history, baseline severity of psoriasis (assessed by Body Surface Area [BSA], PASI, and Static Physician's Global Assessment [sPGA] scores), and duration of disease.

Results:

At week 12, of the 433 patients treated with vunakizumab who achieved PASI 75, 169 were super responders, and 264 were regular responders. Univariate analysis indicated that gender, body mass index (BMI), and a history of smoking were factors associated with super response. Specifically, females, compared to males, had an odds ratio (OR) of 2.08 (95% CI 1.34, 3.23, p=0.0011); baseline BMI had an OR of 0.92 (95% CI 0.88, 0.97, p=0.0029); and those who had quit smoking, compared to those who had never smoked, had an OR of 0.22 (95% CI 0.07, 0.66, p=0.0152). Multivariate analysis demonstrated that BMI was independently associated with super response (OR=0.93, 95% CI 0.87, 0.98, p=0.0119).

Conclusion:

In conclusion, being female and having a lower BMI were factors positively associated with a super response. Additionally, among patients not currently smoking, those who had never smoked were more likely to achieve a super response compared to those who had quit smoking. Furthermore, a lower BMI is independently associated with super response.

Table 1. Prognostic factors for super response

Variables	Univariate model		Multivariate model	
	OR (95% CI)	p value	OR (95% CI)	p value
Age	1.00 (0.99, 1.01)	0.9359	1.00 (0.98, 1.02)	0.8122
Gender (female vs. male)	2.08 (1.34, 3.23)	0.0011	1.65 (0.96, 2.82)	0.0710
Baseline BMI (kg/m^2)	0.92 (0.88, 0.97)	0.0029	0.93 (0.87, 0.98)	0.0119
Baseline BSA	0.99 (0.98, 1.00)	0.1311	1.00 (0.98, 1.02)	0.8786
Baseline PASI Score	0.98 (0.96, 1.00)	0.0692	0.99 (0.94, 1.04)	0.6105
Baseline sPGA Score				
4 vs. 3	0.94 (0.63, 1.39)	0.5019	1.20 (0.74, 1.95)	0.4791
5 vs. 3	0.65 (0.31, 1.33)	0.2473	1.02 (0.39, 2.65)	0.8637
Duration of psoriasis	1.00 (0.98, 1.02)	0.6762	0.99 (0.96, 1.03)	0.7277
Smoking status				
Quit smoking vs. never smoked	0.22 (0.07, 0.66)	0.0152	0.31 (0.09, 0.99)	0.0545
Currently smoking vs. never smoked	0.71 (0.48, 1.06)	0.1908	0.89 (0.55, 1.45)	0.1643
Family history of psoriasis (yes vs. no)	0.85 (0.53, 1.38)	0.5112	0.92 (0.54, 1.58)	0.7701
History of diabetes (yes vs. no)	0.52 (0.23, 1.20)	0.1250	0.39 (0.12, 1.20)	0.1005
History of hypertension (yes vs. no)	0.82 (0.48, 1.38)	0.4474	0.84 (0.44, 1.61)	0.5921
History of hyperlipidemia (yes vs. no)	0.89 (0.54, 1.45)	0.6339	0.54 (0.21, 1.37)	0.1940
History of hyperuricemia (yes vs. no)	0.70 (0.37, 1.31)	0.2594	0.48 (0.20, 1.18)	0.1086

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Abstract N°: 4413

Healthcare resource utilization and costs of generalized pustular psoriasis in Finland - a population-based national register study

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Introduction & Objectives: Generalized pustular psoriasis (GPP) is a severe and chronic inflammatory skin disorder characterized by acute flares that can be life-threatening and often require inpatient care. Although the occurrence of GPP is relatively rare, it is associated with a considerable economic burden for society in terms of healthcare costs. This study is aimed to investigate the healthcare resource utilization (HCRU) and costs of GPP in Finland compared to matched control groups.

Materials & Methods: This non-interventional, retrospective cohort study utilized data from several national Finnish health registers. Patients with two GPP diagnosis at a dermatology clinic were included. Two age- and gender-matched comparator groups were additionally included in the study: a) patients with psoriasis vulgaris (PV) and b) a population-based control group without a GPP or PV diagnosis. All primary and secondary healthcare visits were considered in the analysis, including in- and outpatient visits, emergency room visits, and ICU admissions. Direct costs were calculated using all primary and secondary healthcare services plus total costs of dispensed medications; indirect costs included social benefits, defined as any sickness allowance, rehabilitation benefit or disability/early retirement pensions. The data collection period was from 1996 to 2021.

Results: In total, 286 patients were found eligible with the majority being female (54%) and a mean (SD) age of 56 (17.9) years. The mean annual number of healthcare visits was significantly higher in GPP patients (1.74) compared to PV controls (0.70; $p \leq 0.01$) and population-based controls (0.84; $p \leq 0.01$, Figure 1). Within GPP patients, most healthcare visits were related to hospitalizations (1.15) of which the mean length of stay was 11.9 days. The mean annual direct medical costs were significantly higher in GPP patients (€10.323) compared to PV controls (€3.569; $p \leq 0.01$) and population-based controls (€3.345; $p \leq 0.01$, Figure 2a). The higher direct medical costs within GPP patients were mainly due to hospitalizations (€7.011). The mean annual indirect costs were significantly higher in GPP patients (€1.526) compared to population-based controls (€696; $p \leq 0.01$) but not compared to PV controls (€1.204; $p > 0.05$, Figure 2b).

Conclusion: This large nationwide population-based register study demonstrates a higher economic burden of GPP patients compared to matched control groups, with inpatient visits and medications as most contributing cost factors. The severity of GPP in combination with the significant burden on healthcare highlights the need for improving disease management strategies.

Figure 1: All-cause healthcare resource utilization of GPP patients, PV controls and population-based controls

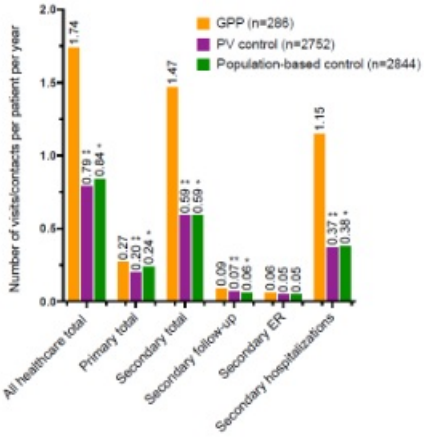
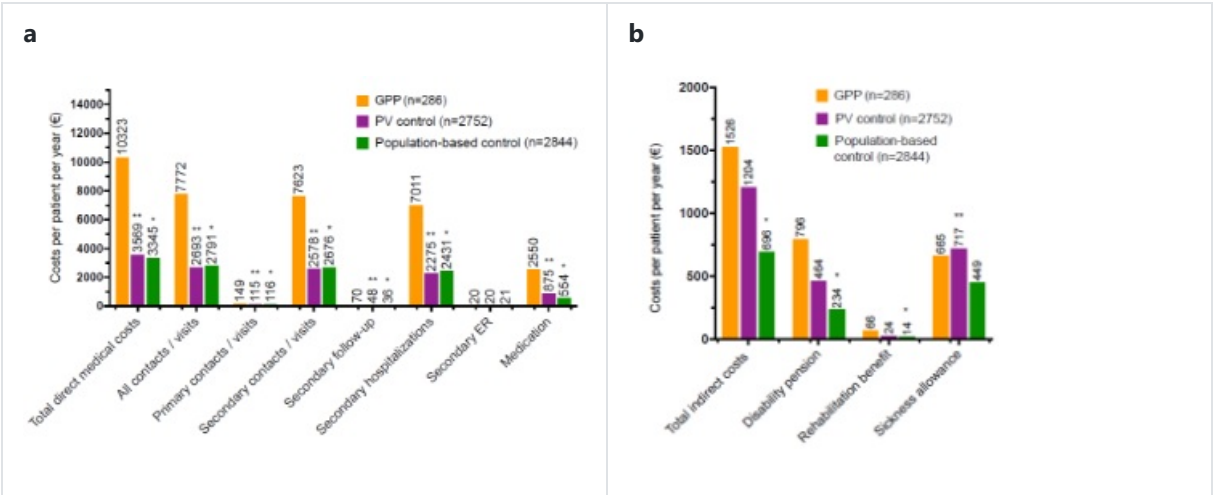


Figure 2: All-cause annual direct (a) and indirect (b) medical costs of GPP patients, PV controls and population-based controls



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Abstract N°: 4417

Evaluation of the effect of Il-23 inhibition with Tildrakizumab on peripheral vascular resistance and cytokine expression in patients with moderate and severe psoriasis, a comparative study.

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Introduction & Objectives:

Psoriasis is a chronic disease in which the effect of Il-23 on the development of clinical lesions and comorbidities is widely established. Tildrakizumab is a monoclonal inhibitor of Il-23 that has shown safety and efficacy in the management of patients with severe plaque psoriasis. However, to date there is scant evidence on the safety profile in certain comorbidities such as peripheral vascular resistance. On the other hand, knowledge of the therapeutic effects of different treatments on cytokine expression is still scarce at present.

Materials & Methods:

A prospective observational study was carried out in patients with moderate and severe plaque psoriasis who were candidates for biologic therapy and who were going to start biologic therapy with tildrakizumab. Epidemiological variables as well as comorbidities were collected. All patients included underwent baseline and 8-month measurements of peripheral vascular resistance parameters (pulse wave velocity, augmentation index and carotid intima-media thickness). Measurements of 96 cytokines were performed in the included patients. The data obtained were compared with another cohort of psoriasis patients treated with methotrexate.

Results:

Twenty patients were included (10 treated with tildrakizumab and 10 with methotrexate). No differences were observed in the baseline characteristics of both samples. Treatment with Tildrakizumab showed a statistically significant difference in the reduction of PASI and BSA at 8 months of treatment. Likewise, changes in cardiovascular risk parameters and cytokine expression profile were assessed before and after treatment, showing significant differences

Conclusion:

Nowadays, the management of psoriatic disease goes beyond the cutaneous and articular improvement of the disease. The presence of effective treatments such as Tildrakizumab which, in addition, have a good safety profile on the cardiovascular comorbidities of patients with moderate and severe psoriasis, and which improves cytokine expression is necessary to be able to carry out a complete treatment of the pathology.

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Abstract N°: 4449

Successful intra-class switching to novel IL-17 inhibitor netakimab in patients with plaque psoriasis in real-world practice

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Successful intra-class switching to novel IL-17 inhibitor netakimab in patients with plaque psoriasis in real-world practice

Introduction & Objectives:

The long-term efficacy of IL 17 inhibitors (IL17i) after intraclass switching is not well established. Netakimab (NTK) is a humanized anti-IL-17A antibody approved for the treatment of moderate-to-severe plaque psoriasis, psoriatic arthritis and ankylosing spondylitis. The aim of this subanalysis was to evaluate long-term efficacy of NTK in patients with psoriasis who were previously treated with other IL17i.

Materials & Methods:

The multicentre, non-interventional, prospective, observational multicentre study ORION enrolled 260 adult patients with moderate-to-severe psoriasis. Of these, 18 patients were previously treated with other IL17i. Due to a loss of efficacy of previous IL17i, the patients were switched to NTK. Patients received NTK 120 mg subcutaneously at wk 0, 1, 2 and Q4W starting from wk 4, during a 2-year follow-up period. Efficacy and life quality outcomes included proportion of patients achieving Psoriasis Area and Severity Index (PASI) 75/90/100, absolute changes in Body Surface Area (BSA), static Physician's Global Assessment (sPGA), Dermatology Life Quality Index (DLQI), Nail Psoriasis Severity Index (NAPSI) in patients with nail involvement. Baseline median values in patients previously treated with IL17i were as follows: PASI: 17.6, BSA: 32.5, sPGA: 3.0, NAPSI: 13.0, DLQI: 12.0.

Results:

Of the 18 NTK patients with a history of IL17i, 16 patients (88.89%) were still on NTK by week 104. The proportion

of patients responding to NTK therapy increased from visit to visit, by 104 weeks of follow-up 80% of patients achieved PASI75, 66.67% PASI 90 and 33.33% PASI 100 (Fig. 1). Median index values by 104 weeks of follow-up: PASI- 1.5, BSA- 2.0, sPGA- 1.0, NAPSI- 0, DLQI- 0 (Fig. 2).

Conclusion:

This prospective, real-world study demonstrated that switching to NTK after previous ineffectiveness of other IL-17i is a promising strategy, resulting in durable responses in the majority of patients and an improvement in quality of life.

Figure 1. Proportion of patients with PASI75/90/100, (n=18)

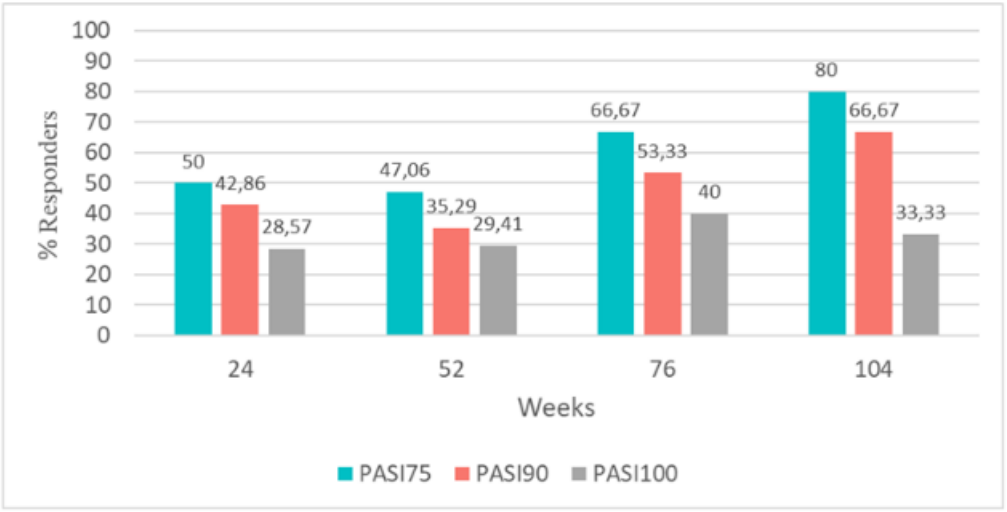
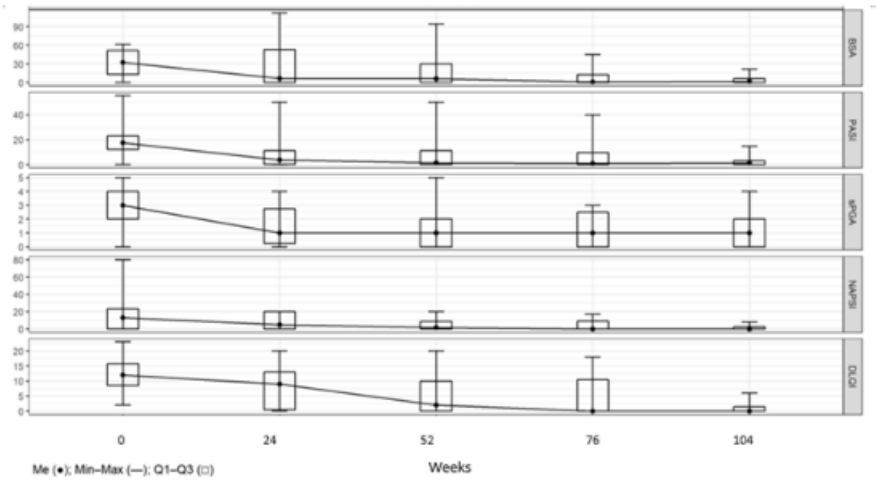


Figure 2. Absolute changes BSA, PASI, sPGA, NAPSI, DLQI, (n=18). Figure shows the medians with quartiles.



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Abstract N°: 4459

Healthcare resource utilization and costs of palmoplantar pustulosis in Finland - a population-based national register study

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Introduction & Objectives: Palmoplantar pustulosis (PPP) is a rare, chronic, recurrent inflammatory disease affecting the palms and/or soles and is characterized by erupting sterile pustules and shown to be often treatment resistant. The economic burden of this debilitating skin condition remains largely unknown with to date to only very few published studies. This study is aimed to assess the all-cause healthcare resource utilization (HCRU) and costs of PPP in Finland compared to matched control groups.

Materials & Methods: This non-interventional, retrospective, population-based register study included patients with two PPP diagnosis (ICD-10: L40.3) from a specialist in a dermatology clinic. Two age- and gender matched control groups were additionally selected for comparison: a) patients with psoriasis vulgaris (PV) and b) a population-based control group without a GPP or PV diagnosis. HCRU analysis included all-cause primary and secondary healthcare contacts incl. in- and outpatients visits, emergency room visits, and ICU admissions. Direct medical costs were calculated based on all provided healthcare services plus dispensed medications; indirect costs included social benefits, defined as any sickness allowance, rehabilitation benefit or disability/early retirement pensions. The data collection period was from 1996 to 2021.

Results: In total, 5469 PPP patients were included in the study of which most are female (74%) with a mean (SD) age of 50 (13.5) years. Compared to PV and population-based controls, the mean annual number of healthcare visits was significantly higher for PPP patients (0.74 vs. 0.68 vs. 0.66, respectively; Figure 1). In PPP, approximately two-third of the contacts were secondary healthcare visits with hospitalizations as most frequent reason. The mean annual direct medical costs were significantly higher for PPP patients (€3132) compared to population-based controls (€2256; $p \leq 0.01$) but not versus PV controls (€2859; $p > 0.05$, Figure 2a). Costs related to dispensed medication was significantly higher in PPP patients compared to both control groups (€1074 vs. ≤873; $p \leq 0.01$). The mean annual indirect costs were also significantly higher in PPP patients (€2216) compared to PV controls (€1486; $p \leq 0.01$) and population-based controls (€1147; $p \leq 0.01$, Figure 2b).

Conclusion: This study found an increased economic burden of disease of PPP patients compared to matched control groups. The most contribution cost drivers within PPP patients were hospitalizations, disability pensions and prescribed medications. These results demonstrate the need for better treatment strategies to address the disease burden more adequately.

Figure 1: All-cause healthcare resource utilization of PPP patients and matched controls

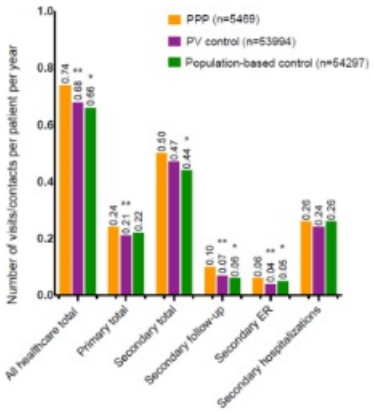
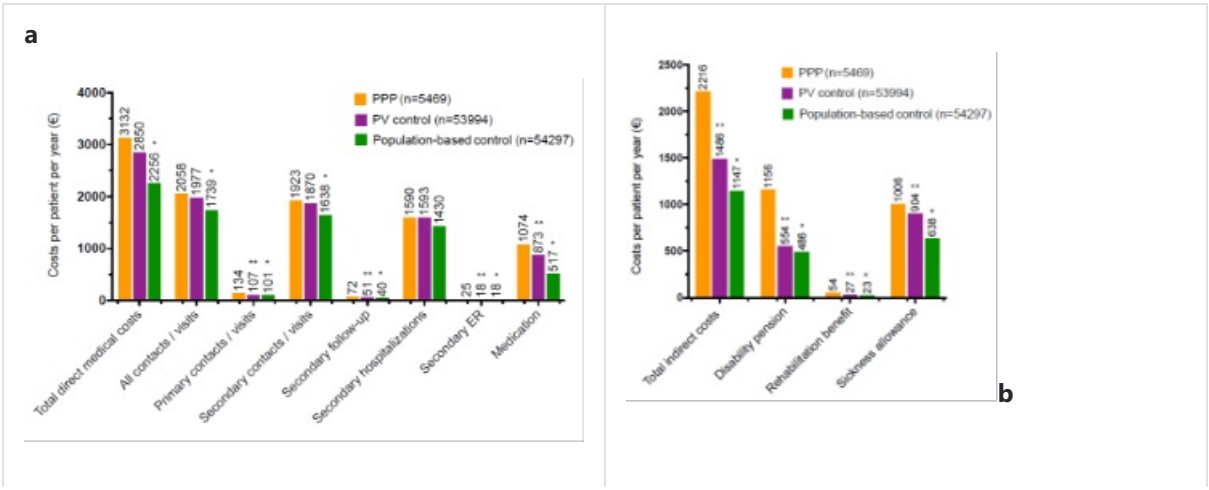


Figure 2: All-cause annual direct (a) and indirect (b) medical costs of PPP patients and matched controls



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Abstract N°: 4470

Thrombospondin-1 Deficient Exacerbates the Pathogenesis of Imiquimod-Induced Psoriasis

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Introduction & Objectives:

Psoriasis is a chronic, relapsing inflammatory skin disorder, characterized by as silver scaling erythematous plaques due to epidermal hyperplasia, aberrant differentiation of keratinocytes, and increased angiogenesis. Thrombospondin-1 (TSP-1) could inhibit angiogenesis in vivo and to suppress vascular endothelial cell proliferation and migration in vitro. TSP-1 has been also described as a key immunoregulatory factor. Interaction of TSP-1 with CD47 promotes the development of regulatory T cells while inhibiting chronic inflammation associated with Th1 or Th17 cells.

Materials & Methods:

IMQ application on wild-type mouse skin induced psoriasis-like reactions, correlating with increased TSP-1 expression. We used TSP-1 to treat imiquimod (IMQ)-induced psoriasis in BALB/C mice and examined the underlying mechanisms.

Results:

Quantitative RT-PCR showed significant elevation of TSP-1 mRNA, peaking at four-fold at 24 hours and remaining elevated over three-fold at 48 and 96 hours before returning to baseline. Immunohistochemistry confirmed heightened TSP-1 expression in epidermal keratinocytes. TSP-1 deficiency exacerbated skin lesions compared to wild-type mice, accompanied by heightened inflammatory cytokines and reduced keratinocyte markers. LSKL treatment worsened lesions and inflammation.

Here we showed that TSP-1 expression is upregulated in skin lesion of IMQ mice model. However, a peptide antagonist of TSP-1, LSKL treated in wild type mice has exacerbated psoriasis-like dermatitis, correlating with increased neovascularization, leukocytes infiltration and IL-17/IL-23 cytokine expression in the skin lesion of IMQ model. In addition, the use of the TSP-mimetic peptide ABT510 drastically reduces psoriasis-like dermatitis and neovascularization in TSP-1-deficient, and wild-type mice

Conclusion:

Our findings underscore TSP-1's pivotal regulatory role in IMQ-induced psoriasiform skin inflammation, thus, wu suggested that TSP-1 may act as an important endogenous negative regulator of psoriasis pathogenesis and may be developed as a novel therapeutic strategy of psoriasis.

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Abstract N°: 4476

Improving the well-being of patients with moderate to severe plaque psoriasis and involvement of impactful areas with Tildrakizumab

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Introduction & Objectives:

The IL23p19 inhibitor Tildrakizumab has been shown to be effective and safe in the treatment of plaque psoriasis in both phase III and real-world evidence studies. The holistic view and the influence of therapy on the well-being of the patient are increasingly coming into focus.

Materials & Methods:

The prospective, multicenter, non-interventional study “TiGER” investigates the influence of Tildrakizumab on the treatment satisfaction and quality of life of patients with plaque psoriasis and involvement of impactful areas. The results of this interim evaluation focus on improving well-being, determined on the basis of the WHO-5 score in patients with involvement of sensitive areas such as scalp, nails, genitals and palmoplantar.

Results:

140 patients were available for this interim analysis, for 123 (87.9%) data at week 28 were available. The average age (MW, mean; SD, standard deviation) is 48 (14.8) years, 65.0% of patients are male.

The WHO-5, the index for well-being, is 45.0 (OC, observed case) and 44.7 (LOCF, last observation carried forward) on a scale of 0-100 at baseline in the study cohort. Over the course of treatment, the WHO-5 improves to 64.3 (OC, LOCF) at week 28. The DLQI at baseline is 14.2 (OC, LOCF) and decreases to 3.8 (OC) and 4.2 (LOCF) at week 28, respectively. The satisfaction score (TSQM) at week 28 is 81,2 (OC) and 81,0 (LOCF) out of 100, respectively. With respect to impactful areas a clear improvement is detected from baseline to week 28; the proportion of patients achieving PGA 0/1 at week 28 is 67,2 %, 81,7 %, 93,1 %, 93,9 % and 92,4 % for total-, scalp-, genital-, nail- and palmoplantar-PGA (all values are OC).

Conclusion:

The results of the interim analysis of the NIS TiGER demonstrate the positive influence of Tildrakizumab on the quality of life and satisfaction of patients. The data of the WHO-5 show very nicely that the well-being of the patients on therapy improves significantly. The patients in the study achieve values similar to the ones described for the healthy population. Treatment with Tildrakizumab is effective on the whole body and in impactful areas, well tolerated and contributes to the well-being of patients.

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Abstract N°: 4517

Multimodal assessments of the treatment response of guselkumab in mild psoriasis patients, an exploratory randomized placebo-controlled clinical trial.

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Introduction & Objectives:

Moderate-to-severe psoriasis are increasingly well-managed as safe and efficacious therapeutics have become readily available. However, this results in fewer patients eligible for clinical trials which negatively impacts the development of new therapies. Mild psoriasis patients are generally not systemically treated and might therefore present a suitable alternative population presuming treatment responses can be demonstrated.

To characterize the treatment effect of guselkumab in mild psoriasis patients with a moderate target plaque.

Materials & Methods:

An exploratory, randomized, double-blind controlled trial was performed in 20 mild and 6 moderate-to-severe patients based on a Psoriasis Area and Severity Index (PASI) of ≤5 and ≥10, respectively. Patients were randomized to standard-of-care Guselkumab 100 mg or placebo (3:1) and treatment response monitored for 24 weeks by clinician-reported outcomes and scoring of a single lesion reinforced with multispectral imaging (MI), optical coherence tomography (OCT) and laser speckle contrast imaging (LSCI) as digitalized endpoints.

Results:

The PASI scores showed a significant decrease in clinical scoring compared to placebo in both the mild ($p=0.009$) and moderate-to-severe treatment group ($p<0.0001$). Focusing on a single target lesion, target severity scores significantly decreased during treatment ($p<0.004$) with objective modalities demonstrating concomitant significant decreases in erythema ($p<0.009$) in MI, cutaneous perfusion ($p<0.001$) in LSCI and epidermal thickness ($p<0.002$) in OCT, in both guselkumab-treated groups.

Conclusion:

Total body clinical scoring and target lesion monitoring enable the detection of a treatment effect in mild psoriasis patients. Although this trial was not powered to demonstrate equivalence between severity groups, results indicate treatment responses follow the same trend in mild and moderate-to-severe patients.

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Abstract N°: 4532

Comparing Clinical Assessment with Microscopic Anatomy in Psoriasis: Towards Personalized Treatment

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Introduction & Objectives:

Psoriasis is typically clinically diagnosed through clinical inspection by dermatologists, who assess the skin for signs such as erythema, induration, and scaling. A good diagnosis is important for effective treatment. Effective treatment can be accomplished by implementation of personalized treatment of psoriasis. Personalized treatment is not the standard in psoriasis treatment. To progress in the personalization of treatment strategies, it is essential to retrieve as much as information as possible from the skin to assess which treatment would be most optimal. However, it is unknown if clinical inspection is a good indicator of the anatomical structures within the skin. The objective of this study was to check the correlation between the observations by the dermatologist and the actual anatomy of psoriatic skin, as observed under the microscope.

Materials & Methods: 23 patients with psoriasis lesions underwent clinical inspection for erythema, induration, and scaling. Additionally, patient data, including itch perception, smoking status, age, BMI, and plaque location were collected. Using sectioned skin biopsies, volumes of blood vessels and nerve fibers in the epidermis, papillary dermis, and reticular dermis were calculated from 3D microscopy images. Epidermal and scaling thickness (µm) were also measured in these images. Anatomical data obtained from microscopy images was then compared to the clinical parameters.

Results: We have provided extensive neuro-vascular anatomical 3D microscopy images of a large group of psoriatic plaques showing the variability in morphologies between patients **(Fig 1).** Using these images we found a significant correlation ($p<0.05$) between the clinical observation scores of induration and scaling with the microscopy-based measurements of epidermal thickness and scaling, respectively **(Fig. 2).** There was no significant correlation between erythema score and blood vessel volume (papillary-, superficial and reticular dermis-, and total vascular volume, %). We also did not see a correlation between perceived itch score and nerve fiber volume (epidermal-, perivascular-, reticular dermis-, and total nerve fiber volume, %). The location of the biopsy, age, BMI, or smoking status did not correlate to the vascular or nerve fiber volumes in the skin.

Conclusions: Clinical inspection of psoriatic lesions only partially aligns with histological features of thickness and scaling but does not correspond to the neuro-vascular anatomy of the skin.

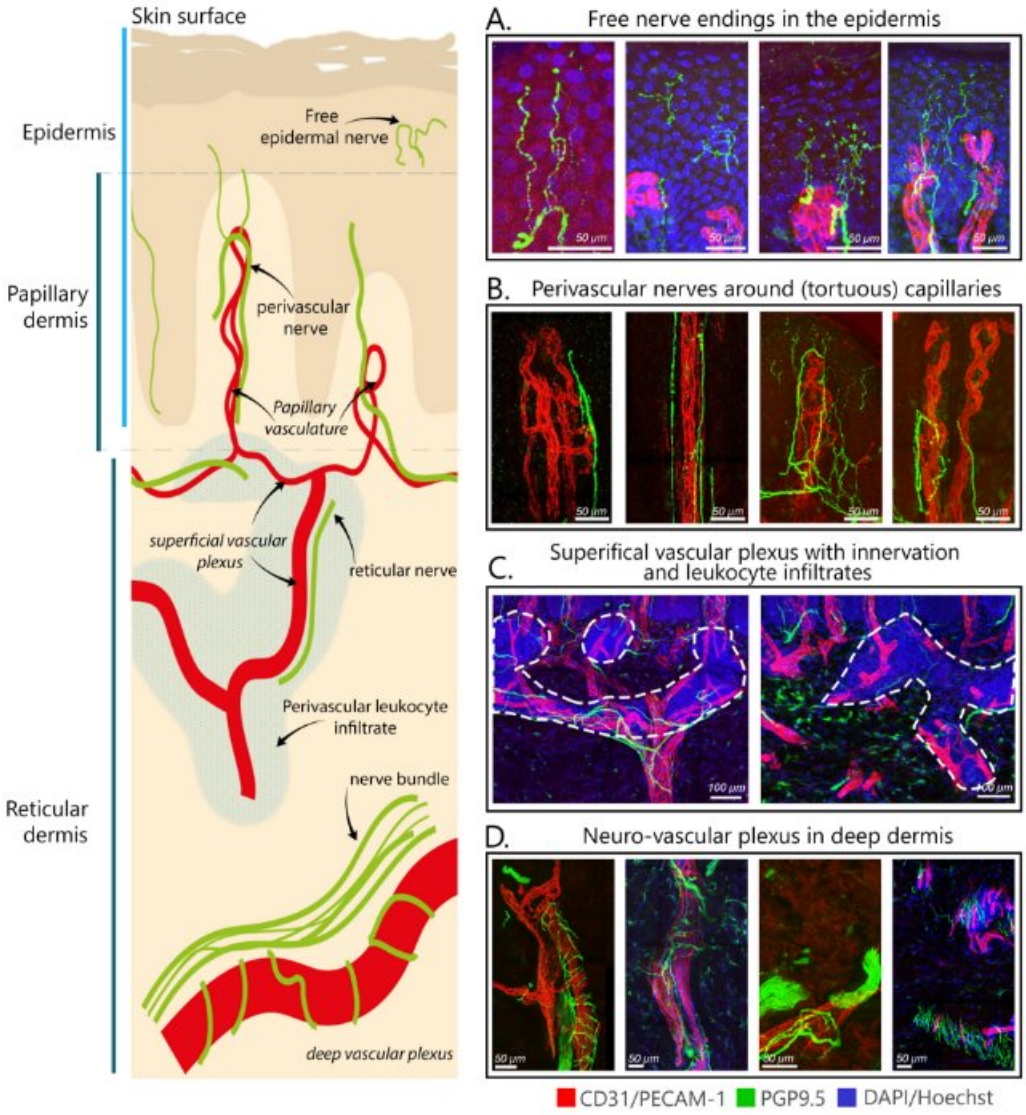

Figure 1 Histopathological characteristics of the neurovascular anatomy in psoriatic skin. Panel A) shows epidermal free nerve endings (PGP9.5+, green) with various branching complexities between patients. Panel B) shows the capillaries (CD31+, red) from different patients that vary in tortuosity and also in the density of perivascular nerves (green). Panel C) shows the horizontal sub-epidermal plexi of supplying (innervated) blood vessels and dense (blue) clouds of nuclei surrounding the vasculature (perivascular leukocyte infiltrates, DAPI). Panel D) shows the blood vessels in the deep dermis, which are highly innervated with thin nerve fibers and nerve bundles running in similar directions. Scale bar indicates 50 µm in A, B, D, and 100 µm in C. Images are depicted as maximal intensity projections of ~70 µm. The blue channel was excluded from certain panels to enhance clarity.

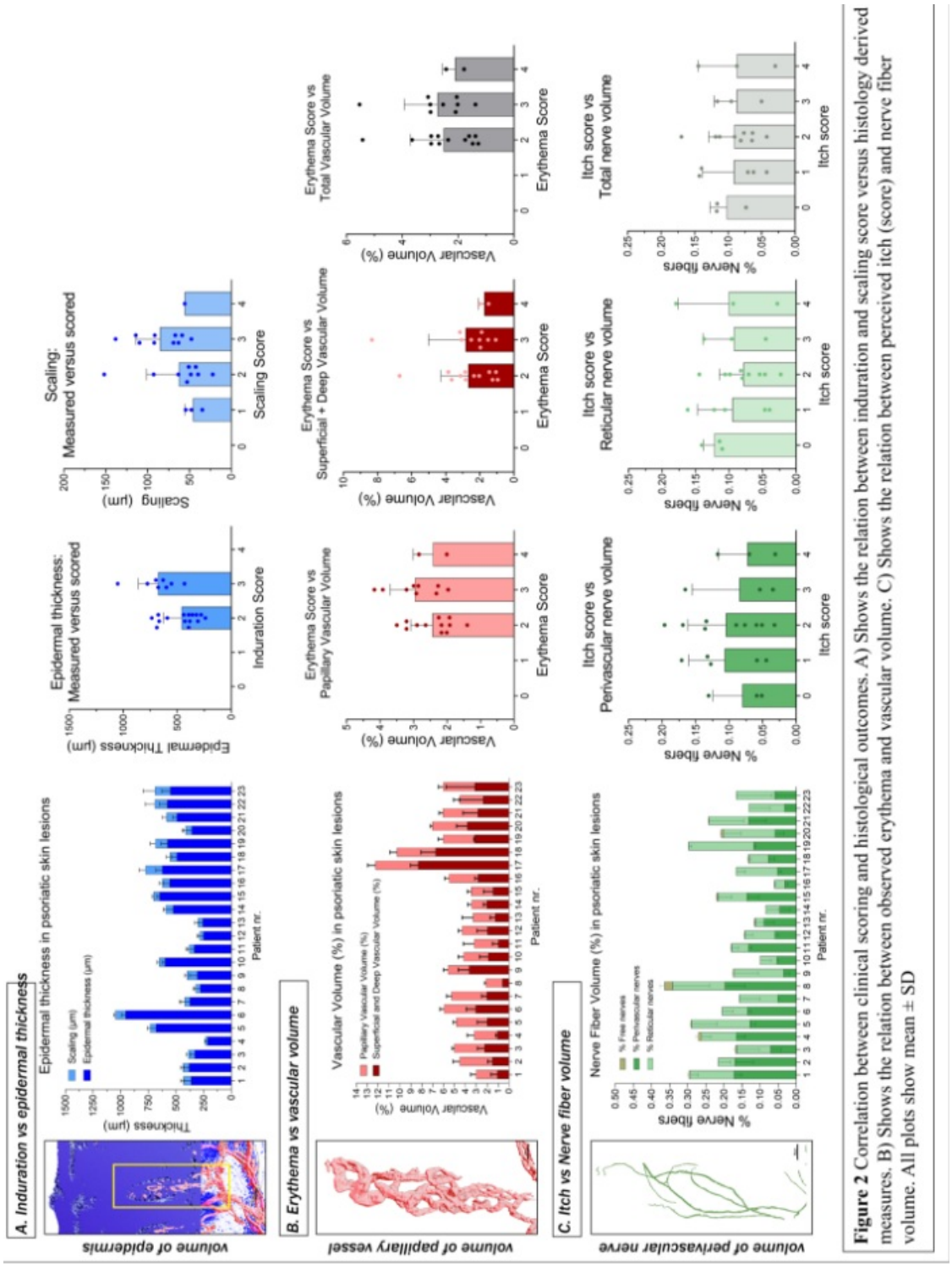

Figure 2 Correlation between clinical scoring and histological outcomes. A) Shows the relation between induration and scaling score versus histology derived measures. B) Shows the relation between observed erythema and vascular volume. C) Shows the relation between perceived itch (score) and nerve fiber volume. All plots show mean ± SD

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Abstract N°: 4572

Successful management of psoriasis in a patient with HIV using risankizumab

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Introduction & Objectives:

Biologic therapies are the gold standard in the treatment of plaque psoriasis. Risankizumab is an anti-Il-23 antibody that has a favorable safety profile compared to conventional systemic treatments. Human immunodeficiency virus (HIV) infection impairs immune function and predisposes people to opportunistic infections and neoplastic processes, as well as exacerbation of immune-mediated diseases, such as psoriasis. There is still very little data on the use of biologics in the HIV population. We report the case of a patient with HIV, previous HBV infection and plaque psoriasis treated with risankizumab.

Materials & Methods:

A 52-year-old man presented with an exacerbation of psoriasis, that he has had for 10 years. He was first diagnosed with HIV more than 10 years ago and had been treated with antiretroviral therapy (ART) since then. At the time of presentation, he was receiving a combination of emcitrabine, tenofovir and bictegravir. He also had a known previous HBV infection. The patient has cardiovascular comorbidities, previous myocardial infarction, arterial hypertension, hyperholesterolemia, obesity. Erythematosquamous plaques were present on the extensor sides of the lower and upper limbs, dorsal to the hands and periungually. The nails had foveoles and oil stains. The PASI score at presentation was 14.2, the BSA 12% and the DLQI 21.

The family history of psoriasis was positive.

The HIV viral load was undetectable and the CD4+ count was normal. In consultation with the treating infectiologist, we decided to introduce risankizumab in the standard dosage for plaque psoriasis.

Results:

At the 4-month follow-up, the absolute PASI score was 0, indicating a complete response. DLQI was 0. The patient reported no adverse effects and the virus remained undetected. After 12 months of treatment, the skin is still clear of psoriasis, with no reported issues.

The treatment of psoriasis in HIV-infected individuals presents a unique challenge characterized by a more severe course of the disease and limited treatment possibilities. Although conventional systemic therapies can be considered, these agents are immunosuppressive, which complicates their use in people with HIV. Biologics are commonly used in people with moderate to severe psoriasis, but data on efficacy and safety in HIV patients are very limited as this patient group is usually excluded from clinical trials. Risankizumab is a selective IL-23 inhibitor with a favorable safety profile and high efficacy in long-term studies and in clinical practice. This current case report presents a HIV- infected individual, plaque psoriasis and multiple comorbidities who was successfully treated with risankizumab with no safety issues reported.

Conclusion:

Although there is limited data on the use of biologics in HIV patients, this case suggests that IL-23 inhibitors may be a valuable therapeutic option for this patient group.

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Abstract N°: 4574

Burden of palmoplantar pustulosis in adults – findings from the Danish Skin Cohort

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Introduction & Objectives:

Palmoplantar pustulosis (PPP) is a chronic relapsing skin disorder characterized by recurrent sterile pustules on an erythematous and desquamative background, located on palms and/or soles. Despite significant impact on patients' quality of life, studies on the burden of PPP are limited with existing studies on PPP primarily being based on registry-based data, necessitating a deeper exploration of the burden of PPP and the impact on affected individuals utilizing patient-reported data to gain better insight into patient perspectives and thus the real burden of this disease. This approach is crucial for developing improved and more patient-centered treatment strategies tailored to the unique challenges faced by individuals with PPP.

This study aimed to investigate the burden of PPP in Denmark using data from the Danish Skin Cohort.

Materials & Methods:

Data were sourced from the Danish Skin Cohort, a prospective injection cohort initiated in 2018 to examine the natural history of skin diseases in Denmark. Participants included individuals with a dermatologist-verified diagnose of psoriasis vulgaris, with a subset having concurrent PPP. Surveys captured demographic information, lifestyle factors, and disease-specific characteristics and burden measures. Statistical analyses compared disease characteristics and burden among psoriasis subgroups; "Psoriasis + PPP", "Psoriasis w/o PPP", "Palmoplantar psoriasis", "Palmar psoriasis", and "Plantar psoriasis", as well as the general population.

Results:

Among study participants, 4.4% (n=129) had current PPP alongside psoriasis. Demographic analysis revealed a median age of 59.5 (SD 10.6) years and a female predominance (60.5%) in the Psoriasis + PPP patient group. Disease characteristics and burden, including disease activity defined as flares in the last 12 months (20.2% vs 9.3% with >10 flares), joint pain (median 5 [IQR 2-7] vs 3 [IQR 1-6], NRS 0-10), skin pain (median 3 [IQR 0-5] vs 1 [IQR 0-3], NRS 0-10), itch (mean 4.3 [SD 2.95] vs 2.87 [SD 2.67], NRS 0-10), and trouble sleeping (mean 4.20 [SD 2.95] vs 3.04 [SD2.78], NRS 0-10) were substantially worse in the Psoriasis + PPP group compared to patients with Psoriasis w/o PPP. Furthermore, scores for disease impact on quality of life measured as DLQI (median 4 [IQR 2-8] vs 2 [IQR 1-5] and 0 [IQR 0-1]), as well as mental health measured using HADS anxiety scale (median 5 [IQR 2-9] vs. 4 [IQR 1-7] and 4 [IQR 1-7]) were higher for patients in the Psoriasis + PPP group than that of patients in the Psoriasis w/o PPP group and general population.

Conclusion:

Our findings underscore the considerable burden of PPP, emphasizing the need for improved diagnostic and treatment strategies tailored to the unique challenges faced by individuals with PPP. This study contributes valuable insights into the disease burden of PPP, which can inform future research and clinical management approaches.

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Abstract N°: 4582

Assessing postoperative complication risk in patients with psoriasis who undergo Mohs micrographic surgery

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Introduction & Objectives:

Patients affected with psoriasis have been shown to be at increased risk of developing both melanoma and non-melanoma skin cancer (NMSC) including squamous cell carcinoma and basal cell carcinoma. Given increased incidence rates of psoriasis, such patients are more likely to undergo skin cancer removal. Despite this increased risk, there is scant literature evaluating post-operative outcomes in patients with psoriasis who undergo Mohs micrographic surgery (MMS). Using the TriNetX US Collaborative Network (55 healthcare organizations),we sought to evaluate the postoperative complication risk in psoriasis patients undergoing MMS.

Materials & Methods:

We identified patients using current procedural terminology (CPT) and International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) codes. Cohorts were stratified by pre-existing psoriasis prior to undergoing mohs surgery. Using a greedy nearest neighbor algorithm, cohorts were 1:1 propensity-matched for age at index, race, ethnicity and potential confounding covariates including diabetes mellitus, nicotine dependence, personal history of irradiation, glucocorticoids, platelet aggregation inhibitors, anticoagulants, immunosuppressants. Index dates were defined as the first instance of MMS in both the exposure and control cohorts. 30-day Cox Proportional Hazards Models with 95% confidence intervals were generated to evaluate the risk of short-term postoperative complications following MMS.

Results:

Following propensity score matching analysis, we identified 8,242 patients with psoriasis matched well with 8,242 controls. Patients with psoriasis were at a significantly increased risk for postoperative complications from Mohs micrographic surgery for infections of skin and subcutaneous tissue (hazard ratio (HR) [95% CI] = 1.31 [1.05, 1.64); hemorrhage (HR [95% CI] = 3.44 [2.95, 4.01]); generalized muscle weakness (HR [95% CI] = 1.96 [1.15, 3.36]); anesthesia of skin (HR [95% CI] = 1.96 [1.55, 2.47]), paresthesia of skin (HR [95% CI] = 2.65 [1.84, 3.83]); rash and other nonspecific skin eruption (HR [95% CI] = 3.68 [2.94, 4.60]); localized swelling, mass, and lump of skin and subcutaneous tissue (HR [95% CI] = 1.79 [1.33, 2.41]); acute postprocedural pain (HR [95% CI] = 2.24 [1.43, 3.53]); pruritus (HR [95% CI] = 3.36 [2.51, 4.51]); hypertrophic scar (HR [95% CI] = 1.67 [1.07, 2.63). We found no increased risk for cellulitis/lymphangitis (HR [95% CI] = 1.05 [0.74, 1.50]) and complications of skin graft (HR [95% CI] = 2.56 [0.91, 7.17]).

Conclusion:

Our findings suggest that patients with psoriasis are at increased risk for acute post-MMS complications. This study may allow Mohs micrographic surgeons to give patients with psoriasis better counseling on the risks of MMS and may increase the postoperative follow-up frequency for these patients.

Supplementary Table. Baseline demographic characteristics of psoriasis and control patients who were treated with Mohs micrographic surgery after propensity score matching.

Characteristic	Psoriasis (n = 8,242)	Control (n = 8,242)	*p-value*
Age at index, mean (SD), y	69.08 (11.52)	69.18 (11.48)	0.58
Sex			
Female	3565 (43.25%)	3566 (43.27%)	0.99
Male	4677 (56.75%)	4674 (56.71%)	0.96
Ethnicity			
Hispanic or Latino	110 (1.34%)	96 (1.17%)	0.33
Not Hispanic or Latino	7540 (91.48%)	7581 (91.98%)	0.25
Race			
White	7752 (94.06%)	7806 (94.71%)	0.07
Black or African American	15 (0.18%)	13 (0.16%)	0.71
Comorbidities			
Diabetes mellitus	2457 (29.81%)	2442 (29.63%)	0.80
Nicotine dependence	1426 (17.30%)	1409 (17.10%)	0.73
Personal history of irradiation	220 (2.67%)	213 (2.58%)	0.73
Glucocorticoids	6134 (74.42%)	6189 (75.09%)	0.32
Platelet aggregation inhibitors	4046 (49.09%)	4093 (49.66%)	0.46
Anticoagulants	2800 (33.97%)	2834 (34.39%)	0.58
Immunosuppressants	2238 (27.15%)	2185 (26.51%)	0.35

Table 1. Risk of postoperative complication development in psoriasis patients who undergo Mohs micrographic surgery.

	Psoriasis w/ Mohs	Control w/ Mohs	
Outcome	**Number of eligible individuals[a] (No. of outcomes, 30 days)**	**Number of eligible individuals[a] (No. of outcomes, 30 days)**	**Hazard Ratio (95% CI)**
Cellulitis and acute lymphangitis	8,242 (63)	8,242 (59)	1.05 (0.74, 1.50)
Infections of skin and subcutaneous tissue	8,242 (178)	8,242 (134)	1.31 (1.05, 1.64)
Hemorrhage	8,242 (713)	8,242 (212)	3.44 (2.95, 4.01)
Generalized muscle weakness	8,242 (40)	8,242 (20)	1.96 (1.15, 3.36)
Anesthesia of skin	8,242 (211)	8,242 (107)	1.96 (1.55, 2.47)
Paresthesia of skin	8,242 (105)	8,242 (39)	2.65 (1.84, 3.83)
Rash and other nonspecific skin eruption	8,242 (359)	8,242 (98)	3.68 (2.94, 4.60)
Localized swelling, mass, and lump of skin and subcutaneous tissue	8,242 (123)	8,242 (68)	1.79 (1.33, 2.41)
Acute postprocedural pain	8,242 (61)	8,242 (27)	2.24 (1.43, 3.53)
Complications of skin graft	8,242 (13)	8,242 (10)	2.56 (0.91, 7.17)
Pruritus	8,242 (196)	8,242 (58)	3.36 (2.51, 4.51)
Hypertrophic scar	8,242 (51)	8,242 (30)	1.67 (1.07, 2.63)

[a]All patients with the clinical outcome of interest prior to the index date were excluded.

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Abstract N°: 4663

Long-term Risankizumab Efficacy for Moderate-to-Severe Plaque Psoriasis in Patients with Prior Biologic Treatment from the LIMMitless Study

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Introduction & Objectives: Moderate-to-severe plaque psoriasis (PsO) is a chronic inflammatory disease that requires long-term management. Patients (pts) on biologic treatment often switch between therapies to maintain clinical response over the course of disease. Risankizumab (RZB) is an IL-23 inhibitor targeting the p19 subunit with high affinity and specificity approved to treat PsO, psoriatic arthritis and Crohn's disease. Using data from the open-label extension (OLE) LIMMitless trial, we previously reported that 84.2% (95% CI; 80.7, 87.7) of pts with prior biologic treatment and 81.7% (95% CI; 72.7, 90.7]) of pts with prior biologic treatment failure achieved a ≥90% improvement in Psoriasis Area and Severity Index (PASI 90) through Week 256 of continuous RZB treatment (44102 Crowley et al. *JAAD*, Vol 89, Issue 3, AB82). Here, efficacy of RZB in pts with a history of prior biologic use and/or failure are reported from LIMMitless through Week 304, the final analysis.

Materials & Methods: LIMMitless (NCT03047395) was a phase 3b single arm, OLE study investigating the efficacy of RZB in pts with PsO who completed a preceding phase 2/3 randomized clinical trial. This analysis includes pts initially randomized to receive RZB 150 mg at Weeks 0, 4, and q12w thereafter in the double-blinded, placebo-controlled phase 3 UltIMMa1(NCT02684370) and UltIMMa2 (NCT02684357) trials. Upon completion, eligible pts were able to enroll in LIMMitless, receiving open-label RZB 150mg q12w through Week 304. Among pts with self-reported prior biologic treatment or failure, efficacy was assessed as proportions of pts achieving PASI 90 and PASI 100; missing data were imputed by modified non-responder imputation (mNRI) and observed cases (OC). Non-response was imputed only for treatment failure defined as pts who had worsening of PsO. Safety for LIMMitless has been previously reported.

Results: Among pts initially randomized to RZB, 418/525 (79.6%) [mNRI] and 304/374 (81.3%) [OC] had received prior biologic treatment, and 71/525 (13.5%) [mNRI] and 49/374 (13.1%) [OC] had failed prior biologic treatment.

PASI 90 was achieved by 85.4% (95% CI: 82.0, 88.8) [mNRI] and 87.2% (95% CI: 83.4, 90.9)[OC] of pts with prior biologic treatment at Week 304. PASI 90 was achieved by 84.9% (95% CI: 78.4, 91.3)[mNRI] and 81.9% (95% CI: 73.6, 90.2)[OC] of pts with prior exposure to anti-TNFs, and 80.0% (95% CI: 72.0, 88.0)[mNRI] and 80.3% (95% CI: 71.0, 89.5)[OC] of pts with prior exposure to IL-17 inhibitors. Among pts with prior biologic treatment failure, 81.7% (95% CI: 72.7, 90.7)[mNRI] and 77.6%(95% CI: 65.9, 89.2)[OC] achieved PASI 90.

PASI 100 was achieved by 57.4% (95% CI: 52.7, 62.2)[mNRI] and 64.5% (95% CI: 59.1, 69.9)[OC] of pts with prior biologic treatment at Week 304. PASI 100 was achieved by 44.5% (95% CI: 35.6, 53.5)[mNRI] and 49.4% (95% CI: 38.6, 60.2)[OC] of pts with prior exposure to anti-TNFs, and 50.5% (95% CI: 40.5, 60.6)[mNRI] and 56.3% (95% CI:

44.8, 67.9)[OC] of pts with prior exposure to IL-17 inhibitors. Among pts with prior biologic treatment failure, 39.4% (95% CI: 28.1, 50.8)[mNRI] and 46.9% (95% CI: 33.0, 60.9)[OC] achieved PASI 100 at Week 304.

Conclusion: Consistently high proportions of pts with prior biologic exposure continue to achieve high rates of clear or almost clear skin with continuous RZB treatment through Week 304. Long-term efficacy of continuous RZB was demonstrated in this population, regardless of prior biologic therapy or patient-reported biologic therapy failure.

Table. Long-term efficacy response to RZB treatment in patients with prior biologic exposure

Responses	RZB 150 mg	
	mNRI	OC
PASI 90, % (95% CI)		
Prior biologic treatment	85.4 (82.0, 88.8)	87.2 (83.4, 90.9)
n/N	357/418	265/304
Prior exposure to anti-TNF	84.9 (78.4, 91.3)	81.9 (73.6, 90.2)
n/N	101/119	68/83
Prior exposure to IL-17 inhibitor	80.0 (72.0, 88.0)	80.3 (71.0, 89.5)
n/N	76/95	57/71
Prior biologic treatment failure	81.7 (72.7, 90.7)	77.6 (65.9, 89.2)
n/N	58/71	38/49
PASI 100, % (95% CI)		
Prior biologic treatment	57.4 (52.7, 62.2)	64.5 (59.1, 69.9)
n/N	240/418	196/304
Prior exposure to anti-TNF	44.5 (35.6, 53.5)	49.4 (38.6, 60.2)
n/N	53/119	41/83
Prior exposure to IL-17 inhibitor	50.5 (40.5, 60.6)	56.3 (44.8, 67.9)
n/N	48/95	40/71
Prior biologic treatment failure	39.4 (28.1, 50.8)	46.9 (33.0, 60.9)
n/N	28/71	23/49

RZB, risankizumab; mg milligram; PASI, psoriasis area and severity index; mNRI, modified non-responder imputation; OC, observed cases; CI, confidence interval; TNF, tumor necrosis factor

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Abstract N°: 4697

Bimekizumab PASI response levels in Week 16 PASI 100 responders with moderate to severe plaque psoriasis through 4 years: Results from BE BRIGHT

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Introduction & Objectives:

Loss of response to biologic therapies is often seen over time in psoriasis; it is important to study long-term efficacy of treatments to determine if responses are maintained throughout long-term management. Bimekizumab (BKZ) has demonstrated high levels of complete skin clearance (100% improvement from baseline in Psoriasis Area and Severity Index; PASI 100) through 4 years in patients with moderate to severe plaque psoriasis, with low drop-off in response rates over time.1

Here, we follow patients who achieved PASI 100 after 4 months (16 weeks) of treatment through 4 years. We report the proportion maintaining the stringent skin clearance outcome PASI 100, alongside the proportions of patients maintaining ≥90% improvement from baseline in PASI (PASI 90) and ≥75% improvement from baseline in PASI (PASI 75), to help understand the magnitude of any fluctuations in their symptoms.

Materials & Methods:

Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 trials, and their open-label extension (OLE), BE BRIGHT.2–5 Included patients were randomised to receive BKZ 320 mg every 4 weeks (Q4W) to Week 16, then received BKZ Q4W or every 8 weeks (Q8W) in the maintenance period and OLE. All patients received BKZ Q8W from OLE Week 48 (Week 100/104) or the next scheduled clinic visit.

PASI 100, PASI 90, and PASI 75 responses are reported in Week 16 PASI 100 responders over 4 years. Data are reported regardless of dosing regimen (BKZ Total), and for the subset of patients who received BKZ Q4W to Week 16 then Q8W continuously into the OLE (Q4W/Q8W; the approved dosing regimen for most patients with psoriasis).6 Responses are reported using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. Observed case results are also reported in the **Figure**.

Results:

Of the 620 BKZ patients who achieved PASI 100 at Week 16, 503 (81.1%) continued on BKZ treatment and entered

the OLE (BKZ Total); 147 of these patients received BKZ Q4W/Q8W.

For the BKZ Total group, high proportions of Week 16 PASI 100 responders maintained PASI 100 to Year 1 (89.3%) and through to Year 4 (73.0%; **Figure**). The vast majority maintained PASI 90 at Year 1 (98.2%) and through to Year 4 (89.3%; **Figure**). Almost all achieved PASI 75 at Year 1 (99.2%) and maintained this through to Year 4 (96.2%; **Figure**).

In the subgroup who received BKZ Q4W/Q8W, PASI 100/90/75 responses were similarly high at Year 1 (93.6%/99.3%/100%) and Year 4 (76.7%/88.1%/95.2%; **Figure**).

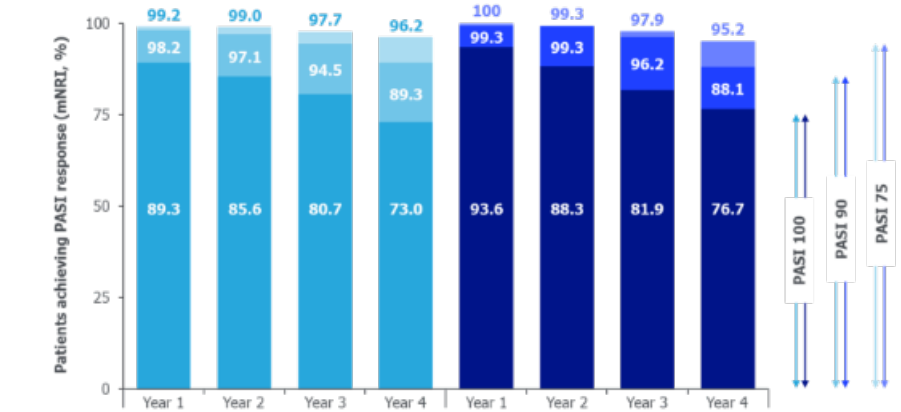
Conclusion:

High proportions of BKZ-treated patients who achieved complete skin clearance (PASI 100) at 4 months (16 weeks) maintained this response through 4 years. Of those who did not, the vast majority maintained PASI 90; almost all patients maintained at least PASI 75 over 4 years.

References:

1. Blauvelt A. Presented AAD 2024, P52661; **2.** Reich K. Lancet 2021;397:487–98, NCT03370133; **3.** Warren RB. N Engl J Med 2021;385:130–41, NCT03412747; **4.** Gordon KB. Lancet 2021;397:475–86, NCT03410992; **5.** Strober B. Br J Dermatol 2023;188:749–59, NCT03598790; **6.** Bimekizumab Summary of Product Characteristics. 2023. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed April 2024].

Figure. PASI Response in Week 16 PASI 100 Responders



OC, n/N_{obs}	BKZ Total				BKZ Q4W/Q8W			
PASI 75	494/495	465/465	446/448	408/411	146/146	137/137	130/131	116/117
PASI 90	489/495	457/465	435/448	387/411	145/146	137/137	129/131	109/117
PASI 100	447/495	414/465	385/448	332/411	137/146	125/137	114/131	100/117

For mNRI, patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. Patients who entered the BE READY escape arm were considered as non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE.[4] Year 1 data were recorded at Week 52; Year 2 data were recorded at Week 100/104 (OLE Week 48), Year 3 data at Week 148/152 (OLE Week 96), and Year 4 data at Week 196/200 (OLE Week 144), depending on feeder study length. BKZ: bimekizumab; mNRI: modified non-responder imputation; N_{obs}: observed N; OC: observed case; PASI: Psoriasis Area and Severity Index; PASI 75/90/100: ≥75%/≥90%/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks.

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Abstract N°: 4701

Bimekizumab: Exploring the fast onset, high level, and durability of clinical and molecular responses in patients with psoriatic disease – Design and rationale behind the exploratory, multicentre, open-label phase 3b BE UNIQUE study

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Introduction & Objectives:

Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17A and IL-17F, pivotal drivers in psoriasis pathogenesis.1 BKZ has demonstrated rapid, superior efficacy vs comparators in multiple phase 3/3b studies in patients with moderate to severe plaque psoriasis, with durable clinical responses.2–6

BKZ has shown rapid normalisation of the psoriatic skin transcriptome and tissue-resident memory T cell signatures by Week 8, which may promote clinical response durability.7,8 Questions remain on the very early and longer-term effects of BKZ on key inflammatory pathways and mechanisms behind observed clinical responses in psoriatic disease. We describe a study designed to investigate molecular/cellular changes associated with BKZ responses in patients with psoriasis and psoriatic arthritis (PsA); we hypothesise that fast and durable complete normalisation of inflammatory gene expression biomarkers correlates with rapid, high, and durable clinical responses.

Materials & Methods:

BE UNIQUE is an ongoing multicentre phase 3b study enrolling 40 adults without concomitant PsA (Cohort A) and 40 with concomitant active PsA (Cohort B). Patients in both cohorts have moderate to severe psoriasis, defined as Psoriasis Area and Severity Index (PASI) ≥12, body surface area (BSA) ≥10%, and Investigator's Global Assessment (IGA) ≥3. PsA is defined as disease meeting Classification Criteria for Psoriatic Arthritis (CASPAR), ≥1 tender joint count, and ≥1 swollen joint count (SJC).

In Part 1, patients will receive BKZ 320 mg every 4 weeks (Q4W) to Week 16, then Q8W to Week 48. In Part 2 (Weeks 48–96), patients with PASI=0 (and low PsA activity for Cohort B) will be randomised 1:1 to BKZ Q8W or Q12W; patients with PASI >0 and/or without low PsA activity will continue on BKZ Q8W (**Figure**). Lesional skin biopsies will be taken at baseline, Week 1, 48, and 96. Non-lesional skin biopsies will be taken at baseline and Week 48. Synovial tissue biopsy will be optional for Cohort B at baseline and Week 48. Biopsies will undergo transcriptomics. Blood samples will be collected.

Baseline skin biopsies and blood samples will be taken from a matching Control Cohort of 10 healthy individuals.

Results:

The primary objective is to assess change in gene expression score using reverse transcription-polymerase chain reaction of skin biopsies, using preselected genes based on BKZ mechanism of action and psoriatic disease pathways. The secondary objective is evaluation of BKZ safety/tolerability.

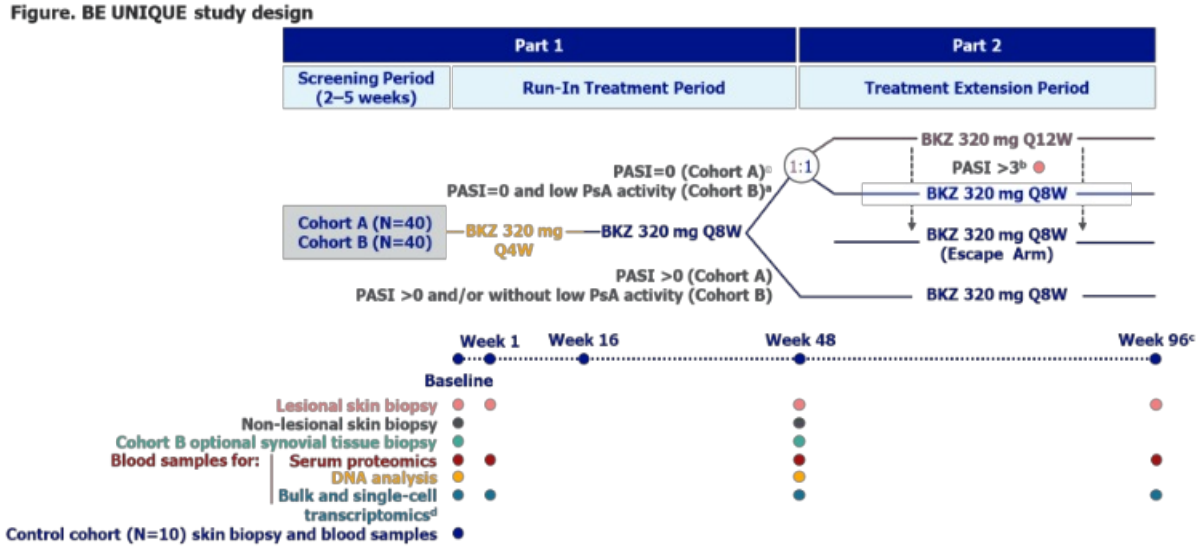
Exploratory objectives include investigating the effect of BKZ on skin and blood bulk, single cell, and spatial transcriptomics. Systemic effects of BKZ on gene and protein expression, and BKZ clinical response, will be assessed.

Conclusion:

BE UNIQUE will enable exploration of mechanisms underlying the rapid, high, durable clinical responses observed with BKZ treatment, and analysis of whether clinical response durability is associated with molecular/cellular changes in skin, blood, and joints of patients with psoriatic disease.

References:

Figure. BE UNIQUE study design



[a] In addition to PASI=0, Cohort B patients must have low PsA disease activity at Week 48 (SJC ≤1 and no increase in concomitant medications for the treatment of PsA symptoms compared with baseline) to enter the Randomised Treatment Extension Period; [b] Patients in Cohort A and Cohort B who have a PASI score >3 during the Randomised Treatment Extension Period will enter an Escape Treatment Period and receive BKZ Q8W to study end, undergoing additional assessments; a lesional skin biopsy will be taken at the visit the patient has a PASI score >3, instead of at Week 96; [c] The safety follow-up visit will occur at least 12 weeks after the final dose and not before 4 weeks after the last skin biopsy; [d] Blood samples for single-cell transcriptomics will be collected from the subset of Cohort A and B patients from whom 6 mm skin biopsies are collected (3 mm or 6 mm skin biopsies will be possible) and from all Control Cohort participants. Blood samples for bulk transcriptomics will be collected from all study participants except the subset of Cohort A and B patients who undergo blood sampling for single-cell transcriptomics. BKZ: bimekizumab; DNA: deoxyribonucleic acid; PASI: Psoriasis Area and Severity Index; PsA: psoriatic arthritis; Q4W: every 4 weeks; Q8W: every 8 weeks; Q12W: every 12 weeks; SJC: swollen joint count.

1. Adams R. Front Immunol 2020;11:1894; **2.** Warren RB. N Engl J Med 2021;385:130–41, NCT03412747; **3.** Reich K. N Engl J Med 2021;385:142–52, NCT03536884; **4.** Reich K. Lancet 2021;397:487–98, NCT03370133; **5.** Gordon KB. Lancet 2021;397:475–86, NCT03410992; **6.** Strober B. Br J Dermatol 2023;188:749–59, NCT03598790; **7.** Oliver R. Br J Dermatol 2022;186:652–63, NCT03025542; **8.** Cutcutache I. Presented at ISDS 2023

EA DV CONGRESS
AMSTERDAM 25-28 SEPTEMBER 2024
EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 4711

Characterization of ORKA-001, a Novel Extended Half-life Monoclonal Antibody Targeting IL-23 for the Treatment of Psoriasis

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Introduction & Objectives:

Interleukin 23 (IL-23) is a proinflammatory cytokine that helps to maintain and activate T helper 17 (Th17) cells, the primary pathogenic cells in psoriasis. IL-23 plays a key role in the pathogenesis of psoriasis, as indicated by the association between the disease and mutations in components of the IL-23 signaling pathway, such as *IL23R*. Antagonism of the p19 subunit of IL-23 (IL-23p19) has proven to have robust efficacy and a favorable safety profile in the treatment of psoriasis. ORKA-001 is a novel, extended half-life, humanized IgG1 monoclonal antibody that binds IL-23p19. ORKA-001 has been engineered to have optimized properties with the aim of delivering an enhanced clinical profile compared to current treatments for psoriasis.

Materials & Methods:

ORKA-001 was evaluated in multiple *in vitro* and *ex vivo* assays in comparison to two benchmark antibodies that target IL-23p19: risankizumab (RIS) and guselkumab (GUS). Binding affinity to IL-23 was determined by surface plasmon resonance (SPR). Antagonism of human IL-23 signaling was evaluated via assays measuring STAT3 activity in cell lines. Inhibition of IL-23-induced IL-17 secretion was assessed using *in vitro* cellular assays, including in human peripheral blood mononuclear cells (PBMC). Half-life extension was measured via pharmacokinetic (PK) analysis in cynomolgus monkeys dosed with a single bolus of ORKA-001.

Results:

ORKA-001 binds specifically to human IL-23 with an affinity below 20pM. It potently inhibits STAT3 activity in cell lines and IL-17 secretion in IL-23-stimulated human PBMC. IL-23 binding affinity and functional potencies for IL-23 antagonism are comparable to or better than those of RIS and GUS. The half-life of ORKA-001 is significantly extended in cynomolgus monkeys compared to both RIS and GUS. Based on allometric scaling of the clearance of ORKA-001 observed in this study, predictive simulations of ORKA-001 PK in humans suggest that subcutaneous maintenance dosing every six to twelve months could be achieved while maintaining high antibody exposures.

Conclusion:

ORKA-001 exhibits high selectivity and affinity for IL-23 *in vitro*, potent inhibition of downstream cellular signaling *ex vivo*, and an extended half-life in non-human primates compared to RIS and GUS. Both affinity and antibody exposure have been shown to have a positive correlation with efficacy in psoriasis, and ORKA-001 has the potential to exceed RIS and GUS on both metrics while requiring significantly fewer doses per year. In total, these data provide preclinical evidence of ORKA-001's clinical potential to improve upon currently available therapies for psoriasis. Clinical studies are warranted to demonstrate this potential.

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Abstract N°: 4715

Exploratory Exposure Response (E-R) Analysis of ESK-001, An allosteric oral TYK2 inhibitor, in Patients with Psoriasis

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Introduction & Objectives: ESK-001** is a highly selective, oral, allosteric inhibitor of tyrosine kinase 2 (TYK2) that targets cytokine-mediated signaling in psoriasis (PsO) and other immune-mediated diseases. ESK-001 was tested in multiple Phase 1 trials and in a Phase 2 program in psoriasis consisting of a 12-week, randomized, placebo-controlled trial (STRIDE, NCT05600036) and an ongoing open-label extension trial (OLE, NCT05739435). Data from these trials were used to develop a population pharmacokinetic (popPK) model to characterize the ESK-001 PK and an exploratory E-R analysis to understand the relationship between exposure and skin improvements (PASI) as well as severity reduction (sPGA) to inform Phase 3 dose selection.

Materials & Methods: The popPK analysis incorporated data from 127 healthy volunteers (HV) and 185 patients with PsO. A limited set of covariates (body weight, fed status) were evaluated for their effects on ESK-001 exposure. The popPK model derived the 24-hour average concentration (Cavg) values for each patient, enabling exploration of the E-R relationship between ESK-001 exposure (Cavg) and efficacy outcomes PASI and sPGA. The Cavg of ESK-001 was categorized into four groups (referred to as bins), where the first bin represented subjects receiving placebo (0 exposure), and the remaining 3 bins were based on tertiles of exposure from low to high. Visual predictive graphs were used to assess this correlation. For each group, the proportion of patients with PASI or sPGA was plotted over time and extended to evaluate the effects of longer-term administration up to 40.

Results: The collected data was best fitted to a two-compartment model with first-order absorption and linear elimination. Body weight had a significant effect on PK. The E-R analysis revealed a strong, positive relationship between exposure and improvement in PASI and sPGA scores. For a given exposure level, there was also a clear positive relationship between time on treatment and PASI and sPGA improvement.

Conclusion: The popPK analysis indicated similar exposures and linear PK in both HV and patients with PsO. The E-R analysis revealed a strong positive correlation between exposure and the key efficacy endpoints. Also, there was a positive correlation between time on treatment and the key efficacy endpoints. The maximum response occurred at the highest dose of 40 mg BID.

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Abstract N°: 4722

Impact of risankizumab on disease symptoms in patients with non-pustular palmoplantar psoriasis: post-hoc analysis of the phase IIIb IMMprint study

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Introduction & Objectives: Non-pustular palmoplantar psoriasis (PPPsO) is a chronic immune-mediated disease that manifests as localized plaques on palms and soles of patients (pts) accompanied by pain that negatively impacts pts' quality of life. Risankizumab (RZB) is an approved, IL-23 inhibitor targeting the p19 subunit with high affinity and specificity, for the treatment of moderate-to-severe PsO, psoriatic arthritis and Crohn's disease. In the phase IIIb IMMprint trial, a significantly higher proportion of pts treated with RZB achieved palmoplantar Investigator's Global Assessment of "clear" or "almost clear" (ppIGA 0/1) compared to placebo (PBO) (33.3% vs 16.1% [p = 0.006]) (Lebwohl et al. *SKIN* 2023, 7(6), s256). Here, we present the impact of RZB on disease symptoms in IMMprint.

Materials & Methods: IMMprint (NCT04713592) was a phase IIIb multicenter, randomized, double-blind, PBO-controlled study that evaluated the safety and efficacy of RZB vs PBO in pts with PPPsO. IMMprint has been previously published (Lebwohl et al. *SKIN* 2023, 7(6), s256). This post-hoc analysis compared item level results on the Patient Global Assessment of Skin Pain (PGA-SP; measures skin pain on the palms of hands and soles of feet) and Psoriasis Symptom Scale (PSS; measures pain, itching, redness, and burning) between RZB and PBO at 16 weeks (wks) and improvements through wk 52. Outcomes evaluated included: change (mean/percent) from baseline and achievement of Minimum Clinically Important Difference (MCID) of PGA-SP in pts with baseline PGA-SP ≥ 4; and achievement of PSS by individual symptom of 0 or 1 (PSS 0/1; none/mild for pain, redness, itch and burning). Missing data were handled using Non-Responder Imputation incorporating multiple imputation for missing data due to COVID-19 (NRI-C) for categorical endpoints, and Mixed-Effect Model Repeat Measurement (MMRM) for continuous endpoints. Long-term (52 wks) efficacy for continuous pain endpoints was summarized using observed cases.

Results: Among 174 enrolled pts, 87 (46.0% female) were randomized to RZB and 87 (51.7% female) were randomized to PBO. Mean age (SD) was 56.9 (12.9) and 53.9 (14.3) years in the RZB and PBO group respectively. Mean (SD) PSS was 10.5 (3.2) in the RZB group and 8.9 (3.4) in the PBO group. PGA-SP (mean [SD]) was 6.8 (2.6) in the RZB group and 5.3 (2.9) in the PBO group.

In pts with baseline PGA-SP ≥ 4, the change from baseline in PGA-SP was -3.3 (RZB) and -0.9 (PBO) at wk 16 and -4.9 (stayed on RZB; RZB/RZB) and -4.8 (switched to RZB at wk 16; PBO/RZB) at wk 52, while their percent change from baseline was -40.9% (RZB) and -9.7% (PBO) at wk 16 and -62.3% (RZB/RZB) and -69.9% (PBO/RZB) at wk 52 (Table). The proportion of pts (RZB vs PBO) achieving MCID of pain in palms of hands and/or soles of feet in pts with baseline PGA-SP ≥ 4 was 67.2% vs 45.1% at wk 16. By wk 52, the proportion of pts (RZB/RZB and PBO/RZB)

was 70.3% and 88.9%.

At wk 16, PSS 0/1 (RZB vs PBO) was achieved by 52.1% vs 40.5% for pain, 49.3% vs 25.7% for redness, 42.5% vs 25.7% for itching and 56.2% vs 44.6% for burning. By wk 52, this had increased to 64.4% and 75.4% for pain, 61.6 and 69.6% for redness, 56.2% and 68.1% for itching and 65.8% and 71.0% for burning (RZB/RZB and PBO/RZB, respectively).

Conclusion: This post-hoc analysis demonstrates that RZB can provide relief in disease symptoms, including skin pain in palms and/or soles of feet, by wk 16 with continued improvement up to wk 52 in this difficult-to-treat PPPsO population.

Table. Patient reported outcomes of patients with PPPsO at week 16 and 52

Responses	Week 16		Week 52	
	RZB	PBO	RZB/RZB	PBO/RZB
Change from baseline in PGA-SP in patients with baseline PGA-SP ≥4 n	-3.3 (-4.1, -2.4)* 57	-0.9 (-1.9, 0.1)* 47	-4.9 (-5.8, -3.9)** 54	-4.8 (-5.7, -3.9)** 43
% change in PGA-SP in patients with baseline PGA-SP ≥4, % (95% CI) n	-40.9 (54.2, -27.5)* 57	-9.7 (-24.3, 4.8)* 47	-62.3 (-74.8, -49.9)** 54	-69.9 (-81.6, -58.2)** 43
MCID of pain in palms of hands and soles of feet of patients with baseline PGA-SP ≥4, NRI-C, % (95% CI) n/N	67.2 (55.7, 78.7) 43/64	45.1 (31.4, 58.8) 23/51	70.3 (59.1, 81.5) 45/64	88.9 (79.7, 98.1) 40/45
PSS 0/1, NRI				
Pain, % (95% CI) n/N	52.1 (40.6, 63.5) 38/73	40.5 (29.4, 51.7) 30/74	64.4 (53.4, 75.4) 47/73	75.4 (65.2, 85.5) 52/69
Redness, % (95% CI) n/N	49.3 (37.8, 60.8) 36/73	25.7 (15.7, 35.6) 19/74	61.6 (50.5, 72.8) 45/73	69.6 (58.7, 80.4) 48/69
Itching, % (95% CI) n/N	42.5 (31.1, 53.8) 31/73	25.7 (15.7, 35.6) 19/74	56.2 (44.8, 67.5) 41/73	68.1 (57.1, 79.1) 47/69
Burning, % (95% CI) n/N	56.2 (44.8, 67.5) 41/73	44.6 (33.3, 55.9) 33/74	65.8 (54.9, 76.6) 48/73	71.0 (60.3, 81.7) 49/69

PPPsO, non-pustular palmoplantar psoriasis; RZB, risankizumab; RZB/RZB: patients who stayed in the RZB group; PBO, placebo; PBO/RZB, patients who switched from placebo to risankizumab at week 16; PSS, psoriasis symptom scale; PGA-SP, Patient Global Assessment of Skin Pain; MCID, Minimum Clinically Important Difference; CI, confidence interval; n, number, NRI, Non Responder Imputation; NRI-C, NRI incorporating multiple imputations to handle missing data due to COVID-19; * Mixed-effect Model Repeat Measure analysis to handle missing data; ** Observed Cases

EADV CONGRESS
AMSTERDAM 25-28 SEPTEMBER 2024
EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 4753

Specific features and therapy of psoriasis and arthropathic psoriasis courses

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Introduction & Objectives: Psoriasis affects about 2% of population. In 30-40% of occurrences arthropathic psoriasis (AP) is diagnosed and it leads to 11-19% of disability cases development. The article analyses features of anamnesis, clinical, instrumental and laboratory tests related to arthropathic psoriasis, considers the relationship of probable mechanisms of disease aggravation and progression with the definition of a treatment method influencing the dynamics of a disease course.

The objective of our work was to improve the diagnostics of AP patients taking into account some indicators of the immune-endocrine system and features of the disease course to specify their role in AP pathogenesis and to develop the system of integrated therapy of patients whose locomotor system is affected due to psoriasis.

Materials & Methods: A total of 178 AP patients have been systematically examined. We have examined AP patients with varying severity of process development, generalization and the severity of skin and osseous-articular apparatus damage, the presence of associated pathology. Additional instrumental studies, determination of biochemical, serological parameters and an assessment of stress-induced immune-endocrine system have been conducted in AP patients. The content of trigger cytokines (IL-1β, IL-8, IL-17, IL-22) in blood serum, stress hormones (ACTH, cortisol), cellular and humoral immunity condition (CD3 +, CD4 +, CD8 +, CD16 +, CD22 +, IgM and IgG levels) have been studied.

Results: The clinical course and characteristic features of AP instrumental tests are extremely versatile as well as the depth of their present study is insufficient. Regardless of the disease duration period, we have detected in blood serum of AP patients probable changes in concentrations of stress-response mediators (decreased parameters of cellular immunity (CD3+, CD4+, CD8+ of T-lymphocytes, CD22+ fraction of B-lymphocytes and compensatory increased CD16+ of T-cells, cytokines – IL-1β, IL-8, IL- 17, IL-22, stress hormones – cortisol, immunoglobulins IgM, IgG, and CIC), which indicate tension of their stress-induced mechanisms even despite occasional clinical stabilization of skin and articular process.

We have offered and tested regiments to treat AP patients, which involve differential application within the integrated therapy of nonsteroidal anti-inflammatory medications (Etoricoxib 30-60 mg 1 time daily / Diclofenac Duo 75 mg daily), disease-modifying medications (Sulfasalazine EH from 500 mg to 2 g daily / Methotrexate 7.5-10 mg/week), lyophilised dialysate of leukocytes.

Conclusion: The analysis of specific features of the AP clinical course and data of integrated studies allows identifying the probability of manifestation or persistence of the pathological psoriatic articular process. The improvement of AP patients diagnostics taking into account some indicators of the immune-endocrine system and specifics of the disease course contributed to the improved therapy and mended quality of life of patients.

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Abstract N°: 4756

Changes of cellular immunological parameters in patients with psoriasis and activated chronic herpes simplex virus infection during treatment

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Introduction & Objectives: The possible role of viral persistence as an epigenetic factor in the development of psoriasis is discussed when a specific antigen (virus, especially type 1,2 (HSV 1,2)) is considered as a trigger factor for direct or indirect action on immunocompetent cells.

The purpose To evaluate the peculiarities of blood lymphocytes phenotyping in patients with psoriasis and activated chronic Herpes simplex virus infection compared to patients with psoriasis, activated chronic Herpes virus infection, and healthy persons during treatment.

Materials & Methods: 120 patients with psoriasis and/or activated chronic, HSV types 1,2 were examed.

Results: In patients with psoriasis and activated HSV types 1,2, there was an increase in the number of T-lymphocytes and NK-lymphocytes, helper and cytotoxic subpopulations of T-lymphocytes in comparison with healthy persons. Also, in this group, the number of cytotoxic lymphocytes and T-helper cells was higher compared to patients with activated HSV 1,2. The functional capacity of T-lymphocytes and the regulatory activity of T-helpers were lower in patients with psoriasis and activated HSV 1,2 compared to healthy persons and patients with psoriasis only. As a result of the antiviral therapy (acyclovir, inosine pranobex) on the background of basic therapy in patients with psoriasis and HSV 1,2, it has been found a decrease in the number of cytotoxic lymphocytes, helpers, NK-cells. It has been found restoring the moderate correlation between the number of T-helper cells and cytotoxic lymphocytes in the studied group of patients after antiviral therapy (r = -0.51) and the number of B-lymphocytes and cytotoxic lymphocytes r = 0.41. A multifactorial relationship between the number of B- and T-lymphocytes and their activated population has been found. In the mild activated HSV 1,2 on the background of psoriasis, a decrease in T-helper cells and an increase in activated and regulatory lymphocytes, when using inosine pranobex as antiviral therapy, have been found. When using basic therapy in this group, there was a further decrease in the number of regulatory T-lymphocytes. In severe activated HSV 1,2, when using combined antiviral therapy with acyclovir and inosine pranobex in patients with psoriasis and HSV 1,2 activated, there have been detected a normalization of NK-cells and an increase of regulatory lymphocytes that were not found in the group which used basic therapy with acyclovir.

Conclusion: The phenotyping of lymphocytes in patients with psoriasis and activated HSV 1,2 was characterized by an increase of NK cells (CD16+56+, CD45+; p=0.0151), cytotoxic T-lymphocytes (CD3+CD8+, CD45+; p= 0.0019), T-helper (CD3+CD4 +, CD45+; p=0.0011) and decreasing activity of their regulatory subpopulation (CD4+, CD25+; p=0.0528) compared to patients with psoriasis. In patients with psoriasis and activated HSV 1,2, the multifactorial relationship between the number of CD19+, CD45+-lymphocytes, CD3+CD8+, CD45+-lymphocytes, and CD3+HLA+-lymphocytes has been detected. The antiviral treatment on the background of basic therapy caused a decrease in the number of T-helpers (p=0.0518), increased activity of T-lymphocytes (p=0.0251) and regulatory cells (p=0.0365) in mild HSV 1,2 using inosine pranobex in patients with psoriasis, and a decrease of NK-cells (p=0.0412) and increasing activity of regulatory lymphocytes (p=0.0351) in moderate and severe HSV 1,2 in patients with psoriasis using inosine pranobex and acyclovir.

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Abstract N°: 4860

Real-world experience of bimekizumab for adult patients with plaque psoriasis: A 52-week multicenter retrospective study

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Introduction & Objectives:

While bimekizumab, a novel interleukin (IL)-17A/IL-17F inhibitor, has recently been approved for adult patients with moderate-to-severe plaque psoriasis based on clinical trial data, real-world data remains limited. Herein, we provide evidence regarding 1-year use of bimekizumab in the routine clinical setting.

Materials & Methods:

Our retrospective multicenter study included adult patients with plaque psoriasis from four practices across Canada who were initiated on bimekizumab. Effectiveness outcomes were measured at week 52±6. Safety was assessed via treatment-related adverse events (AEs).

Results:

Our analysis included 87 patients. Mean age was 45.6 (range: 21-74) years, with 59.8% (52/87) being male. At week 52±6: 87.3% achieved an Investigator Global Assessment score of clear (0) or almost clear (1) (IGA 0/1); 87.4%, 81.6%, and 70.1% of patients achieved 75%, 90%, and 100% improvements in Psoriasis Area and Severity Index (PASI) scores from baseline (PASI75, PASI90, and PASI100, respectively); 86.2%, 80.5%, and 73.6% achieved absolute PASI scores <3, <2, and <1; mean PASI decreased from 11.3 to 0.5 (mean PASI improvement: 93.9%); mean body surface area (BSA) decreased from 11.8% to 0.6% (mean BSA improvement: 94.2%); and mean IGAxBSA decreased from 36.9 to 1.2 (mean IGAxBSA improvement: 95.4%). In patients with prior exposure to other IL-17 inhibitors (47.1%, 41/87), IGA 0/1, PASI90, and PASI100 responses were 76.7% (23/30), 70.7% (29/41), and 63.4% (26/41).

For patients not achieving IGA 0/1, PASI75, PASI90, and PASI100 at week 16±6, responses were subsequently achieved in 100% (5/5), 80% (4/5), 72.2% (13/18), and 56.8% (21/37) of patients at week 52±6. Loss of initial week 16±6 IGA 0/1, PASI75, PASI90, and PASI100 responses occurred in 6.7% (4/60), 2.7% (2/74), 4.9% (3/61), and 2.4% (1/42) patients by week 52±6, respectively. Seven patients (8%) utilized concomitant systemic therapy. During the maintenance period, dose escalation from every 8 weeks to every 4 weeks was required in 8% (7/87) of patients.

Twelve (13.8%) treatment-related AEs were identified, including candidiasis (5.7%, 5/87) and folliculitis (3.4%, 3/87). In total, 7 treatment discontinuations (8%) occurred (lack of efficacy [n=4]; AEs: anxiety [n=1] and inflammatory bowel disease [n=1]; pregnancy [n=1]). No serious infections, suicidal ideation, malignancies, hypersensitivity reactions, major adverse cardiac events, or hepatic abnormalities were observed over 86.8 patient-years of safety follow-up.

Conclusion:

Our real-world study response rates are comparable to phase 3 clinical trial results with a commensurate safety profile. We also found that a similar proportion of patients maintained initial short-term responses at 1-year in our study (PASI90: 95.1%; IGA 0/1: 93.3%) when compared to the BE READY clinical trial (PASI90: 87-91%; IGA 0/1: 90-92%). Study limitations include its retrospective nature and sample size.

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Abstract N°: 4873

Atractylodin reduced the lesion severity of IMQ-induce psoriasis-like mice through inhibiting the NF-κB pathways

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Introduction & Objectives:

Psoriasis is a common chronic, immune-mediated and easily recurred skin disease characterized by circumscribed erythematous scaling plaques. It is also a systemic inflammatory disorder that involves complex pathogenic interactions between the innate and adaptive immune system. Due to worry about side effects of long term systemic treatment, patients preferred topical treatments. Therefore, developments of innovative topical agents that can provide long-term intervention and prevent comorbid diseases are better for patients with psoriasis. Atractylodin (ATL) is one of the major constituents of the rhizome of Atractylodes lancea, and its anti-inflammatory effect has been widely recognized. While the specific mechanism of ATL in psoriasis remains poorly understood, so the goal of this study was to investigate the efficacy and possible mechanism of action of ATL in psoriasis.

Materials & Methods:

ATL-treated IMQ-induced psoriasis-like mice was conducted hematoxylin-eosin, immunohistochemistry and RT-qPCR to evaluate histological changes, the status of keratinocyte proliferation, epidermal differentiation, cutaneous inflammatory cell infiltration and psoriasis-associated inflammatory molecules respectively. For in vivo studies, we evaluated the bioeffects of ATL on keratinocytes and macrophage by detecting the inflammatory cytokines expression and activation of MAPK and NF-κB pathways in LPS-stimulated HaCaT Cells and RAW264.7 cells, respectively.

Results:

Our results showed ATL could lower the PASI scores and improved histopathological psoriasiform lesions on IMQ-induced mice. Furthermore, ATL singificantly decreased the percentage of mice spleen regulatory T cells (CD4+ and CD25+), γδ-T +IL-17A cells and IMQ's ability to increase proinflammatory cytokines such as TNF-α, IL-6, IL-17A, and transcription factor NF-κB was effectively inhibited after ATL treated.

Conclusion:

Our findings provided the pilot evidences about the potential of ATL in psoriasis treatment the its possible mechanisms in inhibiting the pathogenesis of psoriasis. It is worthy further developing ATL as a novel topical treatment for psoriasis in the near future.

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Abstract N°: 4913

Triglyceride-glucose index (TGI), a new biomarker to predict cardiovascular events in psoriasis

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Introduction & Objectives:

Psoriasis is associated with a higher incidence of major adverse cardiovascular events (MACE). However, there is still a need for new metabolic and hematological parameters to monitor the impact of psoriasis and its treatments on subclinical atherosclerosis and the development of MACE by dermatologists in routine clinical practice. The triglyceride-glucose index (TyG) is a simple and widely accessible indicator of insulin resistance that is associated with cardiovascular events and predicts some metabolic abnormalities better than individual components in the index. To date, no studies have characterized the TyG index in quantifying and predicting MACE in patients with psoriasis. Therefore, in this study, we investigated the predictive ability of the TyG index to detect psoriasis patients at high risk of developing a cardiovascular event.

Materials & Methods:

Study Population: Patients with psoriasis followed by the Dermatology Department of the University Clinical Hospital of Valencia were recruited, and their entire medical history from the last 6 years of follow-up in the Psoriasis Unit was retrospectively collected.

Outcome Definition: The primary outcome in this study was the development of MACE or major adverse cardiac events, including acute myocardial infarction (AMI) and stroke, during the follow-up period.

Data Collection: Demographic information and clinical data of the patients included were collected at each visit.

Statistical Analysis: Study participants were divided into four groups according to TyG index quartiles. A Cox regression model was performed to estimate hazard ratios (HR) and 95% confidence intervals (CI) for TyG index quartiles in association with MACE development, with TyG index quartile 1 as the reference group. Finally, a sensitivity analysis was conducted to assess the robustness of the results. Subsequently, the area under the curve (AUC) of psoriasis patient characteristics (ROC curve) and 95% CI were calculated to compare the predictive power of the TyG index model for MACE.

Results:

Data from 150 psoriasis patients were recorded, with a mean age (± SD) of 50.76 ± 13.44 and 58.7% being male. At the end of the follow-up, a total of 12 MACE (11 AMI and 1 stroke) were found, resulting in a prevalence of 8%.

Age, age at psoriasis diagnosis, and BMI in men were more likely to increase across TyG index quartiles. The prevalence of hypertension, type II diabetes, hyperlipidemia, and chronic obstructive pulmonary disease (COPD) also proportionally increased in higher TyG index quartiles. Additionally, higher quartiles showed higher frequencies of positive QuantiFERON tests. Glucose, triglyceride, total cholesterol, and HDL cholesterol index values increased proportionally across TyG index quartiles. Finally, MACE prevalence significantly increased in higher quartiles.

In the ROC curve analysis, we found an area under the curve (AUC) of 0.751 (0.604-0.898) P=0.001.

Conclusion:

The TyG index, a simple and widely available measure, is a useful metabolic parameter for predicting cardiovascular events in patients with psoriasis. While larger studies are needed to evaluate its clinical utility and better understand the relationship between the TyG index and psoriasis, our work highlights the clinical potential of the TyG index for early identification of psoriasis patients at high risk of developing a cardiovascular event.

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Abstract N°: 4979

AHR/TET2 downregulation participates oxidative stress process in psoriatic keratinocytes

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Introduction & Objectives:

Psoriasis is an inflammatory skin disease characterized by a combination of environmental and genetic factors.AHR is an environmental sensor expressed in keratinocytes that regulates epithelial cell and skin barrier homeostasis. Skin exposure to environmental stimuli activates AhR signaling in keratinocytes, inducing oxidative stress that promotes the inflammatory response in psoriasis. Oxidative stress can cause DNA damage, disrupting chromatin structure and causing epigenetic changes. The interaction between oxidative stress and epigenetic modifications explains the complex relationship between environmental factors and gene expression patterns. Oxidative stress has been found to be closely associated with the pathogenesis of psoriasis, and AHR is aberrantly expressed in psoriasis. However, whether AHR is involved in the oxidative stress response in psoriasis through epigenetic modifications needs further investigated.

Materials & Methods:

We examined the expression of AHR and the epigenetic regulatory molecule TET2 in psoriasis lesions. AHR agonists were used to observe altered TET2 expression in keratinocytes. IMQ-induced psoriasis-like mice were treated with benvimod to clarify the AHR and TET2 correlation further. We knocked down AHR and TET2 in keratinocytes, respectively, to observe the regulation of NRF2 expression, a key molecule in oxidative stress. The effect of the epigenetic regulatory molecule TET2 on the methylation level of the NRF2 promoter was assessed using MSP.

Results:

AHR and TET2 expression were reduced in psoriatic lesions and IMQ-induced psoriasis-like mice, and they were positively correlated. AHR agonists in keratinocytes promoted AHR/TET2 entry into the nucleus. AHR and TET2 expression was elevated in benvimod-treated IMQ psoriasis-like mice. Knockdown of AHR in cells decreased both TET2 and NFR2 expression. Further interference with TET2 expression in keratinocytes elevated NRF2 promoter methylation levels.

Conclusion:

This study identifies a novel role for AHR/TET2 in the pathogenesis of psoriasis, where epigenetic modifications are involved in regulating oxidative stress responses, explaining the interrelationship between environmental factors and gene expression.

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Abstract N°: 5086

Investigating Real-World Effectiveness and Safety of Risankizumab in Adult Patients with Plaque Psoriasis: A 1-year International Multicenter Retrospective Cohort Study

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Introduction & Objectives: While Phase III randomized controlled trials (RCTs) have shown risankizumab to be highly effective in treating moderate-to-severe plaque psoriasis, achieving superior skin clearance compared to ustekinumab and adalimumab, comprehensive data on its long-term effectiveness and safety in real-world settings are lacking. This study aims to assess the one-year real-world outcomes of risankizumab in adult patients with moderate-to-severe plaque psoriasis, particularly evaluating its efficacy and safety.

Materials & Methods: We conducted an international, multicenter retrospective study at five tertiary academic dermatology clinics in Canada and Portugal. The study included adults aged 18 years or older diagnosed with moderate-to-severe plaque psoriasis (PGA score of 3 or 4). Patients were evaluated one year after initiating risankizumab treatment, with efficacy defined by achieving Psoriasis Area and Severity Index (PASI90) or Physician's Global Assessment (PGA) scores of 0 (clear) or 1 (almost clear). Safety was assessed by the frequency and nature of adverse events reported.

Results: The study encompassed 291 patients (mean age: 50.7 ± 15.0 years; 62.5% male), who had failed an average of 0.79 systemic biologics before, and 56.4% (164/291) were naïve to systemic biologic therapy. At one-year follow-up, 264 patients (90.7%) achieved PASI90 or PGA 0/1. Moreover, 90.7% of patients reached a PASI ≤2, 56.4% achieved a PASI <1, and 72% reported a Body Surface Area (BSA) <1%. Adverse events were reported by 4.5% of the cohort (13/291), with fatigue being the most common adverse event, affecting 23% (3/13) of those who reported issues. No adverse events were considered severe, and all patients with adverse events continued with the treatment. Discontinuation of treatment was reported in 7.9% (23/291) of the patients, primarily due to lack of efficacy (15/23, 65.2%).

Conclusion: Risankizumab exhibits significant real-world efficacy and safety for the treatment of moderate-to-severe plaque psoriasis, affirming the results seen in phase III RCTs. The treatment demonstrates a high rate of skin clearance and maintains a favorable safety profile over one year. These outcomes validate risankizumab's use in clinical practice, though larger real-world cohort studies with control comparators are necessary to further these findings.

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Abstract N°: 5097

Guselkumab is highly effective in the management of scalp psoriasis: Results from a real-world retrospective study

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Introduction & Objectives: Psoriasis is a chronic systemic auto-inflammatory cutaneous disorder that can affect every part of the human body. Scalp involvement is seen in a significant amount of patients with psoriasis and is a major cause of social and emotional distress. Despite the high frequency of scalp involvement, the successful management of scalp psoriasis can be very challenging mostly because of the difficulties that arise from the chronic application of topical agents along with the disease's refractory nature. The emergence of biological agents and the blockade of the interleukin-23 (IL-23) pathway seem to have improved outcomes in those patients in the recent years, mostly according to data extracted from randomized controlled trials (RCTs). Real-world studies focusing on novel agents, such as guselkumab, for the treatment of scalp psoriasis are limited. The aim of this study was to provide real-world results of the use of guselkumab (IL-23 inhibitor) in patients suffering from moderate-to-severe scalp psoriasis.

Materials & Methods: We retrospectively reviewed all medical records of patients with moderate-to-severe plaque psoriasis who received at least one dose of guselkumab in the standard scheme. Eligible for this study were patients with active scalp disease at the time of guselkumab initiation. In order to assess disease severity, we used the psoriasis scalp severity index (PSSI) which was calculated at baseline and each subsequent visit.

Results: In total, we identified 112 patients that started treatment with guselkumab in our department and included 34 patients that suffered from active scalp psoriasis at the time of treatment initiation. In our cohort, 24 were males and 12 females. The mean (range) age at the time of drug initiation was 50.68 (21-77) years and the mean (range) disease duration was 15.12 (2-42) years. The mean (SD) BMI was 28.94 (5.66) kg/m2. Twenty-three (67.6%) patients suffered from at least one medical comorbidity. Regarding other difficult-to-treat areas, 7 patients (20.6%) had palms and soles involvement, 14 (41.2%) had genital area involvement, 15 (44.1%) had nail disease and 7 (20.6%) had concomitant psoriatic arthritis. Four patients (11.8%) had been treated with more than two biologics and 22 (64.7%) were bio-naïve. At baseline, the mean (SD) PSSI was 10.79 (7.61) with a reduction to 2.35/0.48/0.67/0/0 at weeks 12/24/52/104/156 respectively. After 12 weeks of treatment, the PSSI75/90/100 responses were achieved by 61.5/53.8/53.8% of the evaluated patients, after 24 weeks by 90.9/86.4/81.8% and after 52 weeks by 93.3/80/80% of the patients. At 104 weeks and 156 weeks, all patients evaluated had complete scalp clearance. In this cohort, no serious adverse events were reported and no patient discontinued the medication. One patient was lost to follow-up.

Conclusion: Our study findings confirm data from RCTs and suggest that guselkumab is highly effective in the treatment of moderate-to-severe plaque psoriasis with scalp involvement. Our study is mainly limited by its small sample size and its retrospective design. Large prospective studies are needed to draw stronger conclusions on the real-world efficacy of guselkumab and its' part in the scalp psoriasis treatment algorithm.

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Abstract N°: 5098

"Full-naïve" patient: the impact of previous methotrexate, cyclosporine, and acitretin on first line biologics response.

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Introduction & Objectives:

The impact of traditional systemic drugs to treat psoriasis, such as cyclosporine, methotrexate, and acitretin, (globally called DMARDS) in a subsequent response to biological drugs, has not been adequately addressed in the literature. In clinical practice it is increasingly necessary to initiate, due to concomitant comorbidities, biologic therapy in patients with psoriasis who have not undergone prior treatment with systemic agents, i.e. full-naive.

Materials & Methods:

In the present retrospective study, we analyze the possible impact of DMARDS on the effectiveness and drug survival of first-line biologic drug up to 12 months in 702 bio-naive patients.

Results:

In all, 95 patients with severe psoriasis (13.5%) were full-naive. Being full-naive and having or not having undergone methotrexate or cyclosporine therapy did not impact response to subsequent years of biologic therapy. Only acitretin appeared to promote faster response to subsequent biologic drugs with 59.6% and 74.2% of patients achieving PASI 90 at 16 and 28 weeks, respectively, vs. 50.5% and 65% in patients who had not previously taken the drug (p=0.034 and 0.026 respectively). The percentage of super responders (PASI 100 at 16 weeks and maintained at 28 weeks) was also higher in patients taking acitretin before the biologic drug. In multivariate analysis, the advantage given by acitretin was lost, with the type of inhibitor used, BMI, baseline PASI, joint involvement, and age of onset variably impacting response outcomes.

Conclusion:

Previous systemic therapy in bio-naive patients does not appear to result in a differential response to the biologic drug during the first year of treatment. Thus, being full-naive does not appear to have any significant benefits.

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Abstract N°: 5117

mTORC1 and mTORC2 Levels in Patients with Psoriasis

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Introduction & Objectives: There is a complex interaction of genetic, environmental and immune pathways in the pathogenesis of psoriasis. In recent years, the role of the mTOR pathway, which is one of the intracellular signaling pathways and known as the main control pathway of metabolism, in the pathogenesis of psoriasis has been emphasized. mTOR is a serine/threonine kinase that takes place in the mTORC1 and mTORC2 multiprotein complexes in the cell and forms the catalytic subunit of these complexes. Although there are many reviews in the literature regarding the role of the mTOR pathway in the pathogenesis of psoriasis, there is no study investigating the levels of mTORC1 and mTORC2 in the serum of patients with psoriasis. Therefore, in this study, we aimed to investigate the importance of the mTOR pathway in the pathogenesis of psoriasis by examining the mTORC1 and mTORC2 levels in the serum of patients with psoriasis.

Materials & Methods: Forty patients with psoriasis and 40 healthy volunteers were included in the study. Data including sociodemographic data and clinical features such as disease severity and duration of disease were recorded. Serum samples were taken from all participants, centrifuged under appropriate conditions, and stored in a -80 degree refrigerator until the day of the analysis. Samples collected for the study of serum mTORC1 and serum mTORC2 levels were analyzed with enzyme-linked immunosorbent assay technique..

Results: Serum mTORC1 and mTORC2 levels were lower in patients with psoriasis when compared to the control group, and the difference was statistically significant (p=0.001 for mTORC1, p=0.024 for mTORC2). A positive correlation was found between serum mTORC1 and serum mTORC2 levels in the patient group (p=0,001, r=0,826). The patient group was divided into three subgroups as mild, moderate and severe according to the psoriasis area severity index (PASI) score. The lowest mean serum mTORC1 and mTORC2 levels were found in the severe disease group, while the highest values were found in the mild disease group, but this difference was not statistically significant. Moreover, there was a negative correlation between disease duration and serum mTORC1 and mTORC2 levels (p=0.041, r=-0.320 for mTORC1, p=0.046, r=-0.314 for mTORC2).

Conclusion: This study is the first to examine the serum mTORC1 and mTORC2 levels of patients with psoriasis. In our study, the lower serum levels of mTORC1 and mTORC2 complexes belonging to the mTOR pathway, which are active in the cell, were found to be lower in the patient group, suggesting that it may be an indicator of increased intracellular activation of these molecules, and the positive correlation between serum mTORC1 and serum mTORC2 levels in the patient group supports that both mTORC1 and mTORC2 complexes play an important role in the pathogenesis of psoriasis. A negative correlation was found between the duration of psoriasis disease and serum mTORC1 and mTORC2 levels, which can be explained by the prolongation of the inflammatory process with the increase in the disease duration might be associated with the increased activity of the mTOR signalling pathway intracellularly. Considering all these findings, it is thought that agents that can effectively inhibit both mTOR complexes may be more effective in the treatment of psoriasis and the prevention of accompanying metabolic comorbidities.

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Abstract N°: 5154

Risk of skin cancer in patients with psoriasis: single-center retrospective study comparing anti-TNFa and phototherapy

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Introduction & Objectives:

The risk of developing non-melanoma skin cancers (NMSCs) in patients with psoriasis is highly debated, and, to date, there is no unambiguous consensus opinion. Psoriasis is known to be related to an increased likelihood of other comorbidities such as psoriatic arthritis, obesity, metabolic syndrome, depression, and cardiovascular disease. Regarding cancer risk, previous studies have reported a greater tendency for the development of cutaneous T-lymphoma, colon, breast, kidney, and lung cancers. Furthermore, data from network meta-analyses has shown that patients with psoriasis have a higher risk of developing squamous cell carcinomas (SCC) and/or basal cell carcinomas (BCC). Multiple factors may contribute to the development of NMSCs in psoriatic patients, ranging from immunosuppression induced by biologic agents to previous phototherapy. However, the extent to which each factor may impact this risk has not been entirely assessed. The aim of this study was to evaluate the risk of developing NMSCs in patients with psoriasis observed for at least 5 years, by directly comparing patients only treated with phototherapy and patients treated with anti-tumor necrosis factor a (TNFa) agents, naive to other systemic treatments or phototherapy.

Materials & Methods:

We conducted a single-center retrospective study at Siena University Hospital, Italy, on 200 adult patients with psoriasis divided into two groups: (i) group 1, including 100 patients treated with phototherapy UVB-narrow band (nb-UVB) and (ii) group 2, including 100 patients treated with anti-TNFa. Patients included in group 2 had to be naive for cDMARDs and biologics and treated with anti-TNFa continuously for 5 years without loss of efficacy. All patients were observed for 5 years and underwent annual dermatologic examinations to assess for the occurrence of BCC or SCC.

Results:

34 out 100 patients treated with phototherapy had one BCC or one SCC and 10 out 34 developed two skin cancers. In particular, 5 had both types (one BCC and one SCC), and 5 had two BCCs.

Conclusion:

The results of our study highlight how the risk of developing NMSCs is greater in patients un-dergoing phototherapy compared to those treated with anti-TNFa. It also draws attention to the consideration that patients with scalp psoriasis might need closer follow-up as they could be more at risk of developing NMSCs.

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Abstract N°: 5251

Value-Based Healthcare in Psoriasis: the impact of an Integrated Practice Unit on patient-relevant outcomes

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Introduction & Objectives:

Value-Based Healthcare (VBHC) aims to optimize the healthcare system by focusing on improving patient-relevant outcomes while minimizing costs. Psoriasis is a chronic inflammatory skin disease, known to be associated with a large impact on patients' quality of life and high management costs. As a systemic skin disease, psoriasis is also associated with numerous comorbidities, such as anxiety and depression, psoriasis arthritis or blood lipid abnormalities. Seeing the high impact, integrated care is needed to optimize patient outcomes. By implementing the principles of VBHC in practice and introducing Integrated Practice Units (IPU), PsoPlus as an IPU, aims to optimize these outcomes. The Value in Psoriasis (IRIS) Trial aims to assess the impact of an IPU on the patient-relevant outcomes of patients with psoriasis.

Materials & Methods:

In this prospective clinical trial (NCT05480917), new adult patients with psoriasis vulgaris attending PsoPlus are followed up for one year. Patient-relevant outcomes (n = 21) are measured through a specialized patient platform and collected at baseline, after 6 and 12 months. T-tests and Mann-Whitney U tests were performed to assess the evolution in outcomes after six months of treatment.

Results:

In December 2023, a total of 113 patients were included in the trial. Baseline data showed that most patients had poor comorbidity control of which anxiety (60%), dyslipidemia (55%), smoking (27%), overweight (27%) or obesity (21%) were the most common comorbidities.

A subgroup of 69 patients completed the measurement after 6 months. The data showed a significant improvement in the quality of life ($p < 0.001$), symptom control ($p < 0.001$) and PASI scores ($p < 0.001$). Also, in communication with the healthcare professional ($p = 0.015$), patient experienced treatment efficacy ($p = 0.013$) and treatment comfort ($p = 0.019$). Among working patients, work productivity also increased significantly ($p = 0.015$).

Conclusion:

To our knowledge, this is the first study assessing the impact of integrated care in a comprehensive way. Our data shows that psoriasis management goes beyond the skin, indicating that an integrated approach in the form of IPUs is needed. However, a larger sample size and follow-up period is needed to manage and assess the evolution of the comorbidities.

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Abstract N°: 5353

Risankizumab in very elderly patients in real-world practice

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Introduction & Objectives:

Psoriasis is a chronic inflammatory, immune-mediated disease affecting 1%–3% of general population. Psoriasis may occur at any age but there is a peak of incidence in patients aged between 16-20 years and 57-60 years. Despite that we routinely visit elderly patients with psoriasis, data regarding the therapeutic management of these patients are limited. Data on drug use and their efficacy and safety in this special subset of psoriatic patients are scarce and not included in international guidelines.

Furthermore, we must consider that elderly patients have more comorbidities than younger patients and an increased risk of drug interactions. Biologics drugs are often used even though safety and efficacy data in these patients are limited; indeed, patients aged ≥ 65 years are frequently excluded from clinical trials due to the high rate of comorbidities. Anti-IL-23 biologic agents represent the latest class of biologics approved for the treatment of moderate-to-severe psoriasis. We report the results of a real-world practice multicentric retrospective study evaluating the efficacy (PASI90 and PASI100 at week 16, 36 e 52) and safety of risankizumab in very elderly patients (aged≥ 75 years) affected with moderate-to-severe psoriasis

Materials & Methods:

We conducted a multi-center retrospective study in eight Output Clinic in Tuscany, Italy. We retrieved data on17 patients (9 men and 8 women). Median age at baseline was 79 years (age range 75-86). The most represented comorbidities were: systemic hypertension (8/17 patients, 47%), followed by dyslipidemia (6/17, 35%) and heart diseases (4/17, 23%); 3 (17.6%) patients had concomitant arthritis while 13 patients (81%) were overweight or obese (median BMI 28.62, range 21.3-36.3). Fifteen patients had been treated with at least one conventional systemic drug before the biological treatment. Only 3 patients were naïve to biologics, while 14 had already been treated with at least one biologic agent. Average baseline PASI was 13.5 before starting risankizumab treatment, 3.9 at 16 weeks, 1.3 at 36 weeks and 0.7 at 52 weeks. Fourteen patients (82%) had at least a difficult-to treat site (nails, scalp, face, palms and soles, genital area).

Results:

Only 1 patient discontinued the treatment due to primary failure at week 16, while of the 16 remaining patients, 2 patients (12.5%) reached PASI90 and 2 (12.5 %) reached PASI100 at 16 weeks. At 36 weeks we have data from 15 patients (one patient was lost to follow up after 16 weeks): 8 patients reached PASI100 (53%) and 3 patients

PASI90 (20%). To date, we have data at 52 weeks for 12 patients, of these 6 (50%) reached PASI100 and 3 (25%) PASI-90, the other 3 had a PASI < 3. Treatment was generally well tolerated in the absence of side effects and adverse events (including cutaneous infections, injection site reaction, malignancy or major cardiovascular events).

Conclusion:

Our real-world data showed promising results in terms of both safety and efficacy of risankizumab in very elderly patients. To our knowledge this is the largest population aged over 75 years treated for at least 52 weeks with risankizumab. The limitations of our study included its retrospective nature and the small sample size.

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Abstract N°: 5366

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in the phase 3 clinical trials in psoriasis, POETYK PSO-1 and PSO-2: time to meaningful improvements in itch as assessed by the Psoriasis Symptoms and Signs Diary

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Introduction & Objectives: In the phase 3 POETYK PSO-1 and PSO-2 trials in psoriasis, patients completed the Psoriasis Symptoms and Signs Diary (PSSD) daily, recording the average severity of psoriasis symptoms and signs, including itch, over the past 24 hours. Patients receiving deucravacitinib experienced greater improvement in PSSD scores than patients receiving placebo or apremilast, as previously reported. In this analysis, we evaluate the time to improvement in itch in patients treated with deucravacitinib vs placebo in both POETYK trials.

Materials & Methods: In each trial, adults with moderate to severe plaque psoriasis were randomized 1:2:1 to placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily; at Week 16, patients receiving placebo crossed over to receive deucravacitinib. Adjusted mean score change from baseline for the PSSD itch item was modeled for deucravacitinib vs placebo using an analysis of covariance model with factors for geographic region, body weight, and prior biologic use, and the baseline value as a covariate. Improvements of ≥2 points on individual PSSD items have been established earlier as meaningful to patients. Times to ≥2-, ≥3-, and ≥4-point improvement from baseline to Week 16 on the PSSD itch item were estimated with Kaplan-Meier methods. Cox models estimated hazard ratios (HRs) for these improvements. Missing data for each analysis were imputed using modified baseline observation carried forward methods.

Results: In each trial, significantly greater improvement from baseline in itch score was observed within 2 weeks with deucravacitinib vs placebo. Across both trials, the median (95% confidence interval [CI]) times to ≥2-point and to ≥3-point improvement were 6.0 (5.0– 7.0) and 9.0 (8.0–11.0) weeks, respectively, for patients receiving deucravacitinib and were not reached for patients receiving placebo (censored at Week 16). Patients receiving deucravacitinib were 3 times more likely to achieve a ≥2-point meaningful improvement in itch score than patients receiving placebo (HR [95% CI]: 3.0 [2.1–4.1] and 3.4 [2.6–4.5] in POETYK PSO-1 and PSO-2, respectively). HRs in favor of deucravacitinib increased as the threshold for improvement increased: at ≥3 points, HRs (95% CI) were 4.0 (2.6–6.1) and 4.9 (3.4–6.9), and at ≥4 points, HRs (95% CI) were 6.5 (3.4–12.4) and 8.8 (5.1–15.2), in POETYK PSO-1 and PSO-2, respectively.

Conclusion: Patients receiving deucravacitinib vs placebo experienced improvement in itch within 2 weeks of treatment. About half of patients receiving deucravacitinib experienced meaningful improvement in itch within 6 weeks.

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AMSTERDAM 25-28 SEPTEMBER 2024
EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 5375

The Registry of Psoriasis Health Outcomes (RePhlect): characteristics of early adopters of deucravacitinib in the North American region

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Introduction & Objectives: The Registry of Psoriasis Health Outcomes (RePhlect) assesses the use of deucravacitinib in a diverse, real-world, global population of patients with psoriasis. The North American (NA) cohort of RePhlect evaluates the effectiveness of deucravacitinib over 5 years in adult patients from clinical practices in the US and Canada. This study describes characteristics of early users of deucravacitinib in the cohort.

Materials & Methods: The RePhlect NA cohort includes patients enrolled in the CorEvitas Psoriasis Registry who initiate treatment with deucravacitinib or apremilast. Data are collected during routine dermatology visits approximately every 6 months. Sociodemographics and clinical information are collected during the baseline Registry visit. Outcome measures include body surface area (BSA) involvement, Investigator's Global Assessment (IGA), Dermatology Life Quality Index score, time to discontinuation, Psoriasis Area and Severity Index (PASI) scores, National Psoriasis Foundation target/acceptable responses, and patient-reported measures.

Results: The first patient was enrolled in September 2022. As of July 2023, 258 deucravacitinib initiators were enrolled (mean age, 51.5 [SD, 15.3] years; 58.5% female; 82.6% White). Most (91.5%) had plaque psoriasis, 58.1% had a history of psoriasis in a difficult-to-treat area. Approximately one third (29.2%) screened positive for psoriatic arthritis (PsA) based on the Psoriasis Epidemiology Screening Tool; 39.1% had PsA as determined by their provider. Mean psoriasis duration was 14.5 (SD, 13.6) years, mean BSA was 10.0% (SD, 13.7%), mean PASI (0–72) score was 5.5 (SD, 5.8), and mean IGA was 2.7 (SD, 0.8).

Conclusion: This NA cohort of early adopters of deucravacitinib was characterized by long-standing psoriasis; the majority of patients had moderate to severe disease, and more than half were biologic-naive at therapy initiation. A substantial number of patients on deucravacitinib also had a history of plaque psoriasis or psoriasis in ≥1 hard-to-treat area, with one third having comorbid PsA. Subsequent RePhlect analyses will continue to evaluate the effectiveness of deucravacitinib on patients with psoriasis in the real world.

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Abstract N°: 5376

Provider burden associated with apremilast adverse events

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Introduction & Objectives: The Registry of Psoriasis Health Outcomes (RePhlect) assesses the use of deucravacitinib in a diverse, real-world, global population of patients with psoriasis. The North American (NA) cohort of RePhlect evaluates the effectiveness of deucravacitinib over 5 years in adult patients from clinical practices in the US and Canada. This study describes characteristics of early users of deucravacitinib in the cohort.

Materials & Methods: The RePhlect NA cohort includes patients enrolled in the CorEvitas Psoriasis Registry who initiate treatment with deucravacitinib or apremilast. Data are collected during routine dermatology visits approximately every 6 months. Sociodemographics and clinical information are collected during the baseline Registry visit. Outcome measures include body surface area (BSA) involvement, Investigator's Global Assessment (IGA), Dermatology Life Quality Index score, time to discontinuation, Psoriasis Area and Severity Index (PASI) scores, National Psoriasis Foundation target/acceptable responses, and patient-reported measures.

Results: The first patient was enrolled in September 2022. As of July 2023, 258 deucravacitinib initiators were enrolled (mean age, 51.5 [SD, 15.3] years; 58.5% female; 82.6% White). Most (91.5%) had plaque psoriasis, 58.1% had a history of psoriasis in a difficult-to-treat area. Approximately one third (29.2%) screened positive for psoriatic arthritis (PsA) based on the Psoriasis Epidemiology Screening Tool; 39.1% had PsA as determined by their provider. Mean psoriasis duration was 14.5 (SD, 13.6) years, mean BSA was 10.0% (SD, 13.7%), mean PASI (0–72) score was 5.5 (SD, 5.8), and mean IGA was 2.7 (SD, 0.8).

Conclusion: This NA cohort of early adopters of deucravacitinib was characterized by long-standing psoriasis; the majority of patients had moderate to severe disease, and more than half were biologic-naive at therapy initiation. A substantial number of patients on deucravacitinib also had a history of plaque psoriasis or psoriasis in ≥1 hard-to-treat area, with one third having comorbid PsA. Subsequent RePhlect analyses will continue to evaluate the effectiveness of deucravacitinib on patients with psoriasis in the real world.

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Abstract N°: 5380

Trial-in-progress—deucravacitinib in routine clinical practice: a 5-year, multicenter, prospective, noninterventional cohort study to evaluate effectiveness and quality of life in patients with moderate to severe plaque psoriasis in Germany (DELPHIN)

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Introduction & Objectives: Deucravacitinib (DEUC), an oral, selective tyrosine kinase 2 (TYK2) inhibitor, was approved in Germany in March 2023 for treatment of adults with moderate to severe plaque psoriasis. Efficacy and safety of DEUC were demonstrated in the phase 3 POETYK PSO-1 (n=666; NCT03624127) and POETYK PSO-2 (n=1020; NCT03611751) clinical trials and in the ongoing POETYK long-term extension study (n=1452; NCT04036435). The objective of the current noninterventional post-authorization DELPHIN study is to generate long-term real-world data on DEUC's effectiveness and quality of life (QoL) in patients with plaque psoriasis in Germany.

Materials & Methods: Approximately 450 adults with moderate to severe plaque psoriasis who initiated treatment with commercially available DEUC 6 mg once daily will be enrolled over 24 months at up to 100 sites across Germany and observed over a 5-year period. Patient characteristics are collected at baseline. Primary data collection during routine care can occur at 13 data collection visits throughout the 5-year trial period. The primary objective is to assess the proportion of patients achieving an absolute Psoriasis Area Severity Index (PASI) score ≤3 at Week 24. Secondary objectives of DEUC effectiveness, including its impact on QoL, persistence of DEUC therapy, and patients' satisfaction with DEUC therapy, are evaluated descriptively. Baseline patient characteristics were analyzed for those enrolled by data cutoff (March 11, 2024).

Results: Enrollment began in April 2023. As of March 2024, 208 patients were enrolled in DELPHIN. Approximately 45.2% (n=94) of enrolled patients are female, with a mean age (standard deviation [SD]) of 49.0 (15.8) years and mean (SD) BMI of 28.7 (5.8) kg/m2 at DEUC initiation (index). The mean (SD) PASI score in this population was 13.9 (9.5), the mean (SD) Dermatology Life Quality Index (DLQI) total score was 12.5 (7.5), and the mean (SD) body surface area (BSA) % involvement was 20.2 (16.4). The proportion of patients who received ≥1 prior systemic therapy was 58.7% (n=122). The Table shows baseline characteristics for patients enrolled as of the current data cutoff.

Conclusion: In this actively enrolling study, interim baseline data for 208 patients show that DEUC is taken by patients with various grades of severity within the moderate to severe indication. When comparing the baseline patient characteristics in DELPHIN with those in the POETYK PSO-1 and POETYK PSO-2 trials, real-world patients initiating treatment with DEUC in Germany appear to have less severe disease, as measured by PASI scores and BSA % involvement. Data indicate that DEUC is used early in the treatment algorithm, with approximately 40% of systemic therapy–naive patients. Furthermore, patients experience moderately impaired QoL at enrollment, as indicated by DLQI scores. First interim effectiveness results will be analyzed and implemented in the final publication based on a new data cut in June 2024.

Table. Interim demographics and baseline patient characteristics

Parameter	N=208
Age, mean (SD), years	49.0 (15.8)
Sex, female, n (%)	94 (45.2)
BMI, mean (SD), kg/m^2	28.7 (5.8)
Weight, mean (SD), kg	86.7 (19.5)
Time since first PsO diagnosis, mean (SD), years	15.7 (14.9)
Affected BSA, mean (SD), %	20.2 (16.4)
PASI score, mean (SD)	13.9 (9.5)
DLQI total score, mean (SD)	12.5 (7.5)
Patients with ≥1 prior systemic therapy, n (%)	122 (58.7)
sPGA score, whole body, n (%)	
0, clear	1 (0.5)
1, minimal	2 (1.0)
2, mild	19 (9.1)
3, moderate	149 (71.6)
4, severe	29 (13.9)
Unknown	8 (3.8)

BMI, body mass index; BSA, body surface area; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area Severity Index; PsO, psoriasis; SD, standard deviation; sPGA, Static Physician Global Assessment.

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Abstract N°: 5390

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK 2) inhibitor, in patients with moderate to severe scalp psoriasis: patient-reported outcomes at Week 16 of a phase 3b/4 multicenter, randomized, double-blinded, placebo-controlled trial (PSORIATYK SCALP)

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Introduction & Objectives: Deucravacitinib (DEUC), an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy. PSORIATYK SCALP (NCT05478499), an ongoing 52-week, phase 3b/4 multicenter, randomized, double-blinded, placebo-controlled trial, assesses the efficacy and safety of DEUC in patients with moderate to severe scalp PsO, including those with more limited overall disease. We present patient-reported outcome results at Week 16.

Materials & Methods: Patients aged ≥18 years with scalp-specific Physician Global Assessment scores ≥3, scalp surface area involvement ≥20%, Psoriasis Scalp Severity Index scores ≥12, and body surface area involvement ≥3% were randomized 1:2 to receive once-daily placebo (PBO) or DEUC for 16 weeks. Randomization stratification factors were previous biologic use for PsO or other inflammatory diseases (yes/no) and body weight (≥90 kg or <90 kg). Key secondary endpoints included Week 16 change from baseline in numeric rating scale (NRS) score for scalp-specific itch (11-point scale from 0 [none] to 10 [worst imaginable], rated over the preceding 24 hours). Exploratory endpoints included Week 16 change from baseline in scalp-specific pain and flaking, and whole-body itch NRS scores, as well as response rates for achieving the minimum clinically important difference (MCID; ≥4 points) on each NRS measure. For continuous measures, adjusted means and *P*-values (nominal in the case of exploratory endpoints) were determined with an analysis of covariance model using treatment and randomization stratification factors as fixed effects and the baseline value as a covariate. *P*-values for binary measures were generated using a stratified Cochran-Mantel-Haenszel test.

Results: The full analysis set included 154 patients (PBO, n=51; DEUC, n=103). Mean baseline scores for each NRS measure are presented in Table 1. At Week 16, patients receiving DEUC reported significantly greater mean change from baseline vs PBO in scalp-specific itch NRS score (−3.2 vs −0.7, respectively; *P*<0.0001). Greater improvement was also reported by patients receiving DEUC vs PBO, respectively, for scalp-specific pain (−2.1 vs −0.1), flaking (−3.9 vs −1.0), and whole-body itch (−2.9 vs −0.4) NRS scores (all, *P*<0.0001; Figure 1). Patients receiving DEUC vs PBO had higher response rates, respectively, for achieving the MCID for scalp-specific itch (41.7% vs 9.8%; *P*<0.0001), pain (26.2% vs 11.8%; *P*=0.0372), and flaking (53.4% vs 19.6%; *P*<0.0001), and for whole-body itch (39.8% vs 13.7%; *P*=0.0009; Figure 2) NRS scores.

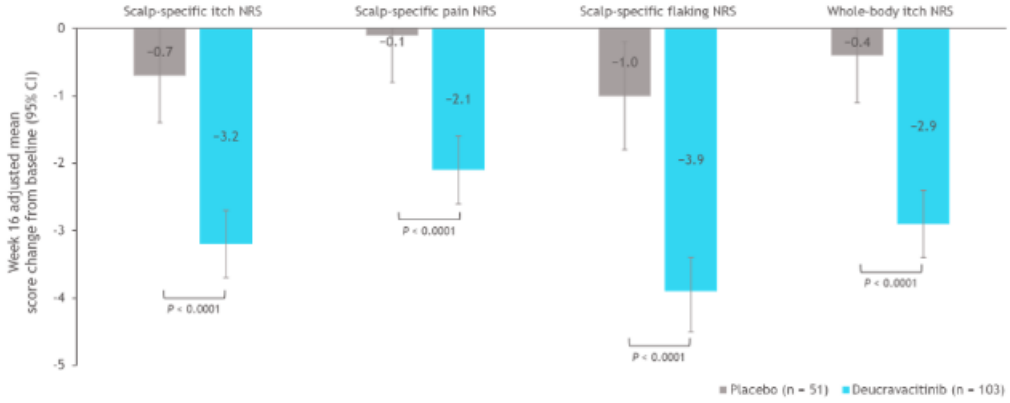
Conclusion: In this scalp-specific PsO trial, DEUC was efficacious** and resulted in significantly greater improvement in scalp-specific symptoms of itch, pain, and flaking, and in whole-body itch. DEUC was also associated with clinically meaningful improvement in each of these NRS measures.

Table 1. Mean baseline numeric rating scale scores

NRS score, mean (SD)	Placebo (n = 51)	Deucravacitinib (n = 103)
Scalp-specific itch	6.4 (1.8)	6.4 (2.3)
Scalp specific pain	4.5 (3.0)	4.0 (2.8)
Scalp-specific flaking	6.7 (2.2)	7.0 (2.3)
Whole-body itch	5.8 (2.4)	5.8 (2.8)

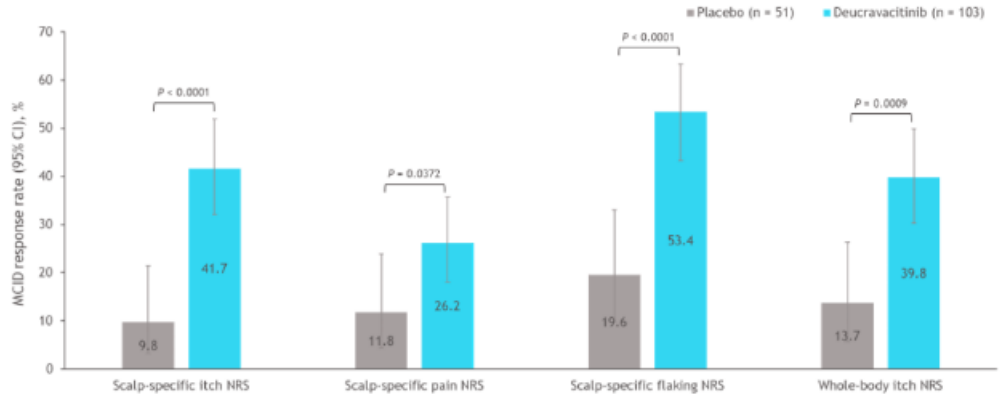
NRS, numeric rating scale; SD, standard deviation.

Figure 1. Week 16 adjusted mean score change from baseline



NRS, numeric rating scale.

Figure 2. Week 16 response rates for achieving ≥4-point MCID



MCID, minimum clinically important difference; NRS, numeric rating scale.

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Abstract N°: 5393

Real-world barriers to optimal care in psoriasis: patient and provider perspectives in the United States, United Kingdom, and Canada

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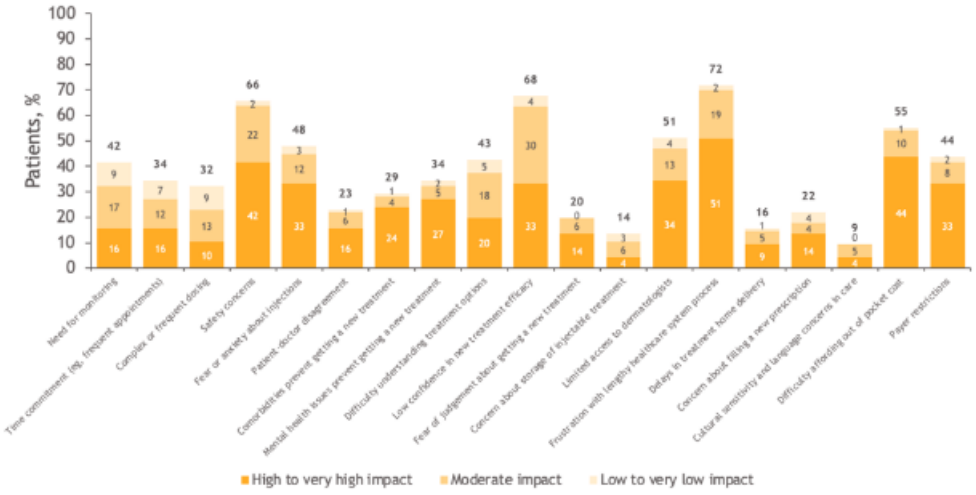
Introduction & Objectives: Despite the availability of various systemic treatments for moderate to severe psoriasis (PsO), substantial proportions of patients remain untreated or discontinue treatment after taking conventional oral medications or apremilast; many who remain on these treatments experience suboptimal outcomes. This study aimed to identify and assess the prevalence and impact of barriers to optimal PsO care from the perspectives of patients and dermatologists.

Materials & Methods: A targeted literature review identified barriers to receiving and providing a new PsO treatment. In-depth 1:1 interviews were conducted with 5 patients and 5 dermatologists in the US and the UK to validate these barriers, to qualitatively characterize their impact, and to identify additional barriers; surveys were then developed based on interview responses. The surveys were completed online by biologic-naive patients with PsO aged ≥18 years who had received ≥3 months of conventional oral systemic treatment or apremilast but self-reported their current PsO burden as moderate to severe, and by practicing dermatologists. Respondents were located in the US, UK, or Canada. The patient survey tested 19 barriers and the dermatologist survey tested 7. For each barrier, if experienced, the impact on a patient's willingness to start or consider a new PsO treatment or on a dermatologist's ability to prescribe a new PsO treatment for a biologic-naive patient was rated on a scale from 1 (very low) to 5 (very high). Results were analyzed descriptively.

Results: The patient survey was completed by 96 patients in the US, 94 in the UK, and 99 in Canada, and the dermatologist survey by 50 dermatologists in the US, 50 in the UK, and 45 in Canada. Across patients in all 3 countries surveyed, barriers with high prevalence and impact included treatment-related factors (eg, safety concerns or anxiety around injectable treatments), system-related factors (eg, limited access to dermatologists or frustration with the lengthy healthcare system process), and low confidence in the efficacy of new treatments (Figures 1-3). Dermatologists in the US and Canada identified administrative burden for treatment authorization as the most prevalent barrier (88%–91%), while those in the UK reported limited time per visit (76%) and guidelines rigidity for prescribing advanced therapies (72%; Figures 4–6).

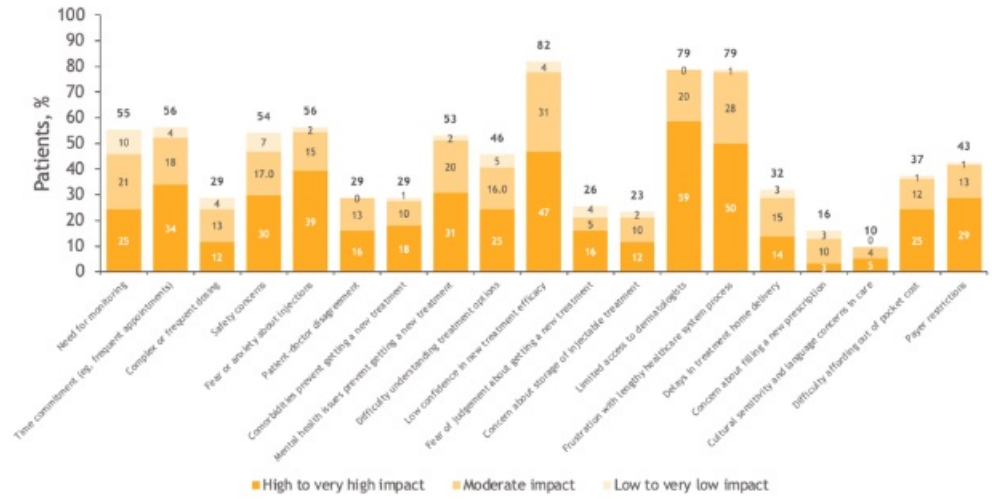
Conclusion: Surveys completed by biologic-naive patients and dermatologists in the US, UK, and Canada indicate that barriers to receiving or prescribing new PsO treatments are commonly experienced and are often of high impact. Unmet needs for safe and effective oral treatments, patient education about new treatment options, and an increase in system efficiency persist in all 3 healthcare systems. Further research is needed to holistically assess the value of new PsO treatments, including their potential to alleviate identified barriers, within a broader value framework.

Figure 1. Prevalence of barriers to starting or considering a new psoriasis treatment as reported by patients in the US[a]



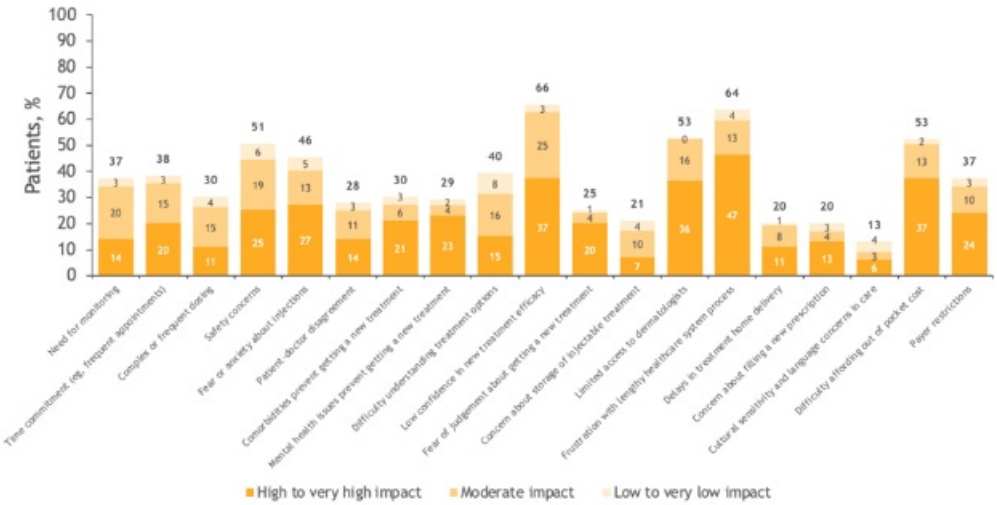
[a]Values are rounded and may not sum to total.

Figure 2. Prevalence of barriers to starting or considering a new psoriasis treatment as reported by patients in the UK[a]



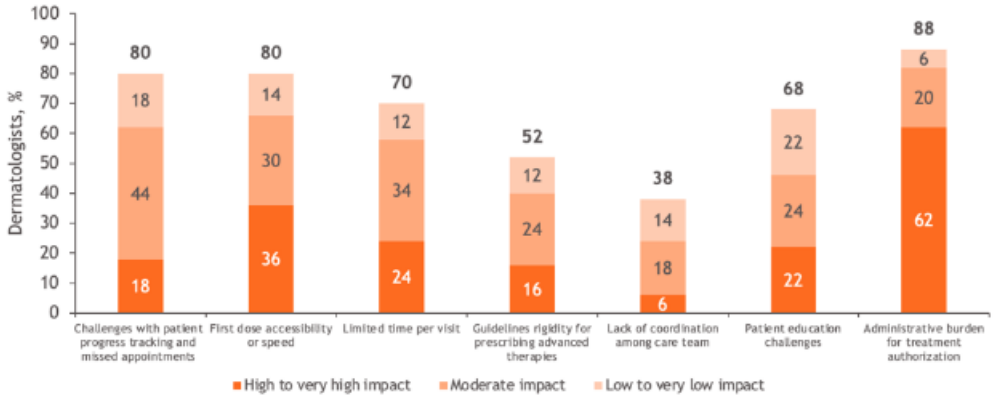
[a]Values are rounded and may not sum to total.

Figure 3. Prevalence of barriers to starting or considering a new psoriasis treatment as reported by patients in Canada[a]



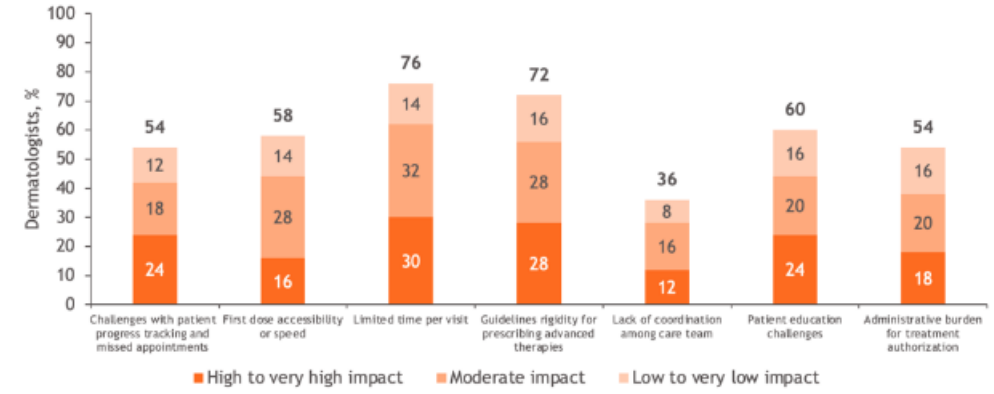
[a]Values are rounded and may not sum to total.

Figure 4. Prevalence of barriers to providing optimal psoriasis care as reported by dermatologists in the US[a]



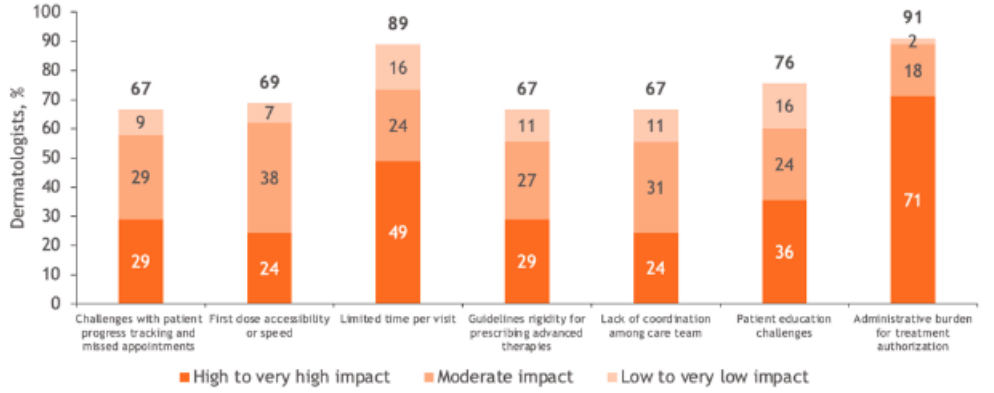
[a]Values are rounded and may not sum to total.

Figure 5. Prevalence of barriers to providing optimal psoriasis care as reported by dermatologists in the UK[a]



[a]Values are rounded and may not sum to total.

Figure 6. Prevalence of barriers to providing optimal psoriasis care as reported by dermatologists in Canada[a]



[a]Values are rounded and may not sum to total.

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Abstract N°: 5429

Psoriasis : Aggravating factors experienced by patients in a global study. Results of the ALL Project.

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Introduction & Objectives:

Apart from its skin-related symptoms, psoriasis presents a cosmetic and functional impairment, especially when it affects the hands. This not only compromises physical appearance but also hampers basic tasks, significantly impacting individuals' daily quality of life and their social interactions.

Materials & Methods:

The ALL PROJECT is a large-scale study of individuals representative of the adult population in 20 countries on five continents: Europe [France, Italy, Germany, Poland, Portugal, Spain, Denmark; n=17500], Latin America[LA] [Brazil, Mexico; n=6501], Asia [China, India, South Korea; n=10500], North America [NA] [Canada, USA; n= 7500); Middle East [ME] [Israel, United Arab Emirates; n=2750], Australia [Australia; n=2000] and Africa [Kenya, South Africa, Senegal; n=1800]

In each of the 20 countries surveyed, representative and extrapolable samples of the general population aged 16 and over were interviewed. This methodology ensures that the results of the study can be generalised to the entire population of each country included in the project, thus providing a global and diversified perspective of the subjects studied. Patients reporting only Psoriasis as confirmed by a healthcare professional, were identified to avoid attributing effects to another skin condition. The results were compared using chi-squared or Fisher's exact test. The alpha risk was set at 5% and two-tailed tests were used. Statistical analysis was performed using EasyMedStat (version 3.34; www.easymedstat.com).

Results:

Psoriasis is a condition that has a profound impact on the emotional and social aspects of patients' lives. In Europe, 40.5% of sufferers experience an impact on their personal lives. In Asia, the Middle East and Africa, the proportion is higher, at 61.4%, 46.6% and 54.2% respectively. In North America and Australia, this proportion is lower than in Europe, at 38.6% and 33.3% respectively. Africa is at 44.4%.The disruption to life as a couple was more pronounced in Asia (36.9%), Africa (33.3%), LA (28.6%) and NA (27.3%) than in Europe (21.1%), reflecting the impact of psoriasis on intimate relationships. With regard to sleep, patients in LA (54.5%) and Africa (66.7%) experienced more disturbances than those in Europe (39.9%) and Asia (34.4%).

Finally, feelings of rejection and disgust serve to exacerbate patients' distress. While 16.9% of European patients feel rejected, this proportion is 27.3% in Asia and 32.5% in LA. Disgust is felt by 18.3% in Europe, 27.3% in LA and 22% in Africa. For the last two, no region is below 15%, which serves to highlight the stigma felt.

These comparisons demonstrate that while psoriasis is a significant issue in Europe, its impact is even more pronounced in other regions, underscoring the pressing need for care strategies that are tailored to each cultural and regional context.

Conclusion:

The findings suggest that psoriasis exerts a significant influence on the emotional and social aspects of life, affecting nearly half of European and Latin American patients' self-esteem and body image. The implications on daily functioning, productivity, and financial burden emphasize the necessity of addressing psoriasis not solely as a dermatological condition but also as a broader public health concern. Recognizing the importance of therapeutic approaches that integrate psychological and social considerations is increasingly vital for enhancing the well-being of individuals coping with psoriasis.

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AMSTERDAM 25-28 SEPTEMBER 2024
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Abstract N°: 5432

Deucravacitinib in plaque psoriasis: 4-year efficacy results by prior biologic treatment in the phase 3 POETYK PSO-1, PSO-2, and LTE trials

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was efficacious versus placebo and apremilast in patients with moderate to severe plaque psoriasis in two 52-week, global, phase 3 trials, POETYK PSO-1 and POETYK PSO-2, and through 4 years in the ongoing open-label POETYK long-term extension (LTE) trial. The current analysis evaluated deucravacitinib efficacy through 4 years in patient subgroups defined by prior use of biologic therapy for the treatment of psoriasis.

Materials & Methods: Response rates for ≥75%/≥90% reduction from baseline in Psoriasis Area and Severity Index (PASI 75/90) and static Physician Global Assessment score of 0 (clear) or 1 (almost clear) (sPGA 0/1) were evaluated in patients who received continuous deucravacitinib treatment from baseline (Day 1) through 4 years (Week 208; data cutoff, November 1, 2023) based on prior biologic therapy use, including anti-interleukin (IL) therapy (anti-IL-17, anti-IL-23, anti-IL-12/23p40) and anti-tumor necrosis factor (TNF) therapy. Response rates were compared with long-term response rates previously reported in the overall study population. Modified nonresponder imputation (mNRI) was used to impute missing data.

Results: In total, 513 patients received continuous deucravacitinib treatment from baseline. A total of 508 patients met the criteria for the mNRI analysis. Of the 513 patients, 37.2% had received prior biologic therapy (anti-IL, 24.2%; anti-TNF, 15.4%). PASI 75 responses were maintained from Week 52 in the parent trials (72.0%) through 4 years in the overall population (71.7%), with slightly lower response rates with versus without prior biologic therapy (any biologic, 65.9% vs 75.1%; prior anti-IL, 63.6% vs 74.3%; prior anti-TNF, 65.2% vs 72.9%, respectively). In addition, PASI 90 responses were maintained at similar rates through 4 years in each population (overall, 47.5%; any biologic, 45.9% vs 48.5%; anti-IL, 42.7% vs 49.1%; anti-TNF, 46.0% vs 47.8%) as were sPGA 0/1 responses (overall, 57.2%; any biologic, 57.8% vs 56.8%; anti-IL, 54.8% vs 57.9%; anti-TNF, 62.0% vs 56.3%).

Conclusion: Deucravacitinib treatment maintained high efficacy rates through 4 years in patients with plaque psoriasis regardless of prior use of biologic therapy, including anti-IL therapy and anti-TNF therapy. These findings provide additional support that deucravacitinib, a once-daily oral drug, is an efficacious therapeutic option through 4 years in patients with plaque psoriasis regardless of prior use of biologics, including anti-IL therapies

that target similar pathways as TYK2 inhibition (IL-23/IL-17).

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Abstract N°: 5436

Deucravacitinib treatment did not impact immune response to SARS-CoV-2 vaccines and infection in patients with plaque psoriasis: results from the phase 3 POETYK long-term extension trial

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was efficacious and well tolerated in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) trials. Patients who completed the parent trials could enroll in the ongoing, open-label POETYK long-term extension (LTE) (NCT04036435) trial, which overlapped with the peak of the global COVID-19 (SARS-CoV-2) pandemic. Incidence rates of COVID-19-related serious adverse events (SAEs) and mortality in deucravacitinib-treated patients were similar to expected infection rates in the placebo arm of a contemporaneous COVID-19 vaccine trial. The majority of COVID-19 infections in the LTE trial were not serious and did not lead to treatment discontinuation. The majority of COVID-19 AEs and SAEs occurred in unvaccinated patients. Here, serological responses and predictors of seroconversion to SARS-CoV-2 vaccination and/or infection during deucravacitinib treatment were investigated in patients in the LTE trial.

Materials & Methods: The LTE trial started August 2019 and overlapped with the COVID-19 pandemic, which first emerged in December 2019. The first infection in the POETYK program was reported March 24, 2020, the first vaccination occurred December 17, 2020, and samples were collected through August 2, 2023. This analysis included patients in the LTE trial who (1) were fully vaccinated with an mRNA vaccine (ie, 2 doses of the Moderna or Pfizer-BioNTech vaccine) or a non-mRNA vaccine (ie, 2 doses of Novavax or 1 dose of the Johnson & Johnson/Janssen vaccine) or had a reported SARS-CoV-2 infection during the LTE and (2) had their first serum sample available ≥15 days after the second mRNA dose or ≥30 days and up to 229 days after a non-mRNA vaccine or infection. Spike RBD antibody level ≥0.8 U/mL and nucleocapsid antibody level ≥1.0 cutoff index (COI) were used as measures of seroconversion; nucleocapsid antibody levels ≥1.0 U/mL were also used as an indicator of prior SARS-CoV-2 infection.

Results: 596 (87.8%) patients were vaccinated (mRNA vaccine, n=498; non-mRNA vaccine, n=98). Baseline characteristics were similar between patients who were vaccinated (n=406), infected (n=83), and both vaccinated and infected (n=190). Seroconversion occurred in 99.2% of mRNA vaccine recipients and 98.9% of non-mRNA vaccine recipients (mean RBD antibody levels, 9085.1 U/mL and 4277.9 U/mL, respectively; range, 0.4-75,000 U/mL [seroconversion, ≥0.8 U/mL titer]). Seroconversion occurred in 100% of infected unvaccinated patients (mean RBD antibody level, 3663.8 U/mL), 99.1% of noninfected vaccinated patients (6384.2 U/mL), and 100% of infected vaccinated patients (23,636.2 U/mL). The mean duration between reported infection and sample collection was 177 days. RBD antibody levels remained high for >24 weeks in mRNA vaccine recipients, regardless of time after vaccination or infection. Age, body mass index, and sex were not predictors of antibody levels or seroconversion.

Conclusion: In the LTE trial, >98% of patients mounted a serologic response to SARS-CoV-2 vaccination and/or infection, with more robust responses in vaccinated than unvaccinated patients. Deucravacitinib did not impact

immune responses to vaccines that protect against COVID-19.

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Abstract N°: 5467

Lesional psoriasis is characterized by a reduced barrier function and an altered stratum corneum ceramide profile

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Introduction & Objectives:

Psoriasis is a chronic, immune-mediated, inflammatory skin disease in which the abnormal proliferation and differentiation of keratinocytes result in a markedly impaired skin barrier. The skin barrier function is dependent on the extracellular lipid matrix which surrounds the corneocytes in the stratum corneum. Ceramides comprise essential components of this matrix. Alterations in the ceramide profile have been directly linked to barrier dysfunction and might be an underlying factor of the barrier impairment in psoriasis. Therefore, the aim of this study was to perform an in-depth characterization of the full stratum corneum ceramide profile in lesional and non-lesional psoriatic skin. Furthermore, we aimed to evaluate the relationship between ceramide profile and barrier impairment by correlating single ceramide characteristics to barrier function.

Materials & Methods:

Lesional and non-lesional skin of 26 psoriasis patients and 10 age-, skin type- and anatomical location-matched healthy controls was analyzed twice over two weeks using in-depth ceramide lipidomics by liquid chromatography-mass spectrometry. Barrier function was assessed by measuring transepidermal water loss.

Results:

The ceramide profile of lesional skin showed a significant decrease in the abundance of total ceramides compared to control and non-lesional skin with significant alterations in the ceramide subclass composition. Additionally, the degree of monounsaturation was significantly increased and the average ceramide chain length significantly decreased in lesional skin. Altogether, this resulted in a markedly different profile compared to controls for lesional skin, but not for non-lesional skin. Furthermore, the barrier function was significantly decreased in lesional skin compared to non-lesional skin and that of controls. We were able to correlate barrier function to alterations in ceramide profile, highlighting their interdependence. By assessing the parameters two weeks apart, we are able to confirm the degree of reproducibility which further affirms this connection.

Conclusion:

To conclude, we show that changes in the ceramide profile and barrier impairment are observed in, and limited to, lesional psoriatic skin. Their direct correlation provides a further mechanistic basis for the concomitantly observed impairment of barrier dysfunction.

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Abstract N°: 5476

Guselkumab normalizes barrier dysfunction and altered stratum corneum ceramide profile in psoriasis

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Introduction & Objectives:

In psoriasis, epidermal inflammation drives skin barrier perturbations. The skin barrier function is mainly provided by the stratum corneum lipid matrix, of which ceramides constitute important components. Changes in the ceramide profile are directly related to barrier function. In this study, we set out to characterize the barrier function and ceramide profile of psoriatic skin before and during anti-Interleukin-23 therapy with guselkumab.

Materials & Methods:

A double-blind, randomized controlled trial was conducted in which 26 mild-to-severe plaque psoriasis patients were randomized 3:1 to 100 mg guselkumab or placebo for 16 weeks. Barrier function was assessed by measuring by trans-epidermal water loss. Ceramide profiling was performed using liquid chromatography-mass spectrometry after stratum corneum was harvested using tape-stripping.

Results:

The barrier function and ceramide profile of lesional skin normalized to that of controls during treatment with guselkumab, but not placebo. This resulted in significant differences compared to placebo at the end of treatment. Changes in the lesional ceramide profile during treatment correlated with barrier function and target lesion severity. Non-lesional skin remained similar throughout treatment.

Conclusion:

Concluding, guselkumab therapy restored the skin barrier in psoriasis. Concomitant correlations between skin barrier function, the ceramide profile and disease severity demonstrate their interdependency.

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Abstract N°: 5498

Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, in moderate to severe plaque psoriasis: patient-reported outcomes over 4 years of treatment in the phase 3 POETYK PSO-1, PSO-2, and PSO-LTE trials

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Introduction & Objectives: Deucravacitinib (DEUC), an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy. In 2 phase 3 trials in patients aged ≥18 years with moderate to severe plaque PsO, POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751), DEUC was more effective than placebo and apremilast across a range of clinician-assessed and patient-reported outcomes (PROs). At Week 52 of each parent trial, patients could enroll in the POETYK long-term extension (LTE) study (NCT04036435) to receive open-label DEUC. We report response rates for meaningful change on 2 PRO instruments, the Psoriasis Symptoms and Signs Diary (PSSD) and Dermatology Life Quality Index (DLQI), through up to 196 weeks of treatment with DEUC.

Materials & Methods: This analysis included patients who completed ≥1 PSSD or DLQI item at baseline in POETYK PSO-1 or PSO-2 and at any point during the LTE study through 208 weeks of enrollment. Meaningful changes from baseline were defined as ≥15-, ≥25-, or ≥30-point improvement in PSSD symptom and sign summary scores and ≥4-point improvement in DLQI scores. Results are reported separately for patients who had received DEUC continuously from Day 1 throughout POETYK PSO-1 and then enrolled in the LTE study (Cohort 1; data are presented from baseline of POETYK PSO-1) and for all patients who enrolled in the LTE (Cohort 2; data are presented from the start of the LTE only). Patients discontinuing from the study owing to worsening psoriasis were imputed as nonresponders; other missing data were analyzed by multiple imputation.

Results: The analysis included 264 patients in Cohort 1 and 799 in Cohort 2 (Table). In Cohort 1, response rates (95% confidence interval [CI]) for ≥25-point change in PSSD symptom and sign scores improved over time and were 61.6% (60.2-63.3) and 68.5% (67.0-70.1), respectively, at the start of the LTE, and 60.5% (58.3-62.7) and 60.8% (58.3-62.9), respectively, at Week 196 (Figures 1 and 2; all 3 thresholds are presented). Response rates (95% CI) for meaningful change in DLQI scores also improved over time; they were 82.2% (82.2-82.2) at the start of the LTE and 79.4% (77.7-81.1) at Week 196 (Figure 3). In Cohort 2, PSSD symptom and sign score response rates (95% CI) for ≥25-point improvement from baseline in the parent studies were 58.1% (56.9-59.3) and 66.6% (65.4-67.7), respectively, at the start of the LTE, and 58.1% (56.5-59.8) and 60.8% (59.1-62.4), respectively, at Week 196 (Figures 4 and 5). Response rates (95% CI) for meaningful change in DLQI scores were 77.9% (77.6-78.1) at the start of the LTE and 75.1% (73.8-76.5) at Week 196 (Figure 6).

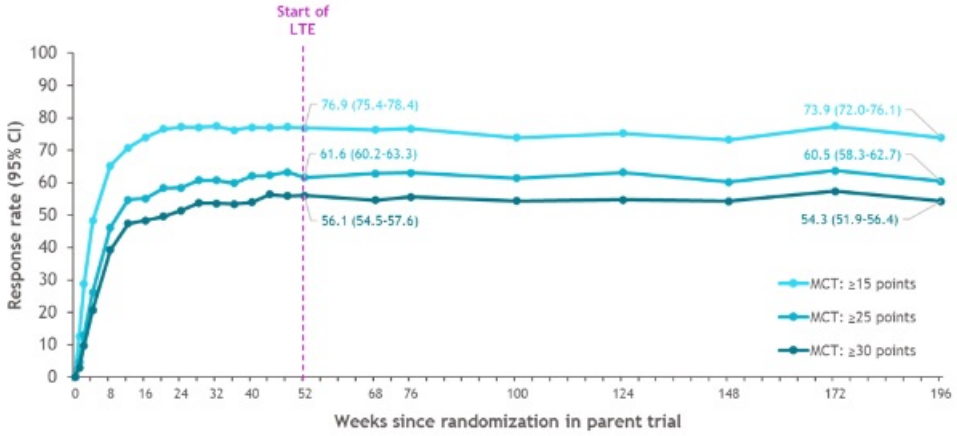
Conclusion: DEUC increased meaningful improvement responses in patient-reported signs and symptoms of PsO and patients' quality of life through Week 52, and maintained these responses over 4 years of treatment.

Table. Demographics and baseline clinical characteristics

Characteristic	Cohort 1[a] (n = 264)	Cohort 2[b] (n = 799)
Age, n (%), years		
<40	86 (32.6)	236 (29.5)
40–65	157 (59.5)	481 (60.2)
≥65	21 (8.0)	82 (10.3)
Body weight, n (%), kg		
<90 kg	99 (37.5)	365 (45.7)
≥90 kg	165 (62.5)	434 (54.3)
Female, n (%)	87 (33.0)	246 (30.8)
PSSD score, mean (SD)		
Symptom	51.4 (25.1)	50.7 (25.8)
Sign	54.6 (21.9)	55.3 (22.2)
DLQI score, mean (SD)	12.3 (6.5)	11.9 (6.6)

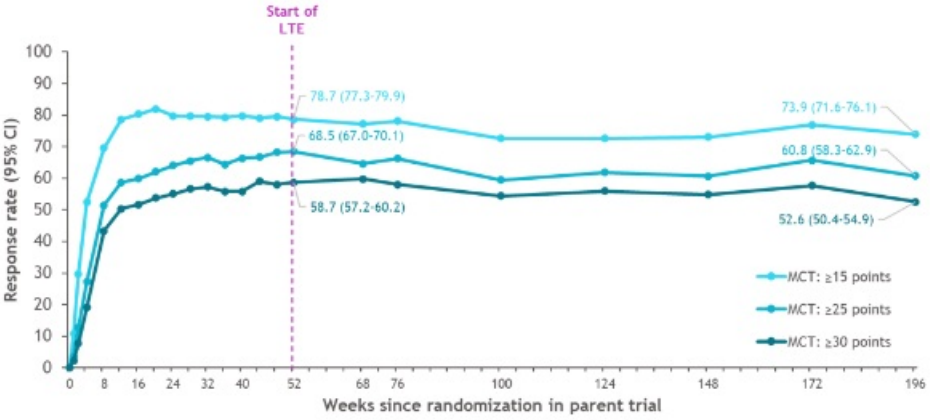
[a]Patients randomized to deucravacitinib at baseline of POETYK PSO-1.
[b]All patients who enrolled in the long-term extension study.
DLQI, Dermatology Life Quality Index; PSSD, Psoriasis Symptoms and Signs Diary; SD, standard deviation.

Figure 1. Cohort 1[a] (n = 264): response rates for meaningful change in PSSD symptom score



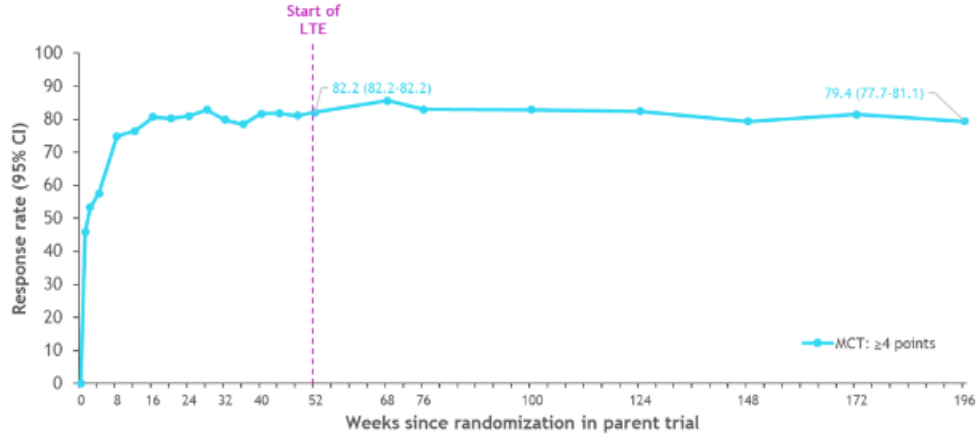
[a]Patients randomized to deucravacitinib at baseline of POETYK PSO-1.
CI, confidence interval; LTE, long-term extension; MCT, meaningful change threshold; PSSD, Psoriasis Symptoms and Signs Diary.

Figure 2. Cohort 1[a] (n = 264): response rates for meaningful change in PSSD sign score



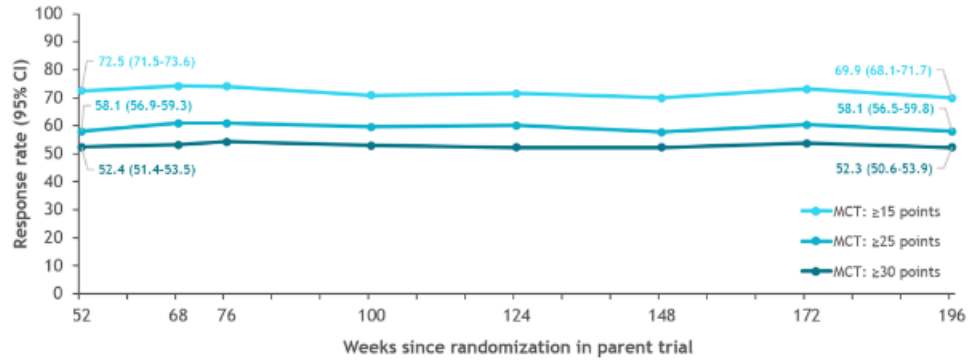
[a]Patients randomized to deucravacitinib at baseline of POETYK PSO-1.
CI, confidence interval; LTE, long-term extension; MCT, meaningful change threshold; PSSD, Psoriasis Symptoms and Signs Diary.

Figure 3. Cohort 1[a] (n = 264): response rates for meaningful change in DLQI score



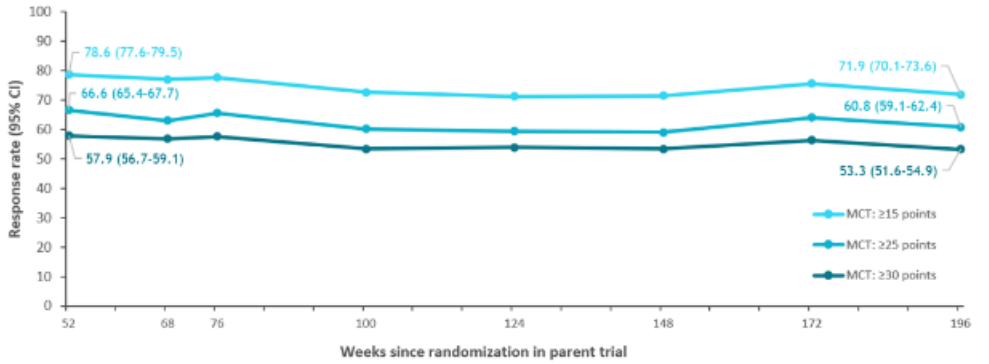
[a]Patients randomized to deucravacitinib at baseline of POETYK PSO-1.
CI, confidence interval; DLQI, Dermatology Life Quality Index; LTE, long-term extension; MCT, meaningful change threshold.

Figure 4. Cohort 2[a] (n = 799): response rates for meaningful change in PSSD symptom score



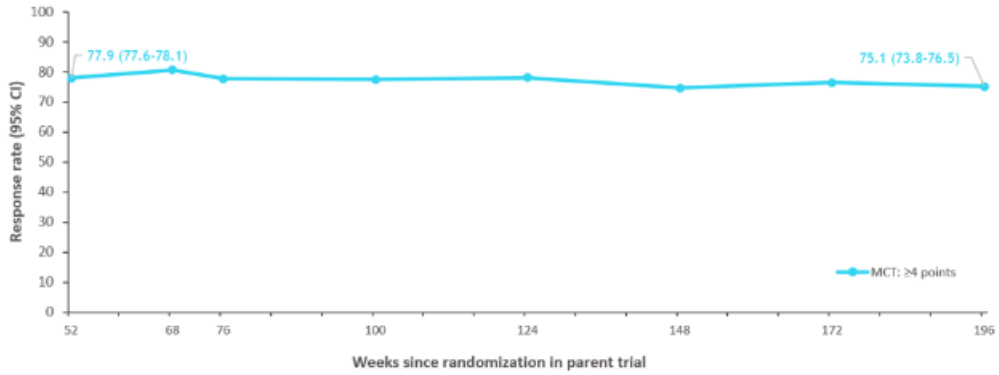
[a]All patients who enrolled in the LTE study.
CI, confidence interval; LTE, long-term extension; MCT, meaningful change threshold; PSSD, Psoriasis Symptoms and Signs Diary.

Figure 5. Cohort 2[a] (n = 799): response rates for meaningful change in PSSD sign score



[a]All patients who enrolled in the LTE study.
CI, confidence interval; LTE, long-term extension; MCT, meaningful change threshold; PSSD, Psoriasis Symptoms and Signs Diary.

Figure 6. Cohort 2[a] (n = 799): response rate for meaningful change in DLQI score



[a]All patients who enrolled in the LTE study.
CI, confidence interval; DLQI, Dermatology Life Quality Index; LTE, long-term extension; MCT, meaningful change threshold.

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Abstract N°: 5500

Real-world effectiveness of deucravacitinib in patients with plaque psoriasis: 6-month analysis of skin clearance from the RePhlect Registry

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Introduction & Objectives: Deucravacitinib is an oral, selective, tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. However, real-world effectiveness of deucravacitinib has not been reported. The Registry of Psoriasis Health Outcomes: A Longitudinal Real-World Collaboration Study (RePhlect) assesses deucravacitinib usage in a diverse, real-world, global population of patients with psoriasis, specifically in North America (US/Canada), Japan, UK, Germany, and France. This analysis assessed the effectiveness of deucravacitinib as measured by skin clearance after 6 months of persistent treatment in the US and Canada.

Materials & Methods: Patients included in the analysis were adults (≥18 years) from** the** US and Canada with plaque psoriasis who were enrolled in the CorEvitas registry, who initiated treatment with deucravacitinib monotherapy between September 2022 and July 2023, and who persisted with deucravacitinib until their follow-up visit 6 months (5–9 month window) after treatment initiation. Demographics and clinical characteristics data were collected at baseline and at each patient's follow-up visit. Skin clearance was measured as change in Psoriasis Area and Severity Index (PASI), percentage of affected body surface area (BSA), and Investigator's Global Assessment (IGA) from baseline to follow-up. Mean changes (95% confidence intervals) were calculated; *P* values were calculated from paired *t* tests to assess changes over 6 months. Proportion of patients achieving PASI ≤3, BSA ≤3%, and IGA 0/1 were also calculated. Analyses were repeated in patients with moderate to severe psoriasis (BSA ≥3%, PASI ≥5, or Dermatology Life Quality Index ≥5).

Results: The analysis included 74 patients in the overall cohort (mean age, 53.6 years [SD 14.6], 55.4% female, and 86.5% White), 66 of whom had moderate to severe psoriasis. In the overall cohort, 51.4% had scalp psoriasis; mean psoriasis duration was 15.1 (SD 13.0) years. Upon follow-up, both the overall cohort and the moderate to severe cohort achieved statistically significant mean decreases in PASI, BSA, and IGA (all, $P<0.001$) (Table, Figure). In the overall cohort, 72.9% achieved PASI scores ≤3; 63.6% of patients achieved a BSA ≤3%; and 44.8% achieved IGA scores of 0/1. Similar results were observed in the 66 patients with moderate to severe psoriasis.

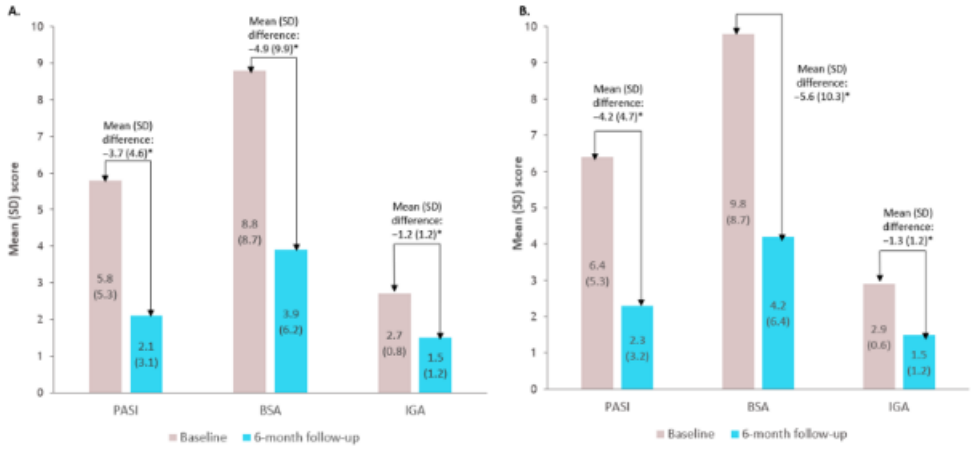
Conclusion: These findings demonstrate that the effectiveness of continuous deucravacitinib use in real-world registry patients was consistent with efficacy outcomes observed in the clinical studies, underscoring the value of deucravacitinib as an effective oral therapy in the diverse patient populations found in clinical practice.

Table. Skin clearance characteristics at baseline and change over 6 months follow up-in patients who initiated and persisted with deucravacitinib treatment

Disease characteristics	Overall (n=74)			Patients with moderate to severe PsO (n=66)		
	Mean (SD)	95% CI	*P*-value	Mean (SD)	95% CI	*P*-value
PASI						
Baseline	5.8 (5.3)			6.4 (5.3)		
Change from baseline	−3.7 (4.6)	−4.8 to −2.6	<0.001	−4.2 (4.7)	−5.3 to −3.0	<0.001
BSA[a]						
Baseline	8.8 (8.7)			9.8 (8.7)		
Change from baseline	−4.9 (9.9)	−7.2 to −2.6	<0.001	−5.6 (10.3)	−8.1 to −3.0	<0.001
IGA						
Baseline	2.7 (0.8)			2.9 (0.6)		
Change from baseline	−1.2 (1.2)	−1.5 to −0.9	<0.001	1.5 (1.2)	−1.6 to −1.0	<0.001

*Percent involvement.
BSA, body surface area; CI, confidence interval; IGA, Investigator's Global Assessment; PASI, Psoriasis Activity and Severity Index; PsO, psoriasis; SD, standard deviation.

Figure. Change in skin clearance measures over 6 months of follow-up in patients who initiated and persisted with deucravacitinib treatment in the overall group of patients (A) and in patients with moderate to severe psoriasis (B)



*P<0.001.
BSA, body surface area; IGA, Investigator's Global Assessment; PASI, Psoriasis Activity and Severity Index; SD, standard deviation.

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Abstract N°: 5504

Real-world effectiveness of deucravacitinib in patients with plaque psoriasis: 6-month analysis of symptom and quality of life improvements from the RePhlect Registry

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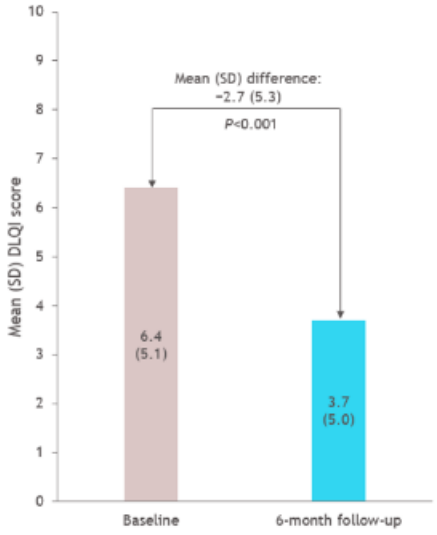
Introduction & Objectives: Despite the availability of highly efficacious treatments for plaque psoriasis (PsO), patients continue to report high symptom burden and a substantial impact on health-related quality of life (HRQoL). Deucravacitinib (DEUC), an oral, selective, allosteric, tyrosine kinase 2 (TYK2) inhibitor, has demonstrated superiority over both placebo and apremilast on multiple efficacy and patient-reported outcome measures in adults with moderate to severe plaque PsO in clinical trials. However, real-world effectiveness data for DEUC has not been reported. The Registry of Psoriasis Health Outcomes: A Longitudinal Real-World Collaboration Study (RePhlect) assesses DEUC use in a diverse, real-world, global population of patients with PsO. This analysis assessed HRQoL outcomes and symptom burden in patients with PsO after 6 months of persistent DEUC treatment in the US and Canada.

Materials & Methods: Included patients were adults (≥18 years) from** the US and Canada with plaque PsO who were enrolled in the CorEvitas registry, who initiated treatment with DEUC monotherapy between September 2022 and July 2023, and who persisted with DEUC up to a 6-month (5–9-month window) follow-up visit after treatment initiation. Demographics and clinical characteristics data were collected at baseline and at follow-up visit. HRQoL was measured using the Dermatology Life Quality Index (DLQI), and symptom burden using visual analog scales (VAS, 0–100 scale) for patient-reported itch, skin pain, and fatigue. Mean change from baseline to follow-up was calculated for all outcomes, and *P* values assessing no change from baseline were calculated from paired *t* tests. Among patients with DLQI >1 at baseline, the percentage achieving DLQI score of 0/1 at follow-up was calculated. Analyses were repeated in patients with moderate to severe PsO at baseline (BSA ≥3, PASI ≥5, or DLQI ≥5).

Results: Among the 74 DEUC initiators included, the mean age was 53.6 (standard deviation [SD], 14.6) years, 55.4% were female, 86.5% were White, and 66 (89.2%) had moderate to severe PsO. The scalp was the most frequently affected hard-to-treat area (51.4%). Mean changes for all outcomes were statistically significant (all, $P<0.05$). At 6 months, the mean (SD) DLQI score decreased by 2.7 (5.3) (Figure 1), and VAS itch, skin pain, and fatigue scores decreased by 25.5 (34.3), 14.6 (31.5), and 8.1 (27.8), respectively (Figure 2). These differences correspond to decreases of 42.2%, 48.9%, 46.2%, and 22.2%, respectively. DLQI score of 0/1 was achieved by 38.7% (24/62) of patients. Results in patients with moderate to severe PsO were similar (Figures 3 and 4).

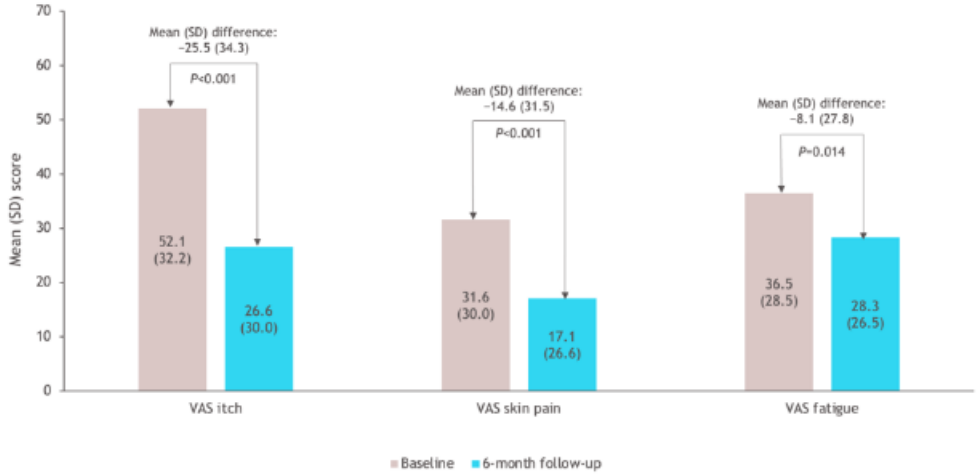
Conclusion: These findings are among the first real-world DEUC effectiveness data for HRQoL; they confirm the clinical efficacy observed in the clinical studies and demonstrate improvements in PsO symptoms and HRQoL with 6 months of persistent use in a diverse patient population in clinical practice.

Figure 1. DLQI score change[a] from baseline to 6 months in the overall cohort of North American RePhlect patients who initiated and persisted on deucravacitinib as monotherapy



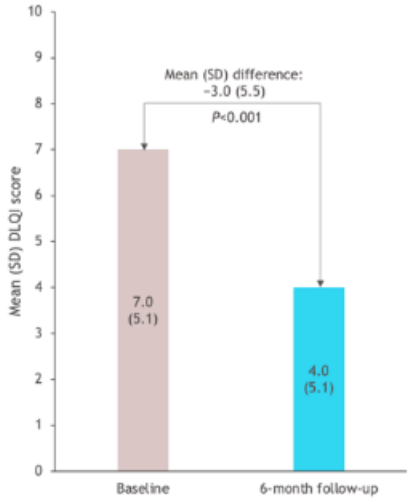
[a]*P* value calculated from paired *t* test assessments of no difference between baseline and follow-up.
DLQI, Dermatology Life Quality Index; SD, standard deviation.

Figure 2. VAS score changes from baseline to 6 months[a] in the overall cohort of North American RePhlect patients who initiated and persisted on deucravacitinib as monotherapy



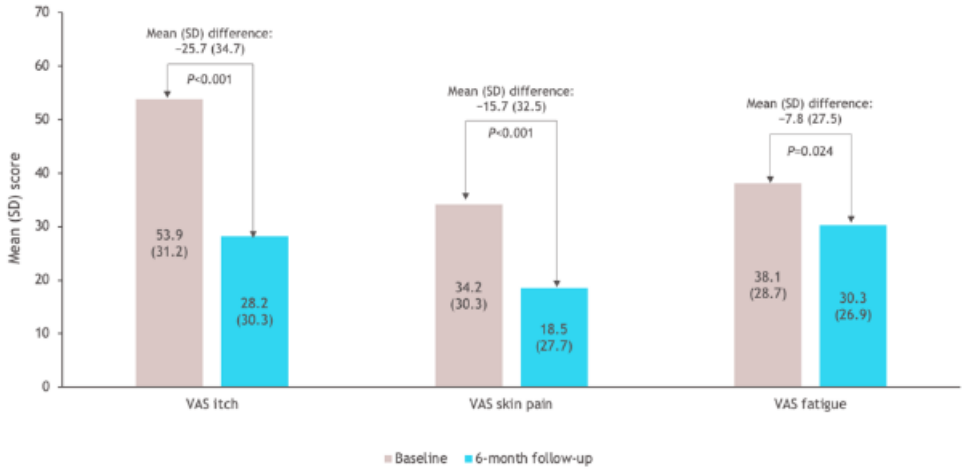
[a]*P* value calculated from paired *t* test assessments of no difference between baseline and follow-up.
SD, standard deviation; VAS, visual analog scale.

Figure 3. DLQI score change from baseline to 6 months[a] in North American RePhlect patients with moderate to severe disease who initiated and persisted on deucravacitinib as monotherapy



[a]*P* value calculated from paired *t* test assessments of no difference between baseline and follow-up.
SD, standard deviation; VAS, visual analog scale.

Figure 4. VAS score changes from baseline to 6 months[a] in North American RePhlect patients with moderate to severe disease who initiated and persisted on deucravacitinib as monotherapy



[a]*P* value calculated from paired *t* test assessments of no difference between baseline and follow-up.
SD, standard deviation; VAS, visual analog scale.

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Abstract N°: 5512

Risankizumab differentially modifies psoriatic pathogenetic T-cells populations based on patient's autoreactivity status.

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Introduction & Objectives:

Psoriasis is an inflammatory and autoimmune disease in which T-cells activation and specific inflammatory cytokines significantly contribute to the pathogenesis. Based on recent studies, the autoimmune reaction to autoantigens such as LL37 and ADAMTSL5, that are increased in psoriatic lesional skin, induces the production of pathogenic cytokines including interleukin IL-23 and IL-17. In a recent work, we found that, while the presence of single autoreactivity to either LL-37 or ADAMTLS5 do not influence the clinical efficacy of the IL-23 inhibitor risankizumab, double auto-reactivity to both LL37 and ADAMTSL5 autoantigens decrease the response to treatment. The objective of our study is to evaluate how risankizumab influence the cellular responses and modulates the circulating pathogenetic T-cells populations based on the autoreactivity status of the subjects.

Materials & Methods:

The presence of circulating LL37- and ADAMTSL5-reactive T-cells was assessed in a cohort of 142 psoriatic patients by proliferation test (Stimulation Index) at baseline. Fifty-one patients resulted auto-reactive (SI>2) and the frequency of specific circulating T-cells populations were analyzed at different time points up to week 52. Thirty-three healthy donors were included for comparison.

Results:

The frequency of proliferating circulating Ki67+CD4+, Ki67+CD8+ T-cells and pathogenetic IL-17+CD8+ and IL-22+CD8+ T-cells positively correlated with baseline PASI in the entire psoriatic cohort and risankizumab treatment reduced their frequencies in the cohort of reactive subjects. Notably, IL-17+CD8+ T-cells decreased both in single-LL37 and single-ADAMTLS5-reactive subjects, but not in double reactive ones. LL37 autoreactivity of CD4+ and CD8+ T-cells decreased with treatment in LL37-reactive subjects, but not for CD4+ in double-reactive subjects. More inconsistent results were seen for ADMTLS5 autoreactivity in CD4+ and CD8+ T-cells populations, with significant changes over time for CD4+ T-cells only in the overall ADAMTSL5-reactive population (double LL37 and ADAMTLS5 reactive and single ADAMTSL5 reactive). Treg frequency negatively correlated with baseline PASI and increased within 16 weeks of treatment, while no significant changes were seen in double-reactive subjects. Considering the overall cohort of psoriatic patients, the IL-17+CD4+/Treg ratio significantly decreased over time, while the IL17+CD4+CD25+ FoxP3+ was constantly lower compared to healthy donors at all time points. Interestingly, the pathogenic subpopulations of IL17+ and IL22+ CD8+MAIT cells, that is probably involved in the development of psoriatic arthritis, also decreased in treated subjects.

Conclusion:

Risankizumab efficiently decreases the pathogenetic T-cells populations in single-LL37- or single-ADAMTLS5-reactive subjects, but not in double-reactive subjects, suggesting a more complex activation of pathogenetic

immune pathways that sustain the psoriatic inflammation alongside with antigen-specific T-cell autoreactivity in this subcategory of patients. In conclusion, the double-autoreactivity status influences both the cellular and clinical responses to risankizumab.

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Abstract N°: 5544

Bimekizumab treatment in psoriasis patients: A mechanistic understanding of the durable clinical response

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Introduction & Objectives:

Dual inhibition of interleukin (IL)-17F in addition to IL-17A with bimekizumab (BKZ) has been associated with long-term skin clearance in psoriasis patients, with >80% maintaining complete skin clearance from Week 16 through 3 years.1 While IL-17A and IL-17F have overlapping biology, their production from IL-17-secreting cells is regulated differently. Chronic stimulation causes preferential IL-17F production, consistent with the greater abundance of IL-17F-secreting cells in psoriatic lesional tissue.2–4 Interest in tissue-resident memory T-cells (Trm) has grown recently due to their implication in disease recurrence at the same location following treatment withdrawal and in disease perpetuation during treatment.5

Here, we examine the molecular mechanisms that lead to the durable and continuous complete skin clearance observed in BKZtreated patients with psoriasis over 3 years.

Materials & Methods:

Several transcriptomics datasets were analysed, including single-cell RNA sequencing (RNA-seq) datasets from lesional psoriasis biopsies (reported elsewhere),4,6,7 alongside pre- and post-treatment bulk RNA-seq data from a phase 2a trial of BKZ in psoriasis (study design previously described; biopsies collected: Weeks 0/8 [lesional/non-lesional skin] and Week 28 [lesional only]).8

Results:

Analysis of the 3 independent psoriasis single-cell datasets consistently highlighted that IL17A- and IL17F-secreting cells have highly similar transcriptomes. IL7R was highly expressed on both IL17A- and, particularly, IL17F-secreting cells, and this may increase the survival of these pathogenic cells, as the IL-7 pathway is associated with cell survival. Presence of IL17A- and IL17F-expressing Trm cells in psoriatic lesional tissue was also indicated, alongside expression of several T cell pro-survival factors. Bulk transcriptomic analysis showed normalisation of a Trm gene signature after only 2 doses of BKZ (median percentage improvement: 78.1% at Week 8, which increased to 87.7% at Week 28, following 3 doses; **Figure**). Additionally, elevated expression of the pro-survival factors IL7R and IL32 was reversed alongside normalisation of an anti-apoptotic gene signature.

Conclusion:

These mechanistic data from patient samples highlight the importance of IL-17F and IL-17A dual neutralisation in normalising both Trm biology and pro-survival factors. These observations have implications for disease modification and are important for the maintenance and durability of complete skin clearance in psoriasis.

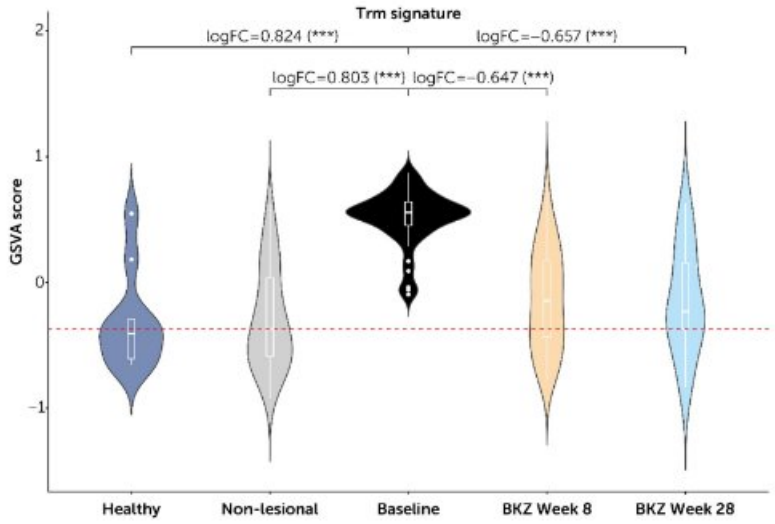
References:

1. Strober B. Br J Dermatol 2023;188:749–59, NCT03598790; **2.** Cole S. J Allergy Clin Immunol 2023;152:783–98; **3.**

Kolbinger F. J Allergy Clin Immunol 2017;139:923–32.e8; **4**. Skelton A. Presented at SID 2022; P038; **5.** Puig L. Br J Dermatol 2022;186:773–81; **6.** Kim J. J Allergy Clin Immunol 2021;148:1281–92; **7.** Reynolds G. Science 2021;371:eaba6500; **8.** Oliver R. Br J Dermatol 2022;186:652–63, NCT03025542; **9.** Hänzelmann S. BMC Bioinformatics 2013;14:1–15; **10.** Ritchie ME. Nucleic Acids Res 2015;43:e47.

Previously presented at the Inflammatory Skin Disease Summit (ISDS) 2023 (abstract subsequently published in the *Journal of Investigative Dermatology* [2023]) and at the 7th World Psoriasis & Psoriatic Arthritis Conference (IFPA) 2024.

Figure. Normalisation of Trm signature (CD103, CD69, CD44) in treated lesional tissue at Weeks 8/28 versus baseline healthy, non-lesional and lesional tissue



Gene Set Variation Analysis (GSVA)[9] was used to estimate gene set level of expression. The red horizontal line corresponds to the median baseline expression in non-lesional tissue. LogFC and FDR-adjusted p-values were calculated using the limma[10] moderated t-test. ***FDR<0.001. BKZ: bimekizumab; FC: fold change; FDR: false discovery rate; GSVA: Gene Set Variation Analysis; Trm: tissue-resident memory T cells.

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Abstract N°: 5545

Bimekizumab treatment in plaque psoriasis resulted in a rapid and deep normalisation of molecular signatures associated with PASI sub-components, that preceded clinical skin clearance

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Introduction & Objectives:

Interleukin (IL)-17A and IL-17F dual inhibition by bimekizumab (BKZ) in patients with moderate to severe plaque psoriasis has shown superiority in skin clearance through rapid onset of response and deep resolution of Psoriasis Area and Severity Index (PASI) score vs IL-17A inhibition alone.1 PASI is the most widely used severity scoring system to assess drug efficacy outcomes in the psoriasis clinical setting.2

To better understand the complete and rapid effects of BKZ on skin at both a molecular and clinical level, here, the three individual PASI sub-components (erythema, thickness, and scaling) and their associated gene signatures were assessed. Analysis of these individual measures is important given they can be obscured in the overall weighted composite score and may contribute to its complexity, as well as some inter-observer variability.3

Materials & Methods:

Gene sets linked with these PASI sub-components were curated using public gene ontologies and refined based on genes found to be dysregulated in psoriasis. Dysregulation of these psoriasis-specific, PASI sub-component gene sets and normalisation post-BKZ treatment was assessed using bulk RNA-seq data from a phase 2a trial.4 The rapid and durable effects of BKZ on the PASI sub-scores were evaluated in BE RADIANT, a phase 3b trial.1

Results:

After two 320 mg doses, by Week 8 of BE RADIANT, BKZ-randomised patients achieved a mean reduction of 89.0%, 92.1%, and 93.3% from baseline in erythema, thickness, and scaling sub-scores, respectively. By Week 12, all three sub-components showed ≥95% mean improvement which was maintained to Year 1 (Week 48; **Figure**), indicating clinical predictivity for sustainable skin clearance as early as 12 weeks.

At the molecular level, bulk RNA-seq data from the phase 2a trial showed complete normalisation (to non-lesional levels and beyond; median % improvement 95.7%–105.3%) of the gene sets associated with the PASI sub-components (**Figure**) by Week 8, after 2 doses.

Furthermore, dysregulation of selected markers associated with erythema (CXCL8), thickness (KRT16), and scaling (LORICRIN) was observed in lesional psoriatic tissue (confirmed by RNAscope imaging) and normalised post-BKZ treatment.

A correlation between baseline changes in IL17A and IL17F expression levels and mean gene expression changes in each curated gene set was identified ($R=0.36–0.53$, $FDR<0.05$), consistent with the known direct effect of IL17 on keratinocytes.5

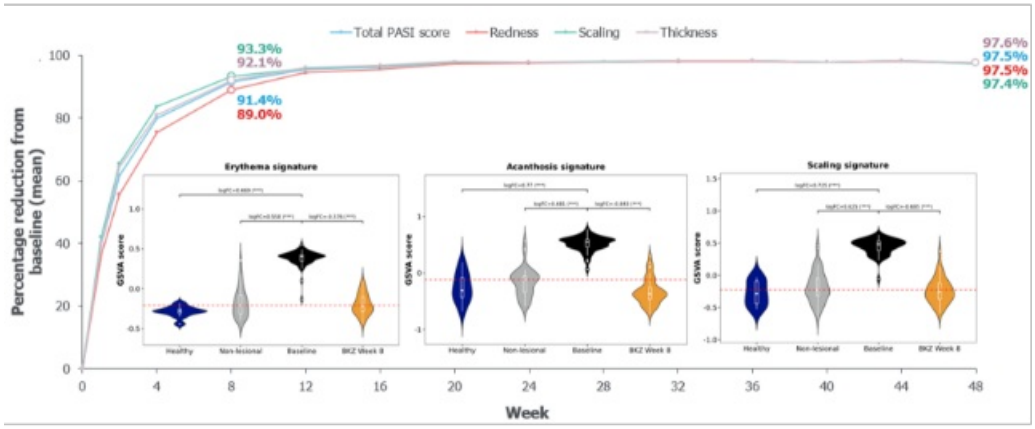
Conclusion:

This is the first analysis showing the effects of BKZ on the PASI sub-components in psoriasis at a molecular and a clinical level. BKZ treatment resulted in significant improvement of all PASI sub-scores by Week 12 and led to a fast and deep normalisation of the molecular signatures associated to these sub-components by Week 8. These findings show that the clinically apparent skin clearance is preceded by molecular resolution of disease. All three sub-components were equally normalised following BKZ treatment, indicating that they are all reliable in evaluating clinical response to BKZ.

References:

1. Reich K. N Engl J Med 2021;385:142–52, NCT03536884; **2.** Puzenat E. J Eur Acad Dermatol Venereol 2010;24:10–16; **3.** Langley RG. J Am Acad Dermatol 2004;51:563–9; **4.** Oliver R. BJ Dermatol 2022;186:652–63, NCT03025542; **5.** Nograles KE. Br J Dermatol 2008;159:1092–102; **6.** Hänzelmann S. BMC Bioinformatics 2013;14:7; **7.** Ritchie ME. Nucleic Acids Res 2015;43:e47.

Figure. PASI mean percentage reduction from baseline across three sub-components in the BE RADIANT trial, and expression of gene signatures of these sub-components in treated lesional tissue at Week 8 versus baseline non-lesional, lesional, and healthy tissue in a phase 2a trial



PASI mean percentage change from baseline is presented using data from observed cases in BKZ-randomised patients only (N=373). Patients with a weighted score of 0 for a given clinical sign at baseline were excluded from the analysis for that clinical sign. Gene Set Variation Analysis[6] was used to estimate gene set level expression. The red horizontal lines correspond to the median baseline expression in non-lesional tissue. LogFC and FDR-adjusted p-values are calculated using the *limma*[7] moderated t-test. ***FDR<0.001. BKZ: bimekizumab; FC: fold change; FDR: false discovery rate; GSVA: Gene Set Variation Analysis; PASI: Psoriasis Area and Severity Index.

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Abstract N°: 5588

The Goeckerman protocol- review of 100 years of experience

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Introduction & Objectives:

The Goeckerman treatment for psoriasis consisting of coal tar ointment followed by ultraviolet light radiation is highly effective, safe, easily available and low cost. It can be used at home in times of pandemics as well as used safetly on children. In celebration of its 100th year of proven usefulness, this treatment is reviewed.

Materials & Methods:

In 2025 we will celebrate 100 years since the publication of the Goeckerman protocol. This treatment is one of the oldest therapeutic treatment protocols still widely used today. It maintains importance because of its efficacy, safety, low cost and widespread availability. In light of these advantages, it was used confidently at home during the pandemic. I would like to review this highly effective treatment.

William H. Goeckerman (1884-1954) was born in Germany but moved to the United States as an infant. He worked in the dermatology department of the Mayo Clinic from 1917-1932. In 1925 he reported the successful use of broad-spectrum UV radiation and topical crude coal tar for the treatment of psoriasis. UVL was generated from quartz lamps, delivered daily in gradually increasing doses for 3-4 weeks. The procedure caught on and became a standard procedure. At that time patients were hospitalized for treatment, and “White’s crude coal tar ointment” was applied to psoriasis patches for a period of 24 hours before removal with oil. The patient was then exposed to UV light, and following bath, the tar was reapplied and the process repeated daily. Goeckerman reported a high effectivness, removing all patches of psoriasis, in practically all cases.

Results:

In my lecture I will review the following topics:

\1. Modification protocols:

with additives such as anthralin, tazarotene and/or calcipotriene as well as with systemic treatments.

\2. Mechanism of action and Anti-inflammatory affect:

Crude coal tar is a byproduct in the coal production chain. It has been said to include thousands of ingredients whereas only about 400 of these have been described. Its full composition and mechanism of action in the treatment of inflammatory skin diseases are poorly understood. But I will review the postulations regarding the possible active ingredients’ mechanism of action.

\3. Clinical effectiveness:

Psoriasis patients treated with Goeckerman protocol achieved a PASI 75 in 3 months. An outcome similar to treatment with the older generation of biologics. Acheived without development of resistance.

\4. Additional applications:

Review of treatment in eczema, uremic pruritus, prurigo nodularis, drug eruption and more in terms of remission length, PASI scores, etc.

\4. Cost comparisson of Goeckerman vs biologics

\5. High Safety profile:

Adverse effects in recent studies were mild folliculitis and UVB induced phototoxicity. Topical steroids under bandages did not cause skin atrophy if used for under a week. Malignancy when using cyclosporine and UVB has not been documented. FDA review of the carcinogenicity of tar revealed no evidence of increased risk of cancer.

Conclusion:

Time proven treatments should not be disposed of where they have been shown to be highly effective. They should be utilized for patients who are wary of newer treatments for a variety of reasons including suffering side effects and development of resistance. Recent experiences with the covid19 pandemic have created a need for safe, effective treatments that can be done at home. Goeckerman’s protocol is one that worked as well 100 years ago as it does today.

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Abstract N°: 5592

Efficacy and Tolerability of a Sensitive Skin Cleansing and Moisturizing Regimen in Patients with Plaque Psoriasis Undergoing Prescription Treatment

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Introduction & Objectives:

Psoriasis is a chronic, inflammatory skin condition that is characterized by the formation of distinct, scale, erythematous plaques. These plaques can be painful, pruritic, and disfiguring. Psoriasis can substantially diminish quality of life and negatively affect a patient's well-being. Skincare products in the treatment of psoriasis have been thought to provide only symptomatic relief, but new evidence suggests moisturizers may offer therapeutic benefit by supporting epidermal barrier repair. The objective of this study is to assess the efficacy and tolerability of a skincare regimen when used in conjunction with prescription treatments for plaque psoriasis.

Materials & Methods:

This is a multi-center, open-label, 8-week in-use study to assess the efficacy and tolerability of topical skincare products on adult patients with plaque psoriasis. Qualified subjects must have mild-to-severe plaque psoriasis with active target lesion plaques, and currently on or starting a prescription treatment for plaque psoriasis. The study skincare regimen includes a gentle skin cleanser (GSC) and a moisturizing cream (MC]), with a daily facial moisturizer with SPF 35 (DFM35) as an optional supporting product. Efficacy assessments include clinical grading of Body Surface Area (BSA), Target Lesion Severity Score (TLSS), and Physician Global Assessment (PGA) by investigator, standardized photography, lesion imaging analysis, quality of life questionnaire, and self-assessment questionnaire. Safety assessments include monitoring of adverse events and cutaneous tolerability grading by investigator and subjects.

Results:

8-week use of this skincare regimen is expected to produce statistically significant decrease in psoriasis clinical grading scores over time when compared to baseline scores. Additionally, the study products should be well tolerated by subjects, with no statistically significant increases in scores for tolerability parameters at any study time point when compared to baseline. The skincare regimen is anticipated to be well-perceived by the subjects for life quality enhancement and skin improvement. Results will be presented at the 2024 European Academy of Dermatology and Venereology Congress.

Conclusion:

This study will show the importance of using skincare products in conjunction with prescription treatments for plaque psoriasis. Not only does the skincare regimen support the skin barrier, it is also expected to improve patient outcomes through efficacy and safety assessments in those that have plaque psoriasis.

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Abstract N°: 5598

Resource use of patients with mild-moderate psoriasis on systemic treatments: A single centre longitudinal evaluation

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Introduction & Objectives:

The cost-effectiveness of targeted immunomodulatory therapy is well-established for the severe psoriasis population. However, most of the 2% of adults in Europe with psoriasis have mild to moderate disease, and yet the clinical course and healthcare costs of this group are poorly described. The aim of this longitudinal evaluation was to describe disease severity and health-related quality of life (HRQoL) over time and estimate the associated healthcare resource use (HCRU) in those with mild-moderate psoriasis requiring systemic therapy.

Materials & Methods:

This was a UK, single centre (general dermatology service) retrospective longitudinal service evaluation. The study population comprised adults with mild-moderate psoriasis (defined as Psoriasis Area and Severity Index (PASI) score < 10, no historical PASI ≥ 10 and no prior biologic treatment use) on systemic therapy between 2014 and 2017, identified from a pharmacy database and electronic healthcare records. Data were retrospectively captured for three subsequent years from the point of their first PASI recording (i.e. pre-COVID) or until study discontinuation. Patients discontinued the study due to progression to severe psoriasis (PASI ≥ 10), starting a high-cost medicine or being transferred to another hospital. PASI and Dermatology Life Quality Index (DLQI) scores were used to capture disease severity and patient's HRQoL. Descriptive statistics were used to summarise patient characteristics and outcomes. A generalised linear model with a Gaussian distribution was used to explore the predictors of total HCRU cost.

Results:

124 patients met the study criteria. Baseline characteristics are shown in Table 1. Whilst there was marked fluctuation in patient PASI and DLQI over time, overall both showed a weak negative trend indicating an improvement. However, when accounting for those who discontinued due to disease progression (21.8 %), the number of patients who improved from baseline was similar to those who worsened (43.5% vs. 47.6%). A similar proportion of patients achieved a PASI score ≤ 2 and DLQI ≤ 5 at least once during the study (54.8% vs. 56.5%). Overall, patients accrued a mean annual cost of £3,361 (median = £1,923) largely driven by healthcare visits. The difference between the maximum and minimum PASI recorded for a patient and follow-up time were statistically significant predictors of total costs ($p < 0.05$). A one-unit increase in max-min PASI results in a 9% increase in total costs, inferring that patients with a greater range in their PASI (potentially indicative of a more unstable disease) are associated with higher total costs.

Conclusion:

Despite incurring high healthcare costs, nearly half of the patients did not achieve clear or nearly clear skin based on PASI. A better understanding of the patient experience and health economics of this population may provide a

basis to challenge current care pathways and access criteria for high-cost treatments.

Table 1: Baseline characteristics and average follow-up time

Variable	All patients n = 124
Age, mean (SD)	43.22 (14.34)
Sex, male (%)	71 (57.3)
PASI, mean (SD)	4.41 (2.37)
DLQI, mean (SD)	7.26 (6.33)
Number of comorbidities, mean (SD)	1.80 (1.88)
Psoriatic arthritis, yes (%)	9 (7.3)
Prior systemic treatment, yes (%)	72 (58.1)
Indices of multiple deprivation (IMD) quintile (%)	
1	13 (10.5)
2	36 (29.0)
3	24 (19.4)
4	26 (21.0)
5	25 (20.2)
Follow-up (years), mean (SD)	2.29 (0.93)

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Abstract N°: 5600

Cost per responder analysis of calcipotriol plus betamethasone dipropionate cutaneous PAD cream for the topical treatment of mild to moderate plaque psoriasis in Italy

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Introduction & Objectives: Pivotal phase 3 clinical trials demonstrated the efficacy of calcipotriol/betamethasone dipropionate (CAL/BDP) poly-aphron dispersion (PAD) cream in the treatment of mild to moderate plaque psoriasis in adults, with favourable safety and quality of life in comparison to other formulation (CAL/BDP gel).1 The aim of this research was to demonstrate efficient flare management through the use of CAL/BDP PAD cream in comparison to gel in the treatment of patients with mild to moderate plaque psoriasis in Italy.

Materials & Methods: An incremental cost per responder analysis was conducted considering the efficacy highlighted in a recent pooled analysis of two phase 3, multicentre, randomized, investigator-blind, active, and vehicle-controlled trials comparing the safety and efficacy of CAL/BDP PAD cream and CAL/BDP gel (NCT03308799 and NCT03802344). Comparative efficacy was evaluated by means of both PGA and mPASI75 clinical measures. In the base-case scenario, treatment-related events were considered similar between groups, following the safety reports from randomized trials. The time horizon of the analyses was defined according to trial duration (8 weeks), and ex-factory drug costs (in € as of 2024) were used. Clinical visits were assumed to be the same for both treatments. The weighted average cost of gel formulations was estimated following the market share of licensed products in Italy. Sensitivity analysis was conducted to test the impact of efficacy rates, drug consumption and market share on the incremental cost per responder analysis.

Results: CAL/BDP PAD cream resulted in a significant incremental rate of responders versus CAL/BDP gel, ranging from 9.8% in mPASI75 to 11.3% in PGA success. The average cost per treated patient was slightly higher in CAL/BDP PAD cream (€7.95 per patient). However, costs per success were higher in CAL/BDP gel for both clinical measures: €340.27 vs €269.68 (PGA) and €314.63 vs €262.98 (mPASI75). Finally, the incremental cost per responder of CAL/BDP PAD cream over CAL/BDP gel resulted in highly cost-efficacy figures: €81.15 and €70.38, according to mPASI75 and PGA criteria, respectively. Importantly, these results come from a conservative approach comparing exclusively the efficacy in terms of treatment response (PGA and mPASI75). Therefore, the potential added value of the improved and significant effects of CAL/BDP PAD cream versus gel on quality of life and convenience/satisfaction was not included in the analysis. Additional economic analyses including these patient-reported outcomes as well as real-world effectiveness should confirm these results.

Conclusion: Based on efficacy results from phase 3 controlled trials, CAL/BDP PAD cream represents an efficient treatment for the management of patients suffering from mild to moderate plaque psoriasis in Italy.

References:

\1. Pinter A, et al. J Eur Acad Dermatol Venereol 2022; 36(2):228-236

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Abstract N°: 5619

Bimekizumab 4-year efficacy in high-impact areas in moderate to severe plaque psoriasis: Pooled results from BE BRIGHT

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Introduction & Objectives:

Scalp and palmoplantar (pp) psoriasis and psoriatic changes in the nails have a large impact on health-related quality of life.1 Though skin lesions can repair relatively quickly, nail repair can take 6–9 months.2 High levels of complete clearance in these high-impact areas have been reported over 3 years of bimekizumab (BKZ) treatment.3 Here, 4-year scalp, nail, and pp outcomes are reported in patients with moderate to severe plaque psoriasis from three phase 3 studies and their open-label extension (OLE), BE BRIGHT.4

Materials & Methods:

Data were pooled from the 52-week BE VIVID and 56-week BE READY and BE SURE feeder studies, and 3 years of BE BRIGHT.4-7 Included patients were randomised to receive BKZ 320 mg every 4 weeks (Q4W) to Week 16, then BKZ either Q4W or every 8 weeks (Q8W) throughout the maintenance period into the OLE. Data are reported for all included patients (BKZ Total) and the subset who received BKZ Q4W to Week 16 then Q8W into the OLE (Q4W/Q8W), the approved dosing regimen for most patients.8

High-impact areas were assessed using the scalp Investigator's Global Assessment (scalp IGA; 5-point scale, 0–4), modified Nail Psoriasis Severity Index (mNAPSI; total fingernail score, 0–130) and pp-IGA (5-point scale, 0–4). Proportions of patients with moderate to severe scalp or pp involvement (scalp or pp-IGA ≥3) or mNAPSI >10 at baseline, who achieved complete clearance in these areas (scalp IGA 0, mNAPSI 0, pp-IGA 0) are reported through Year 4 using modified non-responder imputation (mNRI). Patients who discontinued treatment due to lack of efficacy/treatment-related adverse events were considered non-responders; multiple imputation was used for other missing data. Both mNRI and observed case (OC) data are presented in the **Figure**.

Results:

In total, 771 patients were randomised to BKZ and received BKZ into the BE BRIGHT OLE; 571 (74.1%), 270 (35.0%), and 151 (19.6%) had baseline scalp IGA ≥3, mNAPSI >10, and pp-IGA ≥3, respectively. Of those patients, 197 received BKZ Q4W/Q8W; 152 (77.2%), 67 (34.0%), and 36 (18.3%) had baseline scalp IGA ≥3, mNAPSI >10, and pp-IGA ≥3, respectively.

In BKZ Total patients, 85.6% achieved scalp IGA 0 at Year 1 and 79.5% at Year 4 (**Figure**); in BKZ Q4W/Q8W patients, 94.7% achieved scalp IGA 0 at Year 1 and 86.8% at Year 4. In BKZ Total patients, 58.8% achieved mNAPSI 0 at Year 1 and 61.6% at Year 4 (**Figure**); 59.7% and 67.4% of BKZ Q4W/Q8W patients achieved mNAPSI 0 at Year 1 and 4. In BKZ Total patients, 86.6% achieved pp-IGA 0 at Year 1 and 88.7% at Year 4 (**Figure**); 91.7% and 83.4% of BKZ Q4W/Q8W patients achieved pp-IGA 0 at Year 1 and 4.

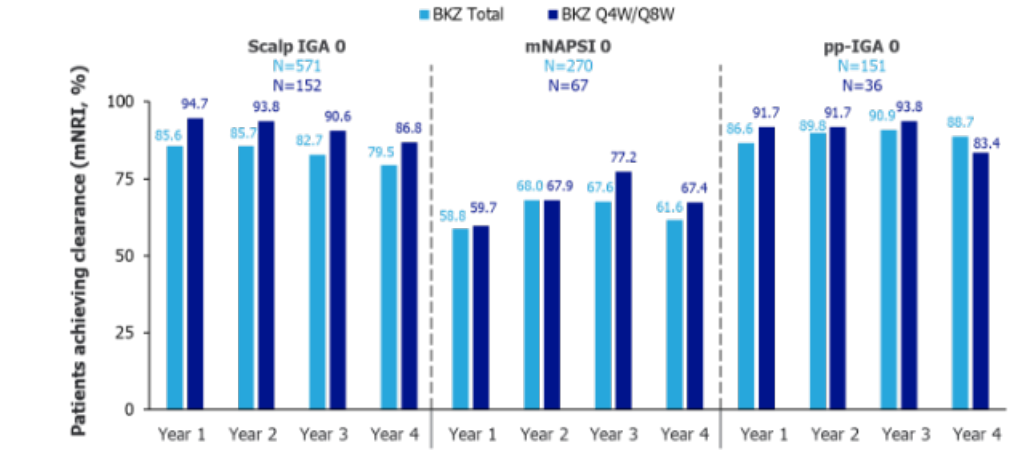
Conclusion:

The majority of BKZ-treated patients achieved and maintained complete clearance of scalp and pp psoriasis over 4 years. Over half achieved complete nail clearance at Year 1, with rates numerically increasing up to Year 2 and remaining high through to Year 4. Complete clearance rates were similarly high in patients who received Q4W/Q8W dosing.

References:

1. Merola JF. Dermatol Ther 2018;31:e12589; **2.** Cashman MW. Clin Dermatol 2010;28:420–5; **3.** Merola JF. Presented at EADV 2023; P2547; **4.** Strober B. Br J Dermatol 2023;188:749–59, NCT03598790; **5.** Reich K. Lancet 2021;397:487–98, NCT03370133; **6.** Gordon KB. Lancet 2021;397:475–86, NCT03410992; **7.** Warren RB. N Engl J Med 2021;385:130–41, NCT03412747; **8.** EMA. Bimekizumab 2023;

Figure. Complete clearance of scalp, nail, and palmoplantar psoriasis over 4 years (mNRI and OC)



OC, n/N_{obs}	Year 1	Year 2	Year 3	Year 4
Scalp IGA 0	478/535 (89.3%) 141/149 (94.6%)	445/508 (87.6%) 131/139 (94.2%)	431/499 (86.4%) 123/132 (93.2%)	388/453 (85.7%) 110/119 (92.4%)
mNAPSI 0	157/252 (62.3%) 40/67 (59.7%)	175/243 (72.0%) 44/64 (68.8%)	172/234 (73.5%) 48/56 (85.7%)	154/226 (68.1%) 41/55 (74.5%)
pp-IGA 0	127/142 (89.4%) 33/36 (91.7%)	116/128 (90.6%) 30/32 (93.8%)	120/127 (94.5%) 30/30 (100.0%)	110/118 (93.2%) 25/28 (89.3%)

Included patients for clearance of scalp, nail, and palmoplantar psoriasis had scalp IGA ≥3, mNAPSI >10, and pp-IGA ≥3 at baseline, respectively. Due to differences in assessment schedules, Year 1 data were collected at Week 48 in BE READY and BE SURE and Week 52 in BE VIVID. Due to differences in feeder study lengths, Year 2 data were collected at Week 100/104, Year 3 data were collected at Week 148/152, and Year 4 data were collected at Week 196/200 (BE VIVID/BE READY and BE SURE). For OC, N_{obs} represents the number of patients with observed data at a given timepoint. BKZ: bimekizumab; IGA: Investigator's Global Assessment; mNAPSI: modified Nail Psoriasis Severity Index; OC: observed case; pp: palmoplantar; Q4W: every 4 weeks; Q8W: every 8 weeks.

www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf.

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Abstract N°: 5623

Bimekizumab long-term efficacy in patients with moderate to severe plaque psoriasis after switching from adalimumab, ustekinumab, or secukinumab: Results from up to 4 years of total treatment from BE BRIGHT and BE RADIANT

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Introduction & Objectives:

To achieve improvements in psoriasis management, patients and clinicians may choose to switch biologics, particularly in cases of suboptimal response and patient decision.1 Rapid skin clearance after switch to bimekizumab (BKZ) has previously been reported in patients who did not adequately respond to either adalimumab (ADA), secukinumab (SEC) or ustekinumab (UST) and was maintained for up to 80 weeks after switch (2 years total treatment).1 Here, we investigate if efficacy and health-related quality of life responses improved and were maintained after switch to BKZ through up to 3 and 4 years of treatment in total in the BE RADIANT and BE BRIGHT phase 3/3b studies, respectively.

Materials & Methods:

Included patients from BE BRIGHT were randomised to ADA to Week 24 and switched to BKZ every 4 weeks (Q4W) to Week 56 (BE SURE), or were randomised to UST to Week 52 (BE VIVID), and then entered the BE BRIGHT open-label extension (OLE) where they switched to BKZ Q4W or Q8W. Included patients from BE RADIANT received SEC to Week 48, and switched to BKZ Q4W or Q8W during its OLE. All patients received BKZ Q8W from OLE Week 16/48 (BE RADIANT/BE BRIGHT) or the next scheduled visit.2–6

Here, ≥90% improvement from baseline in Psoriasis Area and Severity Index (PASI 90), PASI 100, and Dermatology Life Quality Index (DLQI) 0/1 responses are reported by number of weeks after switch to BKZ, for up to 4 years of total treatment, grouped by PASI 90 response status at switch. Patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data (modified non-responder imputation [mNRI]). Observed case (OC) data are also reported.

Results:

Of patients randomised to ADA, SEC, and UST at baseline who entered the respective OLEs, 54/129 (41.9%) ADA, 58/314 (18.5%) SEC, and 44/132 (33.3%) UST patients did not achieve PASI 90 at the time of switch to BKZ (Week 24, 48, and 52, respectively) (OC). At the time of switch, 29.6%, 53.5%, and 50.0% of PASI 90 non-responders had

DLQI 0/1, respectively (mNRI).

In PASI 90 non-responders, following switch to BKZ, rapid responses were observed and maintained in the long-term (**Table 1**). Following switch from ADA and after 176 weeks of BKZ, 92.2%, 74.4%, and 81.0% achieved PASI 90, PASI 100, and DLQI 0/1, respectively (mNRI). Following switch from SEC and after 96 weeks of BKZ, 71.7%, 39.8%, and 64.5% achieved PASI 90, PASI 100, and DLQI 0/1, respectively. Following switch from UST, 82.0%, 58.8%, and 76.6% achieved PASI 90, PASI 100, and DLQI 0/1 after 144 weeks of BKZ, respectively.

Switching ADA, SEC, and UST PASI 90 responders to BKZ resulted in maintained PASI 90, PASI 100, and DLQI 0/1 responses for up to 4 years of total treatment (**Table 2**).

Conclusion:

Switching ADA, SEC, or UST PASI 90 non-responders to BKZ led to most patients rapidly achieving and maintaining PASI 90, for up to 4 years of total treatment. A large proportion of these patients achieved PASI 100 or DLQI 0/1 in the long-term following switch to BKZ. In ADA, SEC, or UST PASI 90 responders, response rates were maintained in the long-term following switch to BKZ.

References:

1. Kokolakis G. Br J Dermatol 2023;188:330–40; **2.** Reich K. N Engl J Med 2021;385:142–52, NCT03536884; **3.** Strober B. J Am Acad Dermatol. 2023;89:486–95; **4.** Warren RB. N Engl J Med 2021;385:130–41, NCT03412747; **5.** Reich K. Lancet 2021;397:487–98, NCT03370133; **6.** Strober B. Br J Dermatol 2023;188:749–59, NCT03598790.

Table 1. Rapid and long-term efficacy in ADA, UST, or SEC PASI 90 non-responders following switch to BKZ (mNRI, OC)

	BKZ baseline (at switch)		BKZ Week 4 after switch		BKZ Week 176 after switch (OLE Week 144)	
Switch from ADA to BKZ (N=54)						
	mNRI, %	OC, n/N_{obs} (%)	mNRI, %	OC, n/N_{obs} (%)	mNRI, %	OC, n/N_{obs} (%)
PASI 90	0.0	0/54 (0.0)	66.7	36/54 (66.7)	92.2	40/43 (93.0)
PASI 100	0.0	0/54 (0.0)	33.3	18/54 (33.3)	74.4	33/43 (76.7)
DLQI 0/1	29.6	16/52 (30.8)	NR	NR	81.0	37/44 (84.1)
Switch from SEC to BKZ (N=58)						
	BKZ baseline (at switch)		BKZ Week 4 after switch		BKZ Week 96 after switch (OLE Week 96)	
	mNRI, %	OC, n/N_{obs} (%)	mNRI, %	OC, n/N_{obs} (%)	mNRI, %	OC, n/N_{obs} (%)
PASI 90	0.0	0/58 (0.0)	54.8	31/56 (55.4)	71.7	38/50 (76.0)
PASI 100	0.0	0/58 (0.0)	21.2	12/56 (21.4)	39.8	21/50 (42.0)
DLQI 0/1	53.5	31/57 (54.4)	NR	NR	64.5	34/49 (69.4)
Switch from UST to BKZ (N=44)						
	BKZ baseline (at switch)		BKZ Week 4 after switch		BKZ Week 144 after switch (OLE Week 144)	
	mNRI, %	OC, n/N_{obs} (%)	mNRI, %	OC, n/N_{obs} (%)	mNRI, %	OC, n/N_{obs} (%)
PASI 90	0.0	0/44 (0.0)	79.5	35/44 (79.5)	82.0	32/36 (88.9)
PASI 100	0.0	0/44 (0.0)	43.2	19/44 (43.2)	58.8	23/36 (63.9)
DLQI 0/1	50.0	22/44 (50.0)	NR	NR	76.6	29/34 (85.3)

Data reported according to weeks since switch to BKZ. Patients switched from ADA to BKZ Q4W at Week 24, then to Q4W or Q8W upon OLE entry at Week 56; PASI 90 response status was determined at Week 24. Patients switched from SEC to BKZ Q4W or Q8W upon OLE entry at Week 48; PASI 90 response status was determined at Week 48. Patients switched from UST to BKZ Q4W or Q8W upon OLE entry at Week 52; PASI 90 response status was determined at Week 52. For mNRI, patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. For OC, N_{obs} represents the number of patients with observed data at a given timepoint.
ADA: adalimumab; BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; mNRI: modified non-responder imputation; NR: not reported; OC: observed case; OLE: open-label extension; PASI 90/100: ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC: secukinumab; UST: ustekinumab.

Table 2. Long-term efficacy in ADA, UST, or SEC PASI 90 responders following switch to BKZ (mNRI, OC)

	BKZ baseline (at switch)		BKZ Week 176 after switch (OLE Week 144)	
Switch from ADA to BKZ (N=75)				
	mNRI, %	**OC, n/N_{obs} (%)**	**mNRI, %**	**OC, n/N_{obs} (%)**
PASI 90	100.0	75/75 (100.0)	90.5	56/59 (94.9)
PASI 100	58.7	44/75 (58.7)	75.2	49/59 (83.1)
DLQI 0/1	69.3	52/75 (69.3)	83.8	54/59 (91.5)
	BKZ baseline (at switch)		**BKZ Week 96 after switch (OLE Week 96)**	
Switch from SEC to BKZ (N=256)				
	mNRI, %	**OC, n/N_{obs} (%)**	**mNRI, %**	**OC, n/N_{obs} (%)**
PASI 90	100.0	256/256 (100.0)	90.0	205/215 (95.3)
PASI 100	65.2	167/256 (65.2)	75.4	180/215 (83.7)
DLQI 0/1	87.5	224/256 (87.5)	82.9	196/218 (89.9)
	BKZ baseline (at switch)		**BKZ Week 144 after switch (OLE Week 144)**	
Switch from UST to BKZ (N=88)				
	mNRI, %	**OC, n/N_{obs} (%)**	**mNRI, %**	**OC, n/N_{obs} (%)**
PASI 90	100.0	88/88 (100.0)	88.6	72/76 (94.7)
PASI 100	69.3	61/88 (69.3)	72.7	60/76 (78.9)
DLQI 0/1	86.4	76/88 (86.4)	78.9	65/75 (86.7)

Data reported according to weeks since switch to BKZ. Patients switched from ADA to BKZ Q4W at Week 24, then to Q4W or Q8W upon OLE entry at Week 56; PASI 90 response status was determined at Week 24. Patients switched from SEC to BKZ Q4W or Q8W upon OLE entry at Week 48; PASI 90 response status was determined at Week 48. Patients switched from UST to BKZ Q4W or Q8W upon OLE entry at Week 52; PASI 90 response status was determined at Week 52. For mNRI, patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data. For OC, N_{obs} represents the number of patients with observed data at a given timepoint.
ADA: adalimumab; BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; mNRI: modified non-responder imputation; OC, observed case; OLE: open-label extension; PASI 90/100: ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SEC, secukinumab; UST: ustekinumab.

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Abstract N°: 5627

Deucravacitinib, an oral selective tyrosine kinase 2 (TYK2) inhibitor, in patients with moderate to severe scalp psoriasis: efficacy and safety results of a phase 3b/4, multicenter, randomized, double-blinded, placebo-controlled trial (PSORIATYK SCALP)

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Scalp psoriasis occurs in ~80% of patients; is associated with itching, pain, and bleeding; disproportionately reduces quality of life; and is challenging to treat with topical agents. An ongoing, 52 week, phase 3b/4, multicenter, randomized, double-blind, placebo-controlled trial (PSORIATYK SCALP) evaluated deucravacitinib efficacy and safety in patients with moderate to severe scalp psoriasis, including those with more limited overall psoriasis, the patient group who are candidates for systemic therapy according to AAD/NPF and IPC guidelines.

Materials & Methods: Adults (≥18 years) with moderate to severe scalp psoriasis defined by more focused and objective inclusion criteria (ss-PGA ≥3, scalp surface area ≥20%, PSSI ≥12) and BSA ≥3% were randomized 1:2 to oral placebo or deucravacitinib 6 mg once daily through Week 16. Stratification factors were previous biologic use for psoriasis or other inflammatory diseases (yes/no) and body weight (≥90 kg or <90 kg). At Week 16, all patients received open-label deucravacitinib through Week 52. The primary efficacy outcome was ss-PGA 0/1 and key secondary outcomes were PSSI 90, change from baseline in scalp-specific itch numerical rating scale (NRS), and sPGA 0/1 at Week 16. Efficacy outcomes are evaluated at Week 16 for the overall population and the subpopulation with global sPGA ≥3. Nonresponder imputation and modified baseline observation carried forward were used for patients who discontinued prior to Week 16 or had missing data for binary and continuous outcomes, respectively.

Results: 154 patients were randomized (placebo, n=51; deucravacitinib, n=103). Baseline characteristics were similar in each group (placebo: mean BSA 10.0%, PASI 9.4, PSSI 32.2; deucravacitinib: mean BSA 10.5%, PASI 10.2, PSSI 33.5). In the overall population, a higher proportion of patients treated with deucravacitinib vs placebo achieved ss-PGA 0/1 at Week 16 (48.5% vs 13.7%; $P<0.0001$). Deucravacitinib was superior to placebo for PSSI 90 (38.8% vs 2.0%; $P<0.0001$) and mean change from baseline in scalp-specific itch NRS (−3.2 vs −0.7;$P<0.0001$). In the subpopulation of patients (sPGA ≥3), a greater proportion achieved an overall psoriasis response of sPGA 0/1 with deucravacitinib vs placebo (51.0% vs 4.3%; $P<0.0001$). The most common adverse events (AEs) in the deucravacitinib group (≥5%) were nasopharyngitis (14.6%), upper respiratory tract infection (11.7%), acne (9.7%), headache (7.8%), COVID-19 (5.8%), and pustular acne (5.8%). Two serious AEs were reported (1 per group); neither was considered treatment-related or led to discontinuation.

Conclusion: In this scalp-specific trial, deucravacitinib was efficacious and well tolerated in patients with moderate to severe scalp psoriasis, including those with less extensive overall psoriasis (BSA ≥3%). This trial enrolled patients with more severe scalp disease compared with the phase 3 POETYK trials. The overall psoriasis response

rate (sPGA 0/1) was consistent with POETYK trial results, despite including patients with more limited BSA involvement. Safety findings were consistent with the known deucravacitinib safety profile. These results support the use of once-daily oral deucravacitinib in moderate to severe scalp psoriasis.

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Abstract N°: 5629

Deucravacitinib efficacy in patients with moderate to severe psoriasis with scalp and fingernail disease: response over 4 years of treatment in the phase 3 POETYK PSO-1, PSO-2, and LTE trials

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy.** Deucravacitinib was superior to placebo and apremilast in two global, phase 3 trials (POETYK PSO-1 and PSO-2) in moderate to severe plaque psoriasis, including patients with moderate to severe scalp or fingernail psoriasis involvement. At Week 52, patients could enter the POETYK long-term extension (LTE) trial and receive open-label deucravacitinib. Long-term efficacy was earlier shown to be maintained through 3 total years of continuous treatment with no new safety signals in the ongoing LTE trial. Here, we evaluate the long-term efficacy of deucravacitinib in patients with limited to severe scalp and fingernail psoriasis involvement over 4 years of treatment.

Materials & Methods: Response rates for scalp-specific static Physician Global Assessment score of 0 (clear) or 1 (almost clear) (ss-PGA 0/1 and ss-PGA 0) and PGA-Fingernail score of 0 (clear) or 1 (almost clear) (PGA-F 0/1 and PGA-F 0) with at least a 2-point improvement from baseline were evaluated in patients pooled from PSO-1 and PSO-2 who had baseline ss-PGA and PGA-F scores ≥1, ≥2, and ≥3 and who received continuous deucravacitinib treatment from baseline (Day 1) through 4 years (Week 208; last timepoint for collection of these data, Week 196; data cutoff, November 1, 2023). Efficacy is reported using the modified nonresponder imputation (mNRI) methodology for missing data used earlier with other psoriasis LTE trials. Patients who reached or discontinued before Week 208 were included; those with missing data who discontinued treatment due to worsening of psoriasis were imputed as nonresponders; all other missing data were imputed by multiple imputation.

Results: Of 513 patients treated with continuous deucravacitinib from Day 1 who entered the LTE, baseline ss-PGA scores ≥1, ≥2, and ≥3 were seen in 444 (86.5%), 406 (79.1%), and 313 (61.0%) patients who reached or discontinued prior to Week 208, respectively; baseline PGA-F scores ≥1, ≥2, and ≥3 were seen in 204 (39.8%), 132 (25.7%), and 66 (12.9%) patients. In patients with a baseline ss-PGA score ≥3, ss-PGA 0/1 scores were maintained from Week 52 (74.0% [95% CI, 69.2%-78.9%]) through Week 196 (70.8% [95% CI, 64.7%-76.8%]), as were ss-PGA 0 scores (Week 52, 55.7% [95% CI, 50.2%-61.2%]; Week 196, 51.5% [95% CI, 45.3%-57.7%]). In those with baseline PGA-F ≥3, scores were also maintained well for PGA-F 0/1 (Week 52, 50.0% [95% CI, 37.4%-62.6%]; Week 196, 57.9% [95% CI, 44.3%-71.5%]) and PGA-F 0 (Week 52, 24.2% [95% CI, 14.5%-36.4%]; Week 196, 31.0% [95% CI, 17.9%-44.1%]). A similar pattern was observed for patients with baseline ss-PGA or PGA-F scores ≥1 and ≥2.

Conclusion: In this post hoc analysis, psoriasis disease burden in the hard-to-treat areas of scalp and fingernail

improved with deucravacitinib treatment through 4 years regardless of severity of baseline involvement in patients with moderate to severe plaque psoriasis. ss-PGA 0/1, ss-PGA 0, PGA-F 0/1, and PGA-F 0 scores were maintained well from Week 52 through Week 196. While this analysis does not include patients with scalp and fingernail involvement in milder plaque psoriasis, these findings support the long-term efficacy of deucravacitinib, a once-daily oral therapy, in psoriasis patients with hard-to-treat scalp and fingernail involvement.

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Abstract N°: 5643

Deucravacitinib efficacy in Psoriasis Area and Severity Index (PASI) target outcomes through 4 years in the phase 3 POETYK trials in moderate to severe plaque psoriasis

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Introduction & Objectives: Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was efficacious and well tolerated in the two global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and POETYK PSO-2 (NCT03611751) parent trials and through 2 additional years in the POETYK long-term extension (LTE) (NCT04036435) trial in patients treated with deucravacitinib from Day 1 of PSO-1/PSO-2. PSO-1 and PSO-2 randomized patients 1:2:1 to oral placebo, deucravacitinib 6 mg once daily, or apremilast 30 mg twice daily. This analysis evaluated the long-term efficacy of deucravacitinib treatment for up to 4 years (Week 208) based on Psoriasis Area and Severity Index (PASI) outcomes in patients who received continuous deucravacitinib treatment from Day 1 of the parent trials and in those who crossed over from placebo to deucravacitinib at Week 16 and who subsequently enrolled in the LTE trial and received open-label deucravacitinib.

Materials & Methods: Efficacy was evaluated in patients who received continuous deucravacitinib treatment from Day 1 of the parent trials and entered the LTE (n=513) and in those who crossed over from placebo to deucravacitinib at Week 16 of the parent trials and entered the LTE (n=298). Outcomes included adjusted mean percent change from baseline in PASI scores and achievement of treat-to-target PASI thresholds of ≤1, ≤2, ≤3, ≤4, ≤5, and ≤6. Missing data for continuous variables were imputed using baseline observation carried forward for discontinuations due to worsening of psoriasis or lack of efficacy, and by multiple imputation for other reasons (miBOCF). Missing data for binary variables was imputed by modified nonresponder imputation (mNRI) using similar methodology.

Results: At baseline, mean (standard deviation) PASI score was 21.1 (7.9) for patients in the LTE who received continuous deucravacitinib from Day 1 (Cohort 1) and 21.0 (8.4) for patients in the LTE who crossed over from placebo to deucravacitinib at Week 16 (Cohort 2). Reductions in PASI score were evident as early as Week 1 and continued through Week 16 in Cohort 1. PASI scores were improved or maintained through Week 52 and then through Week 208 in both cohorts (**Table**). Higher proportions of patients treated with deucravacitinib versus placebo in Cohort 1 achieved absolute PASI thresholds ≤1 (22.3% vs 1.4%), ≤2 (34.7% vs 4.8%), ≤3 (45.1% vs 7.6%), ≤4 (56.2% vs 11.7%), ≤5 (62.3% vs 15.1%), and ≤6 (69.4% vs 16.5%) at Week 16; responses increased through Week 52 and were maintained through 4 years. Results for Cohort 2 were similar to Cohort 1 at Week 52

and were improved or maintained through 4 years.

Conclusion: Patients with moderate to severe plaque psoriasis who received continuous treatment from Day 1 experienced early improvement in PASI score within 1 week and achieved treat-to-target PASI thresholds that were improved through 52 weeks and maintained through 4 years of treatment. Similar results were obtained in patients who crossed over from placebo. These findings support the long-term efficacy of deucravacitinib as a once-daily oral drug in achieving treatment targets through 4 years of continuous treatment.

Table. Adjusted mean percent change from baseline in PASI score (miBOCF)[a]

Adjusted mean % change from baseline PASI score (95% CI)[b]	Continuous deucravacitinib treatment from Day 1 (n=508)	Placebo to deucravacitinib crossover (n=291)
Week 1	-14.8 (-16.7, -12.8)	-8.2 (-10.7, -5.6)
Week 16	-72.1 (-75.8, -68.5)	*-27.7 (-32.4, -23.1)*[c]
Week 52	-82.4 (-84.3, -80.4)	**-85.3 (-87.8, -82.7)**[d]
Week 208	-81.1 (-83.9, -78.4)	**-83.3 (-86.7, -80.0)**[d]

[a]Patients from POETYK PSO-1/PSO-2/LTE who received continuous deucravacitinib treatment from Day 1 or who were randomized to placebo and crossed over from placebo to deucravacitinib at Week 16. miBOCF is presented. Baseline value was used for patients who discontinued due to worsening of psoriasis and multiple imputation was used for patients with missing data due to other reasons. Data in placebo-randomized patients are in italics and in bold after crossover to deucravacitinib following Week 16. [b]The 95% CIs were calculated using the Rubin method. If there were no missing data (ie, no imputed values), the 95% CI was obtained based on the observed data. Adjusted means and 95% CIs were from an analysis of covariance model with a factor for study and baseline value as a covariate. [c]Response rate in placebo-randomized patients at Week 16 prior to crossing over to deucravacitinib treatment. [d]Response rate after crossover to deucravacitinib treatment at Week 16. CI, confidence interval; miBOCF, modified imputation baseline observation carried forward; PASI, Psoriasis Area and Severity Index.

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Comparative evaluation of Liver Function Test in Refractive Psoriasis patients treated with Tofacitinib and Apremilast

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Introduction & Objectives:

For mild to moderate psoriasis topical corticosteroids, vitamin D analogous or retinoid are used. For moderate to severe psoriasis, systemic medications such as methotrexate, cyclosporine, and biological drugs like TNF-alpha inhibitors or interleukin inhibitors are prescribed. Tofacitinib, a Janus kinase inhibitor, operates by disrupting cytokine signalling pathways involved in the inflammatory response has demonstrated remarkable efficacy but associated potential hepatotoxicity.

Apremilast, phosphodiesterase-4 inhibitor modulates inflammatory responses with demonstrated efficacy and safety profile but its impact on liver function, particularly in comparison to tofacitinib remains a subject of investigation.

Systemic side effects with above mentioned drugs are immunosuppression, injection site reactions, increased risk of infections, liver and kidney toxicity, bone marrow suppression etc.

This study aims to compare the Liver safety profiles of Tofacitinib and Apremilast analysing LFT profiles. This data is helpful in understanding the underlying mechanisms of drug-induced liver injury and optimize therapeutic strategies for patients with inflammatory conditions such as refractive psoriasis.

Materials & Methods:

After institutional ethical consideration & informed consent, a prospective cohort study was conducted in 216 refractive psoriasis patients after random selection either to Tofacitinib or Apremilast treatment. The liver function test including serum alanine transaminase, aspartate transaminase, alkaline phosphatase and total bilirubin are used.

Results:

Out of 216, 138 patients fulfilled the criteria required for the study, of which 77 (48.73 %) were male and 61 (43.04 %) were females. Also, these 138 patients were divided into 2 groups- 69 for Tofacitinib and 69 for Apremilast.

After receiving Apremilast treatment, serum levels of Alanine Transferase, Aspartate Transaminase, Alkaline Phosphatase, and Serum Total Bilirubin were not significantly elevated; a p-value of greater than 0 indicates strong evidence in favour of the null hypothesis, implying that there is no difference between the pre- and post-treatment LFT levels.

After receiving tofacitinib treatment, serum levels of alanine transferase, aspartate transaminase, alkaline phosphatase, and total bilirubin increased. The p-value was 0, indicating strong evidence against the null hypothesis and indicating a significant difference between the pre- and post-treatment t-values of 32.7155, 13.2138, 5.0822, and 23.3375, respectively.

Conclusion:

After Apremilast and Tofacitinib treatment, lipid profile is deranged but rise in LFT levels is significant after Tofacitinib than Apremilast. Apremilast is safe and efficacious option for refractive psoriasis than Tofacitinib.

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Abstract N°: 5695

Successful treatment of acrodermatitis continua of Hallopeau with Bimekizumab

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Successful treatment of acrodermatitis continue of Hallopeau with Bimekizumab

Dr. Annie Langley, MD, MSc, FRCPC, DABD

Introduction & Objectives:

Acrodermatitis continua of Hallopeau (ADCH) is an uncommon variety of pustular psoriasis affecting the acral fingers and toes. This chronic condition is characterized by recurrent eruptions of sterile pustules occur around the nails leading to significant pain and potential irreversible destruction of the nail apparatus. Symptoms are often refractory to topical and systemic therapies for psoriasis. There are few case reports of successful treatment of this condition in the literature. Herein, we report a case of severe ACDH successfully treated with Bimekizumab, a monoclonal antibody inhibitor of interleukin-17. This is the second reported case to date of Bimekizumab for ACDH.

Materials & Methods:

This case report presents results of treatment of a healthy 23-year-old female with severe ACDH and associated destruction of 10 fingernails. She was unable to work and has significant sleep disruption due to associated pain.

Results:

Within 4 months of treatment with Bimekizumab, our patient had complete resolution of ACDH and normal regrowth of all fingernails. She remains clear after 1 year of treatment and has tolerated the medication well without side effects.

Conclusion:

Bimekizumab, a monoclonal antibody inhibitor of interleukin-17, is an effective and safe treatment for ACDH, a rare variant of pustular psoriasis that is recalcitrant to most conventional psoriasis treatments.

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Gender-related therapeutical response to apremilast: new insights in a tailored management of psoriasis

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Introduction & Objectives:

Psoriasis is a chronic immune-mediated skin condition, posing both physical and psychological~~ challenges for patients One of the most intriguing challenges in studying psoriasis has been the identification of correlations between this disease and various factors, including gender and body weight. Research has shown that psoriasis may manifest differently depending on the patient's gender. The relationship between psoriasis and obesity is complex and bidirectional. On one hand, obesity may contribute to the onset and severity of psoriasis through mechanisms involving adipose tissue-derived cytokines and insulin resistance, which promote systemic inflammation and exacerbate immune dysregulation. On the other hand, psoriasis itself can influence body weight, as the physical discomfort and self-consciousness associated with skin lesions may lead to lifestyle changes, such as adopting restrictive diets or avoiding physical activities. A multi-centre retrospective study was conducted among patients with moderate-to-severe psoriasis attending the outpatient clinic of six University Hospital in Italy, considering the effects of apremilast on weight and body mass index (BMI) according to gender after 24 weeks and 48 weeks of therapy.

Materials & Methods:

We enrolled retrospectively adult patients (aged>18 year-old) with a confirmed diagnosis of moderate-to-severe psoriasis who underwent apremilast treatment for at least 24 weeks. Baseline characteristics, including age, gender, psoriasis area severity index (PASI), comorbidities, smoking and alcohol habits, relevant medical history and previous psoriasis systemic and biologic treatments were recorded. Weight and body mass index (BMI) were evaluated at baseline (T0) and at 24 (w24) and 48 weeks (w48). A descriptive statistical analysis has been performed.

Results:

A total of 120 patients [M: 63 (52.5%) and F: 57 (47.5%)] with psoriasis treated with apremilast for at least w24 and with a follow-up visit at w48 were enrolled. Mean duration of psoriasis was about 21.9 ± 0.7 years. The mean duration of therapy with apremilast expressed in months was 25.2 ± 19.4 (28.4 ± 20.9 in males and 21.5 ± 17.1 in females). The mean baseline PASI score for all patients was 10.1 ± 3.39 with higher values in males (10.7 ± 4.8) than females (9.75 ± 1.17). Patients' baseline characteristics are reported in Table 1. In male patients mean weight was 87.1 ± 19.7 kg at baseline, 86.8 ± 19.5 at w24 and 87 ± 20.1 at w48, while mean BMI was 24.8 ± 5.1 at baseline, 24.7 ± 5.1 at w24 and 24.6 ± 5.3 at w48. In women, mean weight was 72.1 ± 15.6 at baseline, 69.6 ± 15.3 at w24 and 66.4 ± 15.7 at w 48, while mean BMI was 22.3 ± 4.9 at baseline, 21.5 ±4.8 at w24 and 20.5 ± 5.1 at w48. The analysis showed a significant reduction in body weight in females at w24 and w48 ($p < 0.001$), with a mean difference of −2.6 kg at w24 and of -5.7 k. We observed a reduction of weight of 3.6% at w24, and 7.9% at

w48. Similar assessments were also observed for BMI, which was reduced in women by 3.6% at w24 and 8% at w48. In men, no changes in weight and BMI were observed at w24 and/or w48.

Conclusion:

Understanding the interplay between psoriasis, gender, and body weight is essential for effective disease management and improving patient outcomes. By being able to understand the complexities of these relationships through further research and clinical practice, we can pave the way for more personalized and holistic approaches to psoriasis.

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Abstract N°: 5698

Pustular Psoriasis refractory to Cyclosporine and responsive to Secukinumab.

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Introduction: Generalized pustular psoriasis can affect patients of any age, with a peak incidence between 40 and 59 years old and a female predominance, accounting for approximately 0.6 to 7% of all psoriasis cases. Its etiology is uncertain but is related to some medications, including the abrupt withdrawal of topical and systemic corticosteroids, as well as cyclosporine. Clinical manifestations include sterile pustules on generalized erythema accompanied by fever, pain, and arthralgia, with potential alterations in liver enzymes caused by neutrophilic cholangitis.

Case report: A 53-year-old female presented with generalized pustular psoriasis following treatment with antibiotics and systemic corticosteroids (prednisone 100mg/day) at an external service. She presented to the dermatology department erythrodermic with pustules on her lower limbs and severe arthralgia while taking prednisone 20mg/day. Due to the severe clinical presentation, she was hospitalized and started on cyclosporine 300mg/day. The patient did not experience changes in blood pressure during hospitalization but showed elevated canalicular enzymes (gamma-glutamyltransferase of 2123, alkaline phosphatase of 480) without clinical repercussions. She was discharged and followed up in the outpatient clinic. She showed partial response to cyclosporine after 4 weeks, with improvement in erythroderma but persistent pustules on the lower limbs and abdomen. Prednisone was gradually tapered (5mg per month), and after 3 months, as the patient still had pustules, secukinumab therapy was initiated at the standard dose, and prednisone was discontinued. After 1 month of secukinumab induction therapy, the patient showed clinical improvement with no evidence of pustules or other skin lesions. Cyclosporine dose was reduced to 200mg/day, after 2 months to 100mg/day for 15 days and finally discontinued, while secukinumab was continued monthly, maintaining a PASI 100 response.

Discussion: The patient presented with generalized pustular psoriasis following abrupt tapering of systemic corticosteroids, manifesting cholestasis indicated by elevated bile canalicular enzymes. Tapering prednisone was challenging due to intense arthralgia and the risk of clinical deterioration. While cyclosporine provided partial clinical response with rapid onset of action within 2 weeks, complete response was achieved only with secukinumab (anti-IL17a). Although spesolimab (anti-IL-36) is a specific alternative for pustular psoriasis, in its absence, other anti-interleukin agents with good clinical response can be considered.

Conclusion: Generalized pustular psoriasis exhibits variability in treatment response among patients. Despite the availability of a specific biologic (anti-IL36) for this condition, clinical control can be achieved with classical systemic medications and other classes of biologics.

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Abstract N°: 5745

Early and durable improvements in patient-reported symptoms and signs of moderate-to-severe psoriasis with JNJ-77242113: 1-year results from FRONTIER 1 & 2

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Introduction & Objectives:

Introduction: Nail psoriasis is a chronic, inflammatory condition which is difficult to treat, linked with greater psoriasis severity, and may be associated with anxiety and significant functional impairment of the quality of life. The 1064nm Nd:YAG laser** was reported to yield satisfactory results in the treatment of nail psoriasis.

Objectives:* To assess the clinical and ultrasonographic efficacy of long-pulsed 1064nm Nd:YAG laser in the treatment of fingernail psoriasis and compare its effect to control fingernails.

Materials & Methods:

This intra-patient randomized controlled trial analyzed 86 fingernails collected from 13 patients suffering from cutaneous and nail psoriasis. The nails were randomized into two groups. Group A was treated with Nd:YAG laser once monthly for three sessions while group B served as control. Assessment took place at baseline, 1 and 3 months after the last treatment session. For scoring, the 32-points target NAPSI scoring systems was used. Additionally, two blinded dermatologists' score of improvement, patients' pain assessment by visual analogue score and ultrasonographic assessment were all performed.

Results:

At the end of follow up, the medians of tNAPSI score, plate definition, matrix thickness, bed thickness and bed vascularity decreased significantly in the Nd:YAG laser treated group in comparison to baseline ($p=0.001$, 0.006, 0.039, <0.001 and 0.010, respectively). While, there was a non-significant reduction in median tNAPSI score in the control group at last follow up, however, ultrasonography recorded a significant reduction in the medians of plate definition, bed thickness and vascularity ($p=0.002$, 0.011 and 0.033, respectively) from the baseline. Comparison of the Nd:YAG laser and the control groups showed no significant difference from baseline regarding the medians of tNAPSI, tNAPSI percentile improvement, pits count, blinded evaluation of photographs and ultrasonographic assessments.

Conclusion:

Nd:YAG laser showed clinical and ultrasonographic improvement in fingernail psoriasis. Ultrasonography is a useful noninvasive tool in diagnosing and monitoring the clinical and even the subclinical changes in nail psoriasis. Nail psoriasis although difficult to treat, may show spontaneous improvement.

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Abstract N°: 5781

Clinical features of scalp squamous dermatosis and yeast-like fungi spp

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Introduction & Objectives: Squamous dermatoses refer to the group of chronic inflammatory skin diseases which occur in the form of erythematous spots or plaques with a varying degree of desquamation accompanied by itching and can appear as a result of an inflammatory response to some yeast-like fungi.

Objective. To study the features of scalp lesions in patients with squamous dermatoses and their connection with yeast-like fungi carrier state.

Materials & Methods: 50 patients aged 18 to 68 with squamous dermatoses of the scalp were in the study: seborrheic dermatitis was in 48% patients, psoriasis vulgaris

- in 52%. The disease severity degree was clinically determined. The sampling was performed by scraping off scalp skin. Microscopic examination (10% KOH) of samples was done to detect fungul cells in the analysis.

Results: Microscopic examination of scalp scrapes was made on 50 patients. Yeast cells were in 31 (62%) tests. Yeast-like fungul cells were found in 19 (79,1%) from 24 patients with seborrheic dermatitis, and in 12 (46,1%) from 26 patients with psoriasis vulgaris. Severe psoriasis vulgaris was identified in 12 people (46.1%), moderate - in 8 people (30.7%), mild - in 6 people (23.2%). Severe seborrheic dermatitis was identified in 9 (37.5%) patients, moderate - in 6 people (25%), mild - in 9 people (37.5%). In patients with severe psoriasis, yeast-like fungi were detected in 75% of cases. In patients with severe seborrheic dermatitis, yeast-like fungi were detected in all cases.

Conclusion: Yeast-like fungi were found in more than half of the patients with squamous dermatoses of the scalp. They were more often in patients with seborrheic dermatitis then in patients with psoriasis.

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The Heart-Psoriasis Link: A Case of Guttate Psoriasis after Staphylococcus Infective Endocarditis

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Introduction & Objectives: Guttate psoriasis represents an acute eruptive condition with distinct clinico-pathological features, classically linked to streptococcal infection with both pharyngeal and perianal involvement, either by autoimmune cross-reactivity with skin epitopes or by promoting T-cell proliferation through superantigens. Recent literature has highlighted increased rates of Staphylococcus aureus cutaneous and nasal colonisation and secretion of enterotoxins in chronic plaque-type psoriasis patients, associated with lesion aggravation. However, no reports of staphylococcal infective endocarditis as a trigger to guttate psoriasis have yet been described.

Materials & Methods: We hereby introduce the case of a 24-year-old male who presented for an abrupt onset of vertigo, nausea, vision and coordination impairment. He had known history of mechanical prosthetic replacement for bicuspid aortic valve and Stargardt disease, a rare genetic disease with macular degeneration by lipid accumulation. Anamnesis revealed an episode of subacute ischemic cerebrovascular stroke two weeks prior to current presentation. Computed tomography illustrated an acute right thalamic lesion and ischemic sequelae in the superior cerebellar artery and medial cerebral artery territories. History of valvular prosthesis and recurrent ischemic strokes raised the suspicion of a cardioembolic aetiology. Transoesophageal echocardiography highlighted the presence of two valvular masses, confirmed as vegetations by positron emission tomography-computed tomography scan. Leucocytosis with neutrophilia, increased inflammatory markers (erythrocyte sedimentation rate, C-reactive protein, fibrinogen) and positive haemocultures with methicillin-sensitive Staphylococcus aureus were also indicative of endocarditis

Results: Five days after admission, an eruption of small, erythematous, teardrop-shaped, scaly papules and plaques on trunk, bilateral upper and lower extremities developed, clinically diagnosed as guttate psoriasis. No signs of upper respiratory tract or perianal involvement, elevation of antistreptolysin O, anti-DNase B, family history or recent tumour necrosis factor α-targeted therapies were identified. The patient underwent antibiotic (vancomycin, rifampicin and ceftriaxone), anticoagulant, anti-inflammatory and neurotrophic therapy with progressive remission. A combination of topical corticosteroids and vitamin D analogues (betamethasone and calcipotriol), emollients and narrowband ultraviolet B phototherapy were used with rapid favourable evolution of skin lesions.

Conclusion: The inflammatory milieu of endothelial dysfunction, as well as Staphylococcal superantigens could represent key pathogenic factors in the development of psoriatic lesions in this case, highlighting that a better understanding of triggers in infection-induced psoriasis, including its acute forms, contributes to a greater appreciation of disease pathogenesis.

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Abstract N°: 5787

Rupioid Psoriasis in Childhood: a challenging case report.

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Introduction: Psoriasis is a chronic, inflammatory, immune-mediated disease of big social impact. Among its multifaceted features, it stands out for its skin involvement, which varies in terms of severity, subtype, location and response to available therapies. It has a high prevalence and severely impacts the quality of life of those suffering from this condition, with an even bigger social impact on children and adolescents. In this age group, the journey from diagnosis to treatment is still quite challenging. This article reports a difficult-to-manage case of an extensive Rupioid Psoriasis since childhood.

Case report: 16 years old male, sought the service with skin lesions in hyperkeratotic and crusted plaques, strongly adhered, tending to a conical structure, disseminated on the trunk, back, genital, upper limbs and scalp. He was diagnosed with rupioid psoriasis at age of 6, but had had lesions since 4 years old. In the gap between diagnosis and effective treatment, he experienced difficult times at school, where suffered bullying attacks for a long time. After unsuccessful topical treatments, systemic treatment with oral Methotrexate was started, without response. Then, was put on Cyclosporine, with minimal response either. At the age of 8, he started Etanercept with significant improvement for 4 years, until, at the age of 12, response was lost again. Finally, he started using Ustekinumab, which he uses to this day, with complete regression of the lesions reaching PASI 0. Today he only presents residual hypochromic lesions where, once, there were psoriasiform lesions.

Discussion: Even in the era of immunobiologicals, and with other immunosuppressive therapies, the treatment of psoriasis in children and adolescents continues to be a challenge in the world of dermatology, as well as its clinical diagnosis. In addition to being uncommon at this age, especially in the more severe and extensive forms, therapeutic alternatives are limited due to the variable age at which each drug can be started, reducing the options depending on the patient's age. As an attempt to control the case described, the patient was put on Cyclosporine (rescue drug), Methotrexate (immunomodulator), Etanercept (Tumor Necrosis Factor inhibitor) and finally, the drug that has controlled the disease in the last years after all the previous therapeutic attempts, Ustekinumab (inhibitor of interleukins 12 and 23). As this is a great option for severe cases of psoriasis, with use permitted from 6 years of age, it showed an excellent response above. In the reported case, difficulty in controlling extensive psoriasis was observed in a pediatric patient who, even with different drug options available for his age, presented refractoriness, emphasizing the importance of knowing all possible alternatives in this age group and their indications, always having a next plan to follow when needed, and persist in continuous treatment ensuring quality of life, even with difficulties and therapeutic failures along the way.

Conclusion: Despite the constant evolution of science, the diagnosis and treatment of psoriasis in the pediatric age group are still challenging. In addition, the disease has a high social impact at all ages, but tends to be worse in children. Knowing the best alternatives for each case and possibilities for exchange if refractory, as well as how to manage high-response drugs such as immunobiologicals, is extremely important to restore as soon as possible the patient's quality of life and self-esteem.

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Abstract N°: 5792

Machine Learning Model to Identify Environmental Characteristics that Predict High Psoriasis Incidence using Populational Data

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Introduction & Objectives:

Psoriasis is a chronic, immune mediated skin disease affecting 2-4% of the population globally. While individual level risk factors for psoriasis have been established, limited studies evaluated the larger social, economic, and environmental context, which is becoming increasingly recognized in chronic diseases. Our aim was to use populational data on psoriasis patients and a comprehensive set of environmental variables to identify the top predictors of psoriasis incidence using a machine learning model.

Materials & Methods:

Adult patients (≥20-years-old) with psoriasis were identified from the provincial health administrative database using International Classification of Disease (ICD)-9/10 between 1997 and 2015 per geographic region (Forward Sortation Area (FSA)). Criteria for diagnosis of psoriasis was met if there were ≥2 billing codes for psoriasis in the outpatient setting or ≥1 during a hospitalization. Linear regression analysis was performed to determine trends in incidence over time. Comprehensive data on environmental and socioeconomic factors from 1 year prior to psoriasis diagnosis was obtained from the Canadian Urban Environment Health Consortium (CANUE) and Statistics Canada (StatCan) per FSA. These served as predictors for the gradient boosting machine learning model and model performance was evaluated using the area under the curve (AUC). Parsimonious models and partial dependence plots were determined to assess directionality of the relationship. The spatial distribution of incidence rates per FSA were mapped using ArcGIS 10.8.

Results:

The incidence of psoriasis varied geographically from 1.6 to 325.6/100,000 person-years. A decrease was also noted from 135.55/100,000 in 1999 to 90.93/100,000 2014. The parsimonious model, considering the top 9 predictors, had an AUC of 0.77 to predict high psoriasis incidence. The top predictors with a negative association to psoriasis incidence were ultraviolet (UV) radiation, maximum daily temperature, proportion of females per geographic region, soil moisture, urbanization, and distance to expressways. Nighttime light brightness had a positive association, whereas social and material deprivation indices suggested a higher psoriasis incidence in the middle socioeconomic class neighbourhoods.

Conclusion:

Using a machine learning model, we comprehensively evaluated environmental factors using populational psoriasis data over an 18-year period. We highlight that the living environment, mainly climate, vegetation, urbanization, and neighborhood socioeconomic characteristics may be predictors for increased psoriasis

incidence.

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Abstract N°: 5814

Pulse azathioprine (AZA) and low dose methotrexate (MTX) versus standard dose MTX in treatment of patients with moderate to severe psoriasis, a randomized controlled trial.

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Introduction & Objectives: Psoriasis is a common chronic, immune-mediated inflammatory skin disease. Despite the availability of several systemic therapeutic agents, treatment of psoriasis remains a challenge because of the associated adverse effects and/or the financial burden of these medications, given the chronicity of the disease. We aimed to compare the efficacy and safety of combined pulse azathioprine (AZA) and low dose methotrexate versus conventional dose of methotrexate (MTX) in patients with chronic plaque psoriasis.

Materials & Methods: In this randomized controlled trial, 67 patients with moderate to severe plaque psoriasis were randomized into 2 groups, receiving either combined pulse AZA (300 mg weekly dose) and low dose MTX (10 mg weekly) or conventional dose MTX (0.3 mg/kg/week) for 16 weeks. Patients were assessed for treatment response using PASI score and for the development of any adverse effects at weeks 12 and 16 and for a further 3 months after stoppage of treatment.

Results: A statistically significant higher proportion of the patients receiving combined pulse AZA and low dose MTX achieved PASI 90 and PASI 100 at week 12 and PASI 100 at week 16, compared to those receiving conventional dose of MTX monotherapy. No serious adverse events were reported during the entire study period in the two groups.

Conclusion:

Combination therapy using pulse AZA and low dose MTX can be an efficacious treatment for moderate to severe plaque psoriasis with a relatively good safety profile.

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Abstract N°: 5824

Thirty-six-month follow up of ixekizumab in the BADBIR registry: baseline demographics, drug survival and effectiveness in biologic-naïve versus biologic-experienced patients with psoriasis

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Introduction & Objectives:

The prospective British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR) collects real-world outcomes data on patients in the UK and Ireland receiving biologic and non-biologic immunomodulators for the treatment of psoriasis, including ixekizumab, an interleukin-17A antagonist. Ixekizumab is approved for the treatment of moderate-to-severe plaque psoriasis in adults and children aged ≥6 years with a bodyweight ≥25kg.1 Objective: To provide 36-month follow-up data of biologic-naïve vs biologic-experienced adult patients with psoriasis receiving ixekizumab treatment in real-world settings, reporting patient baseline demographics, drug survival and effectiveness.

Materials & Methods:

Patients enrolled in BADBIR who initiated ixekizumab on-label for the treatment of moderate-to-severe psoriasis between May 2017 and August 2023 were included in these analyses, stratified by biologic status (naïve vs experienced). Ixekizumab survival at 36 months was evaluated in patients with any follow-up data available; patients with 6- and 12-month Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality Index (DLQI) data available were analysed.

Results:

A total of 1093 patients were included in this ixekizumab cohort; 195 (18%) patients were naïve to biologics at the time of starting ixekizumab and 898 (82%) were biologic-experienced patients (**Table 1**). At ixekizumab initiation, 34% of biologic-experienced patients had received one prior biologic, 27% had received two, 21% had received three, and 18% had received four. After 12 months' ixekizumab treatment, 94%, 87% and 76% of biologic-naïve patients achieved PASI ≤ 4, PASI ≤ 2 and DLQI 0/1, compared with 66%, 55% and 49%, respectively, in biologic-experienced patients. At 36 months, mean ixekizumab drug survival was 77% (95% confidence interval 69%, 84%) in biologic-naïve patients, compared with 58% (51%, 65%) for ixekizumab as a second-line biologic, 51% (43%, 59%) for ixekizumab as a third-line biologic and 47% (40%, 53%) for those receiving ixekizumab as a fourth- or fifth-line biologic. Kaplan-Meier analysis of ixekizumab survival by line of biologic treatment is shown in **Figure 1**.

Conclusion:

Data from BADBIR show the effectiveness and survival of ixekizumab in the real-world setting in the UK and Ireland in both biologic-experienced and biologic-naïve patients receiving ixekizumab for the treatment of moderate-to-severe psoriasis. While these data suggest there may be greater effectiveness and drug survival in biologic-naïve patients than in biologic-experienced patients, with a trend towards decreasing survival with increasing line of treatment, no statistical adjustment was performed for differences in baseline characteristics.

References

\1. Ixekizumab summary of product characteristics. https://www.ema.europa.eu/en/documents/product-

information/taltz-epar-product-information_en.pdf.

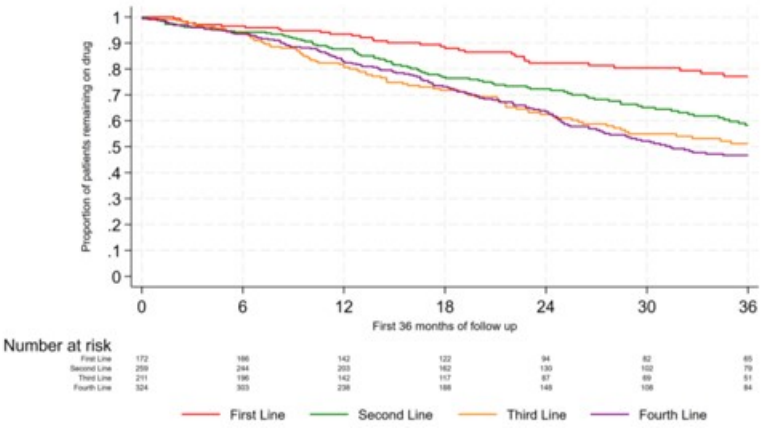
Table 1. Baseline demographics and clinical characteristics in biologic-naïve and -experienced patients with moderate-to-severe psoriasis

	Biologic naïve (n=195)	Biologic experienced (n=898)
Age, years, mean (SD)	46.2 (13.9)	44.5 (12.9)
Female, n (%)	87 (44.6)	401 (44.7)
Age at PsO onset, years, mean (SD)	26.6 (14.3)	24.0 (13.5)
Disease duration, years, mean (SD)	19.6 (11.3)	20.5 (12.7)
Follow-up time, years, mean (SD)	2.2 (1.6)	1.9 (1.4)
BMI, kg/m^2, mean (SD)	32.0 (8.3)	33.0 (7.8)
Baseline PASI, mean (SD)	16.6 (7.9)*	11.7 (8.2)
Baseline DLQI, mean (SD)	18.8 (7.0)*	13.8 (8.5)
Number of comorbidities, mean (SD)*	1.6 (1.5)*	2.0 (1.6)
Psoriatic arthritis, n (%)	45 (23.1)*	331 (36.9)
Previous treatments		
Systemic treatments		
Methotrexate	150 (76.9)	695 (77.4)
Azathioprine	0	1 (0.1)
Acitretin	65 (33.3)***	381 (42.4)
Mycophenolate mofetil	2 (1.0)	15 (1.7)
Ciclosporin	96 (49.2)***	521 (58.0)
Oral retinoids	0	6 (0.7)
Hydroxycarbamide	3 (1.5)***	47 (5.2)
Fumaric acid esters	10 (5.1)*	170 (18.9)
PUVA	2 (1.0)	13 (1.5)
Small molecules		
Apremilast	25 (12.8)**	60 (6.7)
Dimethyl fumarate	3 (1.5)	7 (0.8)

*P<0.001, **P<0.005, ***P<0.05 vs biologic-experienced patients

BMI, Body Mass Index; DLQI, Disability Life Quality Index; PASI, Psoriasis Area and Severity Index; PsA, psoriatic arthritis; PsO, psoriasis; SD, standard deviation

Figure 1. Kaplan-Meier analysis of overall ixekizumab survival by biologic experience



EADV CONGRESS
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Abstract N°: 5850

Psoriasis during natalizumab treatment for multiple sclerosis

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Introduction & Objectives: Psoriasis is a prevalent, chronic, and inflammatory skin disorder, distinguished by well-defined erythematous plaques with micaceous scales. It is known to be influenced by various factors, including genetic predisposition, environmental triggers, and immune dysregulation. While the exact etiology remains elusive, the role of immune-mediated mechanisms, particularly involving T cells and cytokines, has been extensively studied. Natalizumab, a monoclonal antibody targeting α4-integrin, is commonly used in the treatment of multiple sclerosis (MS), a chronic autoimmune disease affecting the central nervous system. However, emerging evidence suggests a potential association between natalizumab therapy and the development or exacerbation of psoriasis. Understanding this relationship is essential for dermatologists and neurologists involved in the management of patients with concurrent MS and psoriasis.

Materials & Methods: Data from medical records and literature review. The keywords included were “psoriasis” and “natalizumab”.

Results: We present a case of a 52-year-old male, diagnosed with multiple sclerosis for 5 years and treated with natalizumab for one year. He had no significant medical history, including dermatological conditions, and no family history of skin diseases. The patient presented to our dermatology department with a 6-month history of non-pruritic skin lesions on the trunk, upper and lower limbs. He denied other symptoms, including joint pain or stiffness. Initial treatment with isoconazole nitrate and diflucortolone valerate cream by his family physician resulted in clinical improvement but subsequent relapse upon discontinuation. On physical examination, hyperkeratotic, erythematous, oval, and well-defined plaques were noted on the dorsum, arms, buttocks, and right foot. Histological analysis of skin biopsies confirmed the diagnosis of psoriasis, with negative microbiological results. The patient was initiated on daily calcipotriene and betamethasone dipropionate foam, resulting in excellent clinical response.

Conclusion: The association between natalizumab and psoriasis has been increasingly recognized in recent years. Natalizumab acts by inhibiting the migration of immune cells, particularly T cells, into the central nervous system, thereby reducing inflammation in multiple sclerosis. However, this mechanism of action may also lead to dysregulation of immune responses in the skin, predisposing patients to the development of psoriasis or exacerbation of pre-existing disease. Our case underscores the need for vigilance in monitoring dermatological symptoms in patients receiving natalizumab therapy, especially those with a history of psoriasis or other autoimmune skin conditions. Prompt recognition and management of psoriasis are crucial to prevent disease progression and ensure optimal patient outcomes. Further research is warranted to elucidate the underlying mechanisms driving the association between natalizumab and psoriasis and to identify strategies for mitigating this adverse effect while optimizing therapeutic benefits in patients with multiple sclerosis.

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Abstract N°: 5902

Thirty-six-month follow-up of ixekizumab in psoriasis patients with and without the involvement of high impact areas (nail, scalp, palmoplantar or PsA): data from the BADBIR registry

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Introduction & Objectives:

The British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR) is a prospective registry of patients receiving treatment with biologic and non-biologic immunomodulators for psoriasis across the UK and Ireland. Ixekizumab, an interleukin-17A antagonist, is a biologic agent approved for the treatment of moderate-to-severe plaque psoriasis in adults and in children aged ≥6 years with a bodyweight ≥25kg.1 Objective: To provide 36-month real-world follow-up data in patients with moderate-to-severe psoriasis with and without involvement of the scalp, nails or palmoplantar region, and with or without psoriatic arthritis (PsA) who are receiving ixekizumab therapy.

Materials & Methods:

Patients initiating ixekizumab treatment for moderate-to-severe psoriasis who were enrolled in BADBIR between May 2017 and August 2023 were included in these analyses. Data were analysed for patients based on the presence or absence of psoriasis of the scalp, nails or palmoplantar region and by the presence or absence of PsA; some patients had involvement of more than one of these areas, but all analyses presented here only compared patients with and without each specific area of involvement.

Results:

A total of 1093 patients were included in these analyses, 45% of whom were female. Overall, 770 (70%) patients had involvement of the scalp, 611 (56%) had nail involvement, 227 (21%) had palmoplantar involvement and 376 (34%) had concomitant PsA (**Table 1**). Ixekizumab survival at 36 months was similar in patients with and without scalp involvement, at 56% (95% confidence interval 52%, 61%) and 55% (48%, 62%) respectively, with and without nail involvement, at 56% (51%, 60%) and 57% (51%, 62%) respectively, and in patients with and without PsA, at 56% (49%, 62%) and 56% (51%, 60%) respectively. In contrast, ixekizumab survival was numerically lower in patients with palmoplantar involvement than in those without such involvement, at 48% (40%, 56%) and 58% (54%, 62%) respectively; Kaplan-Meier survival curves by area of involvement are shown in **Figure 1**. After 36 months' follow up, ineffectiveness was associated with discontinuation in similar proportions of patients with and without scalp involvement (20% vs 22%), nail involvement (22% vs 19%), palmoplantar involvement (24% vs 20%) and with or without PsA (19% vs 22%).

Conclusion:

Ixekizumab is associated with sustained survival in a real-world setting in patients with moderate-to-severe psoriasis regardless of the involvement of the scalp, nails, or palmoplantar region, all of which are considered difficult-to-treat areas, or the presence or absence of PsA, with the data highlighting 36-month ixekizumab survival of approximately 50% to 60% across all of the patient subgroups analysed.

References:

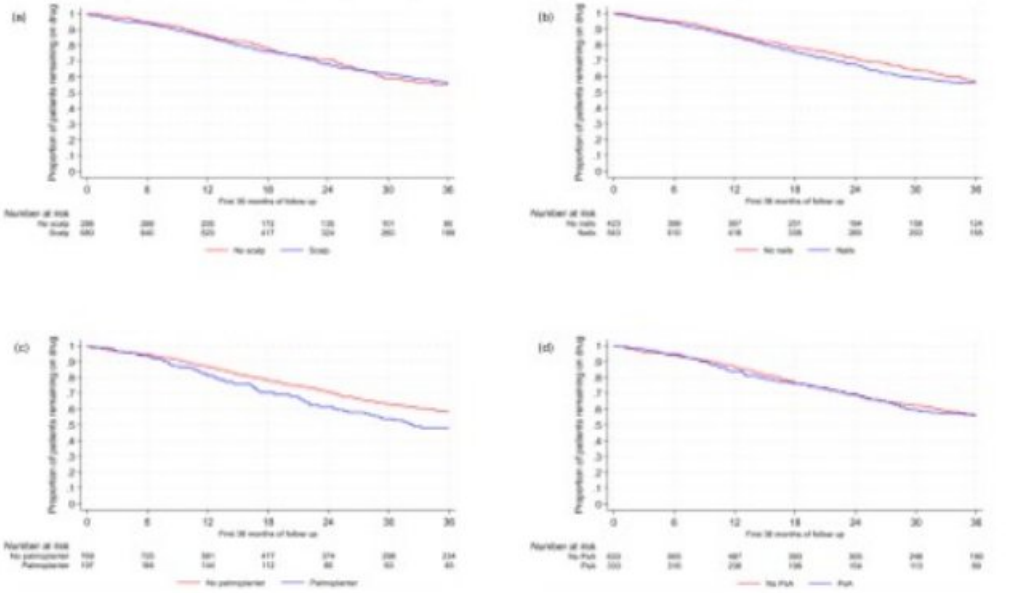
\1. Ixekizumab summary of product characteristics. https://www.ema.europa.eu/en/documents/product-information/taltz-epar-product-information_en.pdf

Table 1. Baseline demographics and clinical characteristics in patients with and without scalp, nail or palmoplantar involvement, or PsA.

	Areas/type of disease involvement, mean (SD)							
	Scalp		Nail		Palmoplantar		PsA	
	Yes (n=770)	No (n=323)	Yes (n=611)	No (n=482)	Yes (n=227)	No (n=866)	Yes (n=376)	No (n=717)
Age, years	43.5 (13.1)**	47.9 (12.6)	44.6 (12.9)	45.0 (13.2)	45.5 (12.9)***	44.6 (13.1)	45.6 (12.2)***	44.4 (13.5)
Age at PsO onset, years	23.8 (13.2)	26.1 (14.6)	24.0 (13.2)	25.2 (14.2)	25.4 (13.9)	24.3 (13.6)	23.9 (12.7)	24.8 (14.1)
Disease duration, years	19.6 (12.1)***	21.9 (13.1)	20.7 (12.3)***	19.9 (12.6)	20.1 (11.8)	20.4 (12.6)	21.6 (13.0)*	19.6 (12.1)
Follow-up time, years	2.0 (1.5)	2.0 (1.4)	2.0 (1.4)	2.0 (1.5)	1.8 (1.4)	2.0 (1.5)	1.9 (1.3)	2.0 (1.5)
BMI, kg/m²	32.8 (8.1)	32.4 (7.5)	32.4 (7.7)	33.1 (8.1)	31.9 (7.7)	32.9 (8.0)	32.8 (6.9)	32.6 (8.4)
Baseline PASI	12.9 (8.6)	12.1 (7.7)	12.8 (8.5)	12.5 (8.1)	13.6 (9.1)	12.4 (8.2)	12.7 (8.7)	12.6 (8.2)
Baseline DLQI	15.9 (8.3)	14.4 (8.6)	15.4 (8.6)	15.6 (8.0)	15.8 (8.4)	15.4 (8.4)	15.8 (8.7)	15.3 (8.2)
Number of comorbidities	1.9 (1.6)*	2.0 (1.5)	2.0 (1.6)	1.9 (1.5)	2.0 (1.6)	1.9 (1.6)	2.9 (1.5)*	1.5 (1.4)
Number of prior biologics	1.9 (1.5)	2.0 (1.5)	2.0 (1.5)	1.9 (1.5)	2.0 (1.5)	1.9 (1.5)	2.1 (1.5)*	1.8 (1.5)

*P<0.001, **P<0.005, ***P<0.05, all for patients with vs those without that disease area involvement
BMI, Body Mass Index; DLQI, Disability Life Quality Index; PASI, Psoriasis Area and Severity Index; PsA, psoriatic arthritis; PsO, psoriasis; SD, standard deviation.

Figure 1. Kaplan-Meier analysis of overall ixekizumab survival for (a) patients with and without scalp involvement, (b) patients with and without nail involvement, (c) patients with and without palmoplantar region involvement, (d) patients with and without psoriatic arthritis.



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Abstract N°: 5917

Insufficient duration of dermatology consultations for psoriasis patients in a worldwide study : Results of the ALL project

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Introduction & Objectives:

The duration of medical consultations impacts the interaction between patients and doctors in medical settings. Extended consultations have the potential to enhance the quality of care and satisfaction among physicians by facilitating more comprehensive patient interactions. However, determining the appropriate duration of consultations remains a subject of debate. Given that the management of psoriasis often entails lengthy and intricate procedures, this study aimed to examine whether psoriasis patients feel the duration of their consultations is adequate, to explore the prevalence of psoriasis patients who perceive their consultations as insufficient, and to assess potential predictors including socio-demographic characteristics and therapeutic approaches.

Materials & Methods:

This online survey was carried out on a representative sample of psoriasis patients in 20 countries, aged 18 or over. The questionnaire collected information on demographic characteristics, the therapeutic management of their psoriasis and their perception of the length of their consultations. A comparison of those who considered the length of consultation insufficient (DCI) and sufficient (non-DCI) was used to assess the predictive factors: socio-demographic, therapeutic management, etc. Descriptive analyses using absolute frequencies were also carried out.

Results:

A population of 706 psoriasis patients was selected, including 384 (54.4%) males and 322(45 .6%) females (mean age 50.1+/- 14 .9 years). min 16-85 years. 401 (56.8%) were treated by dermatologists, 139(19.7%) by general practitioners (GPs) and 35(5%) by complementary health practitioners (CHPs). 217 (30.7%) were treated by dermatologists in general practices and 106 (15%) in public hospitals. 471 (66.7%) excluded local drug treatment, 242 (34.3%) excluded systemic treatment (10.3% injectable and 108 oral). 409 were from Europe, 88 from North America, 96 from Asia, 61 from South America, 29 from Australia, 17 from the Middle East and 6 from Africa. 118 (16.7%) considered that the length of the consultation was insufficient. 18.2% of those followed up by dermatologists 14.4% by GPs and 28.6% by CHPs. Respondents who felt that the consultation time was too short were less satisfied with the explanations given (34.6% vs 91.8%, $p<0.01$) and with the treatment offered (27.7% vs 88.1%, $p<0.01$). The perception of inadequate consultation time was not significantly higher among women (20.5% vs. 13.5%, $p>0.05$), or in the case of hospital treatment (15% vs. 15.7%, $p>0.05$). The prevalence of insufficient consultation time did not differ significantly between countries. Respondents under 35 years of age (30.5% vs. 18.0%) and those with systemic treatments (21.8% vs. 13.6%) were more likely to consider the duration of consultations insufficient.

Conclusion:

This study represents the first inaugural examination of the perception of insufficient consultation duration among

psoriasis patients. It reveals that individuals receiving systemic treatment for psoriasis were more prone to feeling that their consultation time was insufficient. Such patients might require lengthier consultations to ensure ample opportunity for reflection on their condition and to address any questions or concerns that impact their daily lives and personal management approaches.

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Abstract N°: 5921

Safety of tildrakizumab in patients with moderate-to-severe psoriasis: 52-week data from the phase IV POSITIVE study

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Introduction & Objectives: Psoriasis is a chronic immune-mediated disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being.1 Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.2 Long-term observational studies are needed to confirm safety in daily clinical practice bridging the gap between clinical trials and the real-world setting.3 The objective of this analysis was to assess the safety of tildrakizumab in patients with moderate-to-severe psoriasis in routine care in the POSITIVE study.

Materials & Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.4 Safety assessments were based on reports of adverse events (AEs). Here, we report 52-week interim data.

Results: A total of 400 patients were included (63.3% male, mean±95%CI age of 46.5±1.5 years). At the point of this analysis, 23.3% of patients had ≥1 AE, with infections and infestations (12.0%), mostly COVID-19 (3.8%) and nasopharyngitis (3.0%), being the most common system organ class and preferred terms, respectively, and 3.8% of patients had ≥1 related AE (**Table 1**). Only 2 patients (0.5%) discontinued the study due to AEs.

Table 1. Summary of patients with adverse events (AE)

n (%)	N=400
Patients with ≥1 AE (all SOC)	93 (23.3)
Patients with mild AEs	61 (15.3)
Patients with moderate AEs	27 (6.8)
Patients with severe AEs	8 (2.0)
Patients with ≥1 related AE	15 (3.8)
Patients with ≥1 serious AE	9 (2.3)
Patients with ≥1 serious related AE*	1 (0.3)
Patients withdrawing from the study due to AEs	2 (0.5)
Patients with ≥1 AE resulting in death	0 (0.0)

* A case of recovered/resolved bursitis. SOC, system organ class.

Conclusion: In a real-world setting, tildrakizumab maintained a favorable safety profile in patients with moderate-to-severe chronic plaque psoriasis over 52 weeks, consistent with previous studies.2,3

References: 1Armstrong AW, et al. PLoS One 2012;7:e52935. 2Thaçi D, et al. BJD 2021;185:323–34. 3Tsianakas A, et al. JEADV 2023;37:85–92. 4Augustin M, et al. BMJ Open 2023;13:e060536.

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Abstract N°: 5926

High effectiveness of tildrakizumab regardless of baseline characteristics in patients with moderate-to-severe psoriasis: 52-week results from the POSITIVE study

Ulrich Mrowietz*[1], Rachel Sommer[2], Ziad Reguiai[3], Sascha Gerdes[4], Esteban Daudén[5], Wolfgang Weger[6], Julia-Tatjana Maul[7], Philip Laws[8], Luigi Naldi[9], Pierre-Dominique Ghislain[10], Elke de Jong[11], Sicily Mburu[12], Volker Koscielny[13], Eric Massana[13], Ismail Kasujee[13], Matthias Augustin[2]

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Introduction & Objectives: Psoriasis is a chronic immune-mediated disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being.1 Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.2,3** The objective of this analysis was to examine the response to tildrakizumab in different subgroups of patients from the POSITIVE study defined by baseline characteristics.

Materials & Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.4 Effectiveness assessments in this analysis included proportions of patients who achieved an absolute Psoriasis Area and Severity Index (PASI) of ≤3 and ≤1. Subgroups were defined based on baseline patient characteristics: gender (male/female), age (18-<30/≥30-<60/≥60 years), body mass index (<25/≥25 kg/m2), baseline PASI (≤10/>10), and time since diagnosis (cut-off values based on quartiles). Here, we report 52-week interim data using an observed cases approach.

Results: A total of 400 patients were included (63.3% male, mean±95%CI age of 46.5±1.5 years). For the overall population, mean±95%CI PASI decreased from 13.1±0.8 at baseline to 1.7±0.3 at week 28 and to 1.5±0.3 at week 52 ($p<0.0001$, both). At week 28 and week 52, respectively, 85.8%/54.8% and 88.4%/56.8% of patients achieved an absolute PASI of ≤3/≤1. The proportions of patients who achieved an absolute PASI of ≤3 and ≤1 at weeks 28 and 52 by subgroups of baseline characteristics are shown in **Table 1**. Overall, tildrakizumab showed high levels of effectiveness regardless of patients' baseline characteristics.

Table 1. Patients achieving an absolute PASI of ≤3 and ≤1 at weeks 28 and 52 by subgroups of baseline characteristics

	PASI ≤3, n (%)	PASI ≤1, n (%)
	Week 28	Week 52
Gender		
Male	173 (82.0)	172 (87.8)
Female	110 (92.4)	94 (89.5)
Age (years)		
18-<30	42 (89.4)	34 (79.1)
≥30-<60	187 (84.6)	175 (88.4)
≥60	54 (87.1)	57 (95.0)
BMI (kg/m2)		
<25	88 (91.7)	75 (89.3)
≥25	187 (83.1)	184 (88.5)
PASI		
≤10	115 (88.5)	104 (88.9)
>10	167 (83.9)	160 (87.9)
Time since diagnosis (years)*		
1st quartile	73 (85.9)	62 (89.9)
2nd quartile	63 (81.8)	63 (88.7)
3rd quartile	68 (87.2)	63 (85.1)
4th quartile	74 (87.1)	75 (89.3)

*Q1: 0-4.7; Q2: >4.7-12.1; Q3: >12.1-22.5; Q4: >22.5-55.2. BMI, body mass index; PASI, Psoriasis Area and Severity Index.

Conclusion: In a real-world setting, tildrakizumab demonstrated high effectiveness through week 52 regardless of baseline characteristics in patients with moderate-to-severe plaque psoriasis.

References: 1Armstrong AW, et al. PLoS One 2012;7:e52935. 2Thaçi D, et al. BJD 2021;185:323–34. 3Tsianakas A, et al. JEADV 2023;37:85–92. 4Augustin M, et al. BMJ Open 2023;13:e060536.

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Abstract N°: 5936

High effectiveness of tildrakizumab in bio-naïve and bio-experienced patients with moderate-to-severe psoriasis: 52-week results from the POSITIVE study

Ulrich Mrowietz*[1], Rachel Sommer[2], Ziad Reguiai[3], Sascha Gerdes[4], Esteban Daudén[5], Wolfgang Weger[6], Julia-Tatjana Maul[7], Philip Laws[8], Luigi Naldi[9], Pierre-Dominique Ghislain[10], Elke de Jong[11], Sicily Mburu[12], Volker Koscielny[13], Eric Massana[13], Ismail Kasujee[13], Matthias Augustin[2]

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Introduction & Objectives: Psoriasis is a chronic immune-mediated disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being.1 Tildrakizumab is an interleukin-23p19 inhibitor for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.2,3** Patients previously treated with biologics are more likely to experience lower levels of efficacy with subsequent courses of biologic therapies vs bio-naïve patients.4 The objectives of this analysis were to assess the effect of tildrakizumab on the overall well-being, skin symptoms, and health-related quality of life (HRQoL) in bio-naïve and bio-experienced patients with moderate-to-severe psoriasis in routine clinical practice.

Materials & Methods: POSITIVE is an ongoing 24-month, phase IV observational study in adults with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.5 Well-being was assessed through the 5-item WHO Well-being Index (WHO-5; range 0-100, where 0=absence of well-being and 100=maximal well-being).6 Effectiveness assessments in this analysis included Psoriasis Area and Severity Index (PASI) and Physician Global Assessment (PGA). The HRQoL instrument was Dermatology Life Quality Index-Relevant (DLQI-R; range 0-30, where a higher score represents a greater impairment in HRQoL; 0-1.99=no effect on patient's life).7 Here, we report 52-week (W) interim data using an observed cases approach.

Results: A total of 400 patients were included (63.3% male, mean±95%CI age of 46.5±1.5 years), of whom 290 (72.5%) were bio-naïve and 110 (27.5%) bio-experienced patients. Mean±95%CI WHO-5 score increased from 52.6±2.6/56.9±4.3 at baseline to 64.6±2.8/69.5±4.2 at W28 and 63.9±3.1/69.6±5.2 at W52 in bio-naïve/bio-experienced patients ($p<0.0001$ compared with baseline, all). Mean±95%CI PASI decreased from 13.7±0.9/11.6±1.3 at baseline to 1.3±0.2/2.5±0.9 at W28 and 1.3±0.2/1.8±0.7 at W52 in bio-naïve/bio-experienced patients ($p<0.0001$ compared with baseline, all). At W28 and W52, respectively, 87.9%/56.1% and 90.8%/57.3% of bio-naïve and 80.2%/51.6% and 81.9%/55.4% of bio-experienced patients achieved PASI ≤3/≤1. Mean±95%CI

PGA improved from 2.9±0.1/2.7±0.2 at baseline to 0.8±0.1/1.0±0.2 at W28 and 0.8±0.1/0.9±0.2 at W52 in bio-naïve/bio-experienced patients. Mean±95%CI DLQI-R score decreased from 13.0±0.9/11.5±1.7 at baseline to 2.9±0.6/4.4±1.5 at W28 and 3.2±0.7/3.0±1.2 at W52 in bio-naïve/bio-experienced patients ($p<0.0001$ compared with baseline, all). At W28/W52, 50.0%/47.5% of bio-naïve and 36.8%/46.7% of bio-experienced patients with DLQI-R >1.99 at baseline had a DLQI-R score between 0 and 1.99.

Conclusion: In both bio-naïve and bio-experienced patients, tildrakizumab significantly improved patients' well-being, skin symptoms, and HRQoL after 28 weeks, and this improvement was maintained through W52 in a real-world setting.

References: 1Armstrong AW, et al. PLoS One 2012;7:e52935. 2Thaçi D, et al. BJD 2021;185:323–34. 3Tsianakas A, et al. JEADV 2023;37:85–92. 4Hung Y-T, et al. TACD 2021:12:20406223211046685. 5Augustin M, et al. BMJ Open 2023;13:e060536. 6Topp CW, et al. PP 2015;84:167–76.7Rencz F, et al. BJD 2018; 179:1102–8.

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Abstract N°: 5941

The dermatologist's role in cardiovascular risk screening in moderate-to-severe psoriasis

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Introduction & Objectives:

Cardiovascular (CV) comorbidities are well-grounded consequences of psoriasis disease. A significant proportion of psoriatic patients are cardiovascularly asymptomatic; however, they have substantial subclinical atherosclerosis when examined. For this reason, screening of CV risk in this patient group is particularly important during dermatological care as well. Moreover, the effect of systemic antipsoriatic treatments and biologicals on CV comorbidities has not yet been completely cleared. This summary presentation discusses the authors' results and available literature data on CV screening and the impact of specific biological therapies on CV comorbidity in psoriatic patients.

Materials & Methods:

To assess the CV risk of our patients with moderate-to-severe psoriasis, CV risk estimation with conventional calculators, coronary artery calcium calculation by cardiac computed tomography, and intima-media thickness (IMT) measurement with peripheral arterial ultrasound (US) were performed in a cross-sectional design including also a non-psoriatic control group. We also conducted prospective studies on the effect of the tumour necrosis factor and interleukin-17 inhibitor (TNFi, IL-17i) therapies on the IMT. We performed a meta-analysis to compare CV events' incidence near TNFi and conventional therapies.

Results:

In our cross-sectional study of moderate-to-severe psoriatic patients, the psoriatic group had a significantly higher coronary artery calcium score (CACS) compared to the non-psoriatic control group. 64% of the patients had some degree of calcified plaque burden (CACS>0) in the coronary arteries. In CACS>0 patients, CV risk estimations by conventional calculators and the maximal value of IMT in the carotid arteries were significantly higher than in CACS=0 patients. After six months of follow-up, significant decreases in IMT values in carotid, brachial and femoral arteries were detected in a significant proportion of TNFi-treated and also in IL-17i-treated patients. The result of our recent meta-analysis showed a significant risk-reducing effect of TNFis on the risk of major adverse CV events compared to conventional systemic drugs treated groups.

Conclusion:

Dermatologists can be advised to screen the CV risk of cardiovascularly asymptomatic moderate-to-severe psoriasis patients using easily applicable conventional risk estimators and to request cardiological consultation and further risk management. Effective anti-inflammatory therapies should be considered with regard to their beneficial CV effects. Future therapeutic guidelines should more highlight these recommendations.

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Abstract N°: 5949

Effectiveness of tildrakizumab in patients with moderate-to-severe psoriasis located in special areas: 52-week results from the POSITIVE study

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Introduction & Objectives: Psoriasis is a chronic immune-mediated disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being.1 Psoriasis commonly affects special areas, such as the scalp, palms or soles, or nails. The burden of disease, particularly when special areas are affected, is very high.2 Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.3,4** The objective of this analysis was to assess the effectiveness (overall and in special locations) of tildrakizumab in patients with moderate-to-severe psoriasis in routine care.

Materials & Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.5 Effectiveness assessments in this analysis included Psoriasis Area and Severity Index (PASI) and five-point Physician Global Assessment (PGA). In addition, scalp-PGA, palmoplantar-PGA, and nail-PGA were used to assess tildrakizumab effectiveness in special areas.6 Here, we report 52-week interim data using an observed cases approach.

Results: A total of 400 patients were included (63.3% male, mean±95%CI age of 46.5±1.5 years). Mean±95%CI Psoriasis Area and Severity Index (PASI) decreased from 13.1±0.8 at baseline to 1.7±0.3 at week 28 ($p<0.0001$), with a mean change from baseline of -11.3, and to 1.5±0.3 at week 52 ($p<0.0001$), with a mean change from baseline of -11.7. At week 28 and week 52, respectively, 85.8%/54.8% and 88.4%/56.8% of patients achieved PASI ≤3/≤1. The mean±95%CI PGA improved from 2.9±0.1 at baseline to 0.9±0.1 at week 28, and to 0.8±0.1 at week 52. At week 28 and week 52, 84.4% and 83.4% of patients with a PGA score >1 at baseline achieved a PGA score of 0 or 1. At baseline, 71.2% of patients had scalp psoriasis (scalp-PGA>0), 25.5% of patients had palmoplantar psoriasis (palmoplantar-PGA>0), and 39.9% of patients had nail psoriasis (nail-PGA>0). At week 28 and week 52, respectively, 87.0%/90.5%/77.9% and 88.5%/94.5%/85.7% of patients with a scalp-PGA/palmoplantar-PGA/nail-PGA score >1 at baseline achieved a scalp-PGA/palmoplantar-PGA/nail-PGA score of 0 or 1.

Conclusion: In a real-world setting, tildrakizumab significantly improved skin symptoms in patients with moderate-to-severe plaque psoriasis after 28 weeks, and this improvement was maintained through week 52. In addition, tildrakizumab showed marked and sustained improvement in areas of special burden such as the scalp, palms or soles, and nails.

References: 1Armstrong AW, et al. PLoS One 2012;7:e52935. 2Egeberg A, et al. BMC Dermatol 2020;20:3. 3Thaçi D, et al. BJD 2021;185:323–34. 4Tsianakas A, et al. JEADV 2023;37:85–92. 5Augustin M, et al. BMJ Open 2023;13:e060536. 6Langley RG, et al. J Dermatolog Treat 2015;26:23–31.

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Abstract N°: 5955

Impact of patient psoriasis on partner well-being in a real-world setting: 52-week interim data of the phase IV POSITIVE study

Ulrich Mrowietz*[1], Rachel Sommer[2], Ziad Reguiai[3], Sascha Gerdes[4], Esteban Daudén[5], Wolfgang Weger[6], Julia-Tatjana Maul[7], Philip Laws[8], Luigi Naldi[9], Pierre-Dominique Ghislain[10], Elke de Jong[11], Sicily Mburu[12], Volker Koscielny[13], Eric Massana[13], Ismail Kasujee[13], Matthias Augustin[2]

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Introduction & Objectives: Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition as well as their families'. However, evaluation of the impact of psoriasis on patients' families, particularly partners, in a robust prospective study is missing. In addition, an effective control of the disease can help maintaining patients' and partners' well-being in long-term. Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.1,2 The objective of this analysis was to investigate the impact of psoriasis on the well-being of partners of patients included in the POSITIVE study.

Materials & Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.3 Partner's well-being was assessed through the FamilyPso questionnaire, which is a partner self-administrated questionnaire, in absence of the patient, to assess the burden on partners of patients with psoriasis.4 The questionnaire has 15 items divided into five factors: (1) perceived strain by social reactions to the partner's psoriasis; (2) strain caused by cleaning; (3) acute emotional strain attributed directly to the psoriasis; (4) restrictions of social life; and (5) general emotional strain. The items are scaled in a 5-point Likert format (range 0-4; 0=not true, 4=very true). FamilyPso total scores below 1.27 indicate normal-to-moderate strain.4 Here, we report 52-week interim data using an observed cases approach.

Results: The cohort comprised 400 patients, of whom 248 (62.0%) were married or living in marital union. Mean±95%CI age of patients was 46.5±1.5 years (19.5% ≥60 years), and 63.3% of them were male. Mean±95%CI time since psoriasis diagnosis was 15.1±1.3 years. Mean±95%CI total FamilyPso score decreased from 1.3±0.1 at baseline to 0.9±0.1 at week 16 ($p<0.0001$), with a mean change from baseline of -0.5, to 0.8±0.2 at week 28 ($p<0.0001$), with a mean change from baseline of -0.6, and to 0.7±0.2 at week 52 ($p<0.0001$), with a mean change from baseline of -0.7. The mean±95%CI FamilyPso scores by factor at baseline, week 16, and week 52 were 1.1±0.2, 0.8±0.2, and 0.7±0.2 for "perceived strain by social reactions to the partner's psoriasis", 1.4±0.2, 0.8±0.2,

and 0.7±0.2 for “strain caused by cleaning”, 1.2±0.2, 0.7±0.2, and 0.5±0.2 for “acute emotional strain attributed directly to the psoriasis”, 0.9±0.2, 0.5±0.2, and 0.4±0.1 for “restrictions of social life”, and 1.9±0.2, 1.4±0.2, and 1.2±0.2 for “general emotional strain”, respectively ($p<0.001$ for all comparisons with baseline).

Conclusion: There is an impact of patient’s psoriasis on social and emotional well-being of their partners, which highlights the unmet needs not only in the management of psoriatic patients but also their families. Tildrakizumab significantly improved partners’ well-being after 16 weeks and continued to improve through 52 weeks.

References: 1Thaçi D, et al. BJD 2021;185:323–34. 2Tsianakas A, et al. JEADV 2023;37:85–92. 3Augustin M, et al. BMJ Open 2023;13:e060536. 4Mrowietz U, et al. JEADV 2017;31:127–34.

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Abstract N°: 5957

Human leucocyte antigen risk alleles for psoriatic arthritis among patients with psoriasis

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Introduction & Objectives:

Psoriatic arthritis is a chronic inflammatory disease of the joints, spine and entheses that can occur in patients with psoriasis. A delay in diagnosis of psoriatic arthritis of even 6 months is associated with a deterioration in long-term radiological and functional outcomes, which leads to disability. Early diagnosis of joint damage may be possible with the predictors (prognostic markers) of the risk of developing psoriatic arthritis in patients with psoriasis. Genes that differentiate patients with psoriatic arthritis from those with plaque psoriasis may serve as markers for the development of joint damage. The aim of the study is to determine associations between human leucocyte antigen (HLA) alleles and psoriatic arthritis.

Materials & Methods:

190 adult patients with plaque psoriasis and 60 adult patients with psoriatic arthritis were genotyped for HLA I (HLA-A, HLA-B, HLA-C) and II (HLA-DRB1, HLA-DPB1, HLA-DQB1, HLA-DRB3/4/5) alleles. Bioinformatics analysis of the obtained HLA typing data in fastq format was carried out using specialized software HLA-Expert 2.0 (DNA-Technology, Russian Federation). Data analysis was performed using the R (programming language) version 4.3.1.

Results:

The HLA-C*12:03:01G allele in patients with psoriasis increases the risk of developing psoriatic arthritis by 2.92 times (OR=2.92; [95% CI: 1.42 – 6.00], p=0.04). Allele B*13:02:01G (OR=0.37; [95% CI: 0.15 – 0.96], p=0.04) may exert a protective role. Its presence in patients with psoriasis can reduce the risk of developing joint damage by 2.7 times. The allele C*06:02:01G, which was found in 55.81% of patients with plaque psoriasis and in 23.73% of patients with psoriatic arthritis, can also be considered as a protective allele (OR= 0.43 [95% CI: 0.22 – 0.84], p = 0.02).

The most common variant of the HLA-B gene alleles in the group of patients with psoriatic arthritis is the B*38:01:01G allele with a frequency of occurrence of 28.81% versus 8.08-8.14% in groups of patients with plaque psoriasis (OR=3.57; [95% CI: 1.45 – 8.77], p = 0.005).

Conclusion:

A number of alleles have been identified as predictors of the development of psoriatic arthritis, and a number of alleles as protective.

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Abstract N°: 5962

Effectiveness of tildrakizumab for itch, pain, and fatigue in patients with moderate-to-severe psoriasis: 52-week results from the real-world POSITIVE study

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Introduction & Objectives: Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being.1 Itch and skin pain can be two of the most burdensome symptoms associated with psoriasis.2 Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.3,4 The objectives of this analysis were to assess the effectiveness of tildrakizumab on burdensome symptoms in patients with moderate-to-severe psoriasis in routine care.

Materials & Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.5 Patient-reported outcomes in this analysis included 11-point Itch-, Pain-, Joint Pain- and Fatigue-Numeric Rating Scale (NRS), ranging from 0 to 10 (10=worse symptoms).6 The percentage of patients with a reduction in NRS scores from baseline ≥4 points was calculated for patients with a baseline NRS scores ≥4. Here, we report 52-week interim data using an observed cases approach.

Results: A total of 400 patients were included (63.3% male, mean±95%CI age of 46.5±1.5 years). The mean±95%CI Itch-NRS improved from 5.7±0.3 at baseline to 2.2±0.3 at week 16, to 2.1±0.3 at week 28, and to 2.4±0.4 at week 52 ($p<0.0001$, all). The mean±95%CI Pain-NRS improved from 4.1±0.3 at baseline to 1.5±0.3 at week 16, to 1.4±0.3 at week 28, and to 1.2±0.3 at week 52 ($p<0.0001$, all). The mean±95%CI Joint Pain-NRS improved from 2.5±0.3 at baseline to 1.6±0.3 at week 16, to 1.5±0.3 at week 28, and to 1.4±0.3 at week 52 ($p<0.0001$, all). The mean±95%CI Fatigue-NRS improved from 3.8±0.3 at baseline to 1.9±0.3 at week 16, to 1.8±0.3 at week 28, and to 1.9±0.3 at week 52 ($p<0.0001$, all). At week 28 and week 52, respectively, 69.3%/74.0%/52.1%/65.6% and 64.1%/83.1%/56.0%/60.0% of patients with a baseline Itch-/Pain-/Joint Pain-/Fatigue-NRS score ≥4 achieved a ≥4-point reduction in Itch-/Pain-/Joint Pain-/Fatigue-NRS.

Conclusion: Patients treated with tildrakizumab in a real-world setting achieved rapid and significant reductions in burdensome symptoms of psoriasis (itch, skin pain, joint pain, and fatigue) after 16 weeks, which were maintained through week 52.

References: 1Armstrong AW, et al. PLoS One 2012;7:e52935. 2Ljosaa TM, et al. ActaDV 2010;90:39–45. 3Thaçi D, et al. BJD 2021;185:323–34. 4Tsianakas A, et al. JEADV 2023;37:85–92. 5Augustin M, et al. BMJ Open 2023;13:e060536. 6Kimball AB, et al. BJD 2016;175:157–62.

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Abstract N°: 5968

Quality of life, work productivity and treatment satisfaction with tildrakizumab in moderate-to-severe psoriasis patients: 52-week interim data of the real-world POSITIVE study

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Introduction & Objectives: Psoriasis is an immune-mediated disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being.1 Tildrakizumab (TIL) is an interleukin-23p19 inhibitor for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.2,3 The objectives of this analysis were to assess the effect of TIL on health-related quality of life (HRQoL) and impairments in work and activities, as well as treatment satisfaction and patient-relevant benefits with TIL in patients with moderate-to-severe psoriasis in routine care.

Materials & Methods: POSITIVE is a 24-month, phase IV observational study in adults with moderate-to-severe plaque psoriasis treated with TIL designed to investigate patient-reported well-being using TIL in a real-world setting.4 The HRQoL instrument was Dermatology Life Quality Index-Relevant (DLQI-R; range 0-30, where a higher score represents a greater impairment in HRQoL; 0-1.99=no effect on patient's life).5 Treatment satisfaction was assessed through the Treatment Satisfaction Questionnaire for Medication (TSQM-9: 3 domains ranging 0-100 with higher scores representing higher satisfaction on that domain).6 The Patient Benefit Index (PBI) evaluates patient-relevant treatment needs (with the Patient Needs Questionnaire [PNQ] at baseline) and benefits (with the Patient Benefit Questionnaire at follow-up visits). The PBI score ranges 0-4 (4=maximal benefit; PBI ≥1=relevant benefit).7 The Work Productivity and Activity Impairment (WPAI) questionnaire gives 4 scores (%): work time missed, impairment while working, overall work impairment, and activity impairment. Here, we report 52-week (W) interim data using an observed cases approach.

Results: 400 patients were included (63.3% male, mean±95%CI age 46.5±1.5 years). Mean±95%CI DLQI-R score decreased from 12.6±0.8 at baseline to 3.3±0.6 at W28 (mean change from baseline: -8.9), and to 3.1±0.6 at W52 (mean change from baseline: -9.2) ($p<0.0001$, both). At W28/W52, 46.5%/47.3% of patients with DLQI-R >1.99 at baseline had a DLQI-R score between 0 and 1.99. At W28/W52, the mean±95%CI scores on TSQM-9 domains were 75.4±2.9/77.4±3.2 for effectiveness, 82.2±2.1/81.5±2.6 for convenience, and 77.3±2.6/81.1±2.6 for global satisfaction. Regarding treatment goals (PNQ), ''to be healed of all skin defects" and ''to regain control of the

disease" were rated as "very much" important by 82.1% and 81.2% of patients at baseline. At W28/W52, 93.6%/97.2% of patients achieved a PBI score ≥1. All WPAI domain scores improved after 28 and 52 weeks (e.g., mean±95%CI percent overall work impairment score decreased from 25.2±3.6 at baseline to 7.0±2.4 at W28 [mean change from baseline: -18.0] and to 7.3±2.5 at W52 [mean change from baseline: -16.8] [p<0.0001, both]).

Conclusion: In a real-world setting, TIL demonstrated improvements in HRQoL and work productivity with high rates of treatment satisfaction in patients with moderate-to-severe plaque psoriasis after 28 weeks, which were maintained through W52. Most desired treatment goals were reached in a high proportion of patients.

References: 1Armstrong AW, et al. PLoS One 2012;7:e52935. 2Thaçi D, et al. BJD 2021;185:323–34. 3Tsianakas A, et al. JEADV 2023;37:85–92. 4Augustin M, et al. BMJ Open 2023;13:e060536. 5Rencz F, et al. BJD 2018; 179:1102–8. 6Bharmal M, et al. HQLO 2009;7:36. 7Augustin M, et al. ADR 2009;301:561–71.

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Abstract N°: 5973

Effectiveness and Nail Assessment in Psoriasis and Psoriatic Arthritis (NAPPA) of tildrakizumab patients with nail psoriasis: 52-week results from the phase IV POSITIVE Austrian subset

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Introduction & Objectives: Psoriasis is a chronic inflammatory disease that profoundly impairs patients' social, emotional, functional, and physical condition, impacting on their overall well-being.1 Nail psoriasis is a difficult-to-treat manifestation of psoriatic disease affecting 40-60% of patients with plaque psoriasis and often causing significant impairments in health-related quality of life (HRQoL).2,3 Tildrakizumab is an interleukin-23p19 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis with demonstrated long-term efficacy and safety.4,5 The objectives of this analysis were to assess the effectiveness and Nail Assessment in Psoriasis and Psoriatic Arthritis (NAPPA) of tildrakizumab patients in Austrian patients with nail psoriasis in routine care.

Materials & Methods: POSITIVE is an ongoing 24-month, phase IV observational multinational study in adult patients with moderate-to-severe plaque psoriasis treated with tildrakizumab designed to investigate patient-reported well-being using tildrakizumab in a real-world setting.6 The NAPPA (Nail Assessment in Psoriasis and Psoriatic Arthritis) was used for the assessment of clinical and patient-reported outcomes in nail psoriasis. Effectiveness assessments in this analysis included Nail Psoriasis Severity Index (NAPSI) score and Nail Physician Global Assessment (nail-PGA). Here, we report 52-week interim data of Austrian patients with nail psoriasis using an observed cases approach.

Results: A total of 42 patients were included (81.0% male, mean [95%CI] age of 48.2 [43.8, 52.6] years, mean body mass index of 29.4 [27.7, 31.1] kg/m2, 47.6% current smokers). Mean (95%CI) time since psoriasis diagnosis was 14.0 (10.0, 18.0) years. Mean (95%CI) NAPSI decreased from 44.4 (34.9, 53.9) at baseline to 21.9 (14.5, 29.3) at W28 ($p<0.001$), with a mean change from baseline of -22.1, and 15.7 (9.5, 21.9) at week 52 ($p<0.001$), with a mean change from baseline of -32.1. Mean (95%CI) NAPPA-QoL global score decreased from 1.5 (1.2, 1.8) at baseline to 0.7 (0.5, 0.9) at week 28 and 0.6 (0.3, 0.9) at week 52. Mean (95%CI) NAPPA-PBI increased from 1.7 (1.1, 2.3) to 3.1 (2.7, 3.5) at week 28 and 3.5 (3.2, 3.8) in week 52. At week 28 and week 52, respectively, 65.9% and 62.9% of patients achieved a nail-PGA score of 0 or 1. At the point of this analysis one patient had a treatment related AE (mild nausea). No patients discontinued due to AEs.

Conclusions: In a real-world setting, tildrakizumab significantly improved nail psoriasis patients' symptoms and quality of life without safety concerns, and this improvement was maintained through week 52. In addition, tildrakizumab showed marked and sustained improvement in a difficult to treat area such as nails.

References: 1Armstrong AW, et al. PLoS One 2012;7:e52935. 2Augustin M, et al. Br J Dermatol 2010;163:580–5; 3Klaassen KMG, et al. Br J Dermatol 2013;169:314–9 4Thaçi D, et al. BJD 2021;185:323–34. 5Tsianakas A, et al. JEADV 2023;37:85–92. 6Augustin M, et al. BMJ Open 2023;13:e060536.

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Abstract N°: 6107

Efficacy and Safety of Tildrakizumab in Patients with Plaque Psoriasis not controlled with Ustekinumab: A Multicenter Retrospective Study

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Introduction & Objectives:

Plaque psoriasis is a chronic inflammatory skin disease with treatment options including tumor necrosis factor-alpha inhibitors, interleukin-17 antagonists, and interleukin-23 inhibitors. This study focuses on assessing the response in patients unresponsive (with suboptimal response o inadequate response) to ustekinumab, an interleukin-12/23 inhibitor, following a switch to tildrakizumab, a selective interleukin-23 inhibitor.

Materials & Methods:

A multicenter retrospective study was conducted involving patients over 18 years with moderate to severe plaque psoriasis who demonstrated inadequate response (o suboptimal) to ustekinumab. Patients were administered tildrakizumab according to standard clinical practice (ficha tecnica o SmPc). Efficacy was assessed using the Psoriasis Area and Severity Index (PASI) and the Physician Global Assessment (PGA), and Dermatology Life Quality Index (DLQI).

Results:

The adverse event rate was consistent with the known safety profile of tildrakizumab, with no new risks identified. The efficacy profile of tildrakizumab was maintained.

Conclusion:

Findings suggest that tildrakizumab may offer an effective and safe option for patients with plaque psoriasis (moderate to severe) unresponsive (suboptimal o inadequate response) to ustekinumab. This study contributes valuable evidence on the intraclass switch of interleukin inhibitors, expanding therapeutic options for this challenging patient population. Tildrakizumab demonstrated efficacy and safety as an alternative in patients with plaque psoriasis (moderate to severe) unresponsive (suboptimal o inadequate response) to ustekinumab. Prospective studies are needed to confirm these findings.

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Abstract N°: 6110

Integrated bioinformatic meta-analysis of differentially expressed genes reveals key roles of autophagy and FOXO pathways in plaque psoriasis

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Introduction & Objectives: Advances in molecular biology technologies have allowed for deeper insights and the identification of key factors in the pathophysiology of psoriasis. Although transcriptome studies have been conducted in groups of patients, few works aggregate data from different series. This work aims to gather and understand the underlying immunological and genetic factors in psoriasis.

Materials & Methods: Following PRISMA guidelines, publicly available data from the Gene Expression Omnibus on gene expression of patients with psoriasis (lesional and non-lesional skin) and healthy controls were collected. A differential expression analysis and a functional enrichment analysis were performed to identify which molecular pathways were altered in psoriasis, based on the KEGG, Gene Ontology, and Reactome databases. Subsequently, the clinical significance of these molecular pathways and their relationship with psoriasis was reviewed

Results:

A total of 1,780 differentially expressed genes between lesional and non-lesional skin were identified. When compared with the literature, a match of 62.86% was found, identifying 661 specific genes in our meta-analysis. Functional enrichment analysis was then performed, and subsequently, 157 (8.8%) genes with significant differential expression in our meta-analysis, not previously reported, and not included in the pathways of the enrichment analysis were selected. Among them, the pathways of gluconeogenesis, FoxO signaling; and in mitophagy and selective autophagy stand out. The identification of pathways related to the regulation of FoxO and mitophagy suggests a negative regulation by the PI3K/AKT signaling pathway. Chronic inflammation, especially exposure to antiTNF, has been linked to a decrease in autophagy, and this, in turn, to aberrant differentiation of keratinocytes and an increase in the production of proinflammatory cytokines. Polymorphisms in the ATG16L1 gene, which participates in autophagy, have been associated with an increased risk of developing plaque psoriasis.

Conclusion: In the skin of patients with plaque psoriasis, compared to healthy skin, a differential expression of genes from the autophagy and mitophagy pathway is observed. These findings could allow for a deeper understanding of the pathogenesis of psoriasis

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Abstract N°: 6213

Association Between Covid-19 Vaccine Platform and Psoriasis Flares Among Adults With Psoriasis: A Retrospective Cohort Study

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Introduction & Objectives:

Psoriasis is a chronic, immune-mediated inflammatory disease where patients are prone to triggers such as stress, medications, and infection. There is currently a growing concern that COVID-19 vaccination has led to flaring and new onset of psoriasis in some patients. There is currently limited data regarding the safety and efficacy of the available COVID-19 vaccine platforms (mRNA, inactivated virus vaccine, and viral vector vaccine) in the market today, especially for patients with chronic inflammatory conditions such as psoriasis.

Materials & Methods:

A retrospective study design was conducted among psoriasis patients at a tertiary hospital. Previously recorded psoriasis patients from the online and face-to-face census from August 2021 to August 2022 were contacted. Eligible adult patients with psoriasis were contacted to obtain their COVID-19 vaccination details such as date of vaccination, doses, and type or brand of vaccine administered. Next, chart review of patients was done to assess if their date of consult following vaccination coincided with the inclusion criteria of 2 weeks to at most 2 months post-vaccination. PASI and BSA of patients pre- and post-vaccination were also obtained from the charts. Total enumeration was done. Out of the 145 respondents, only 68 patients satisfied the selection criteria.

Results:

PASI and BSA scores post-vaccination of those who received Inactive Virus platform were higher in comparison to those who received other types of vaccines. But chi-square test of independence at alpha=0.05 revealed that there is no significant association between vaccine platform and experiencing psoriasis flares ($\chi 2 = 3.849$, $p=0.146$).

Conclusion:

Results show that there is no significant association between COVID-19 vaccine platform used and psoriasis flaring. Thorough epidemiological studies are still required to establish any link between COVID-19 vaccination and psoriasis development or exacerbation. The benefits of COVID-19 vaccination still outweigh the risks to patients with psoriasis, thus patients should be encouraged to have the vaccination regardless of the vaccine platform available.

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Abstract N°: 6214

Sex- and Age-Related Protein Expression Differences in Serum of Patients with Psoriasis

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Introduction & Objectives:

Visible symptoms guide diagnosis and treatment decisions in psoriasis, which may not accurately reflect the underlying systemic disease burden, particularly in female patients. Here we identify proteomic signatures in the serum of pre- and post-menopausal female patients compared to age-matched male patients.

Materials & Methods:

The serum of 11 pre- and 10 post-menopausal female, as well as 24 plus 10 age-matched male patients respectively (n = 55), were analyzed using high-throughput, data-independent (DIA), SWATH Liquid chromatography mass spectrometry (LC-MS/MS). Patient samples were retrieved from the University Hospital of Zürich's Dermatology Biobank. Each patient had severe psoriasis (PASI ≥ 10) and was without psoriatic arthritis. Differential expression analysis was calculated using R Limma (Bioconductor).

Results:

In total, 283 proteins were identified in 86% of all acquisitions. Limma analysis of pre-menopausal female vs. male patients revealed 14 differentially expressed proteins. Most notably alpha 2-macroglobulin (A2M) shown to be involved in the development of atherosclerosis and cartilage oligomeric matrix protein (COMP) associated with arthritis were differentially expressed. When comparing post-menopausal female patients to age matched male patients, 25 proteins were found to be differentially expressed. Among others, sex-specific variations were detected in apolipoprotein C1 (APOC1), serum amyloid A4 (SAA4) and adiponectin (ADIPOQ), each of which have been independently related to atherosclerosis and cardiovascular disease risk (CVD). Further differences were seen in cyclic adenosine monophosphate (cAMP) that has been extensively studied in relation to PDE-4 inhibitors and modulating inflammation, as well as superoxide dismutase (SOD3), cystatin C (CST3), osteopontin (SPP2) and fetuin B (FETUB) implicated in inflammatory processes, particularly arthritis. Taken together, these results further strengthen our recent findings using a highly specific 500-reference protein panel in a similar cohort of patients. There we also revealed differential expression of proteins involved in inflammation and CVD risk, notably also in the apolipoprotein pathway discovered here.

Conclusion:

These results highlight significant sex- and age-related differences in protein expression among patients with psoriasis and potential implications for differences in cardiovascular disease risk between these groups. This stresses the importance of considering sex and age, particularly in relation to hormonal life-cycles such as menopausal status, in assessing the risk and severity of systemic diseases in patients with psoriasis. Taken

together, our results support a more nuanced clinical approach and further research into integrating systemic disease marker analysis to tailor intervention strategies, ultimately addressing the distinct needs of female and male patients with psoriasis.

Table 1. Baseline Patient Characteristics

	Female ("Pre")	**Female** ("Post")	**Male** ("Pre-Matched")	**Male** ("Post-Matched")
n (total = 55)	11	10	24	10
Age mean±SD	30.4 ±7.5	64.4 ±8.6	34.6 ±5.2	57.0 ±5.5
Age min. – max.	20 - 42	52 - 78	26 - 41	51 - 66
PASI mean±SD	15.1 ±4.9	10.9 ±2.7	14.4 ±4.6	12.0 ±1.7

"Pre": pre-menopause; "Post": post-menopause; "Pre-/Post-Matched": age matched male cohort; PASI: Psoriasis Area Severity Index

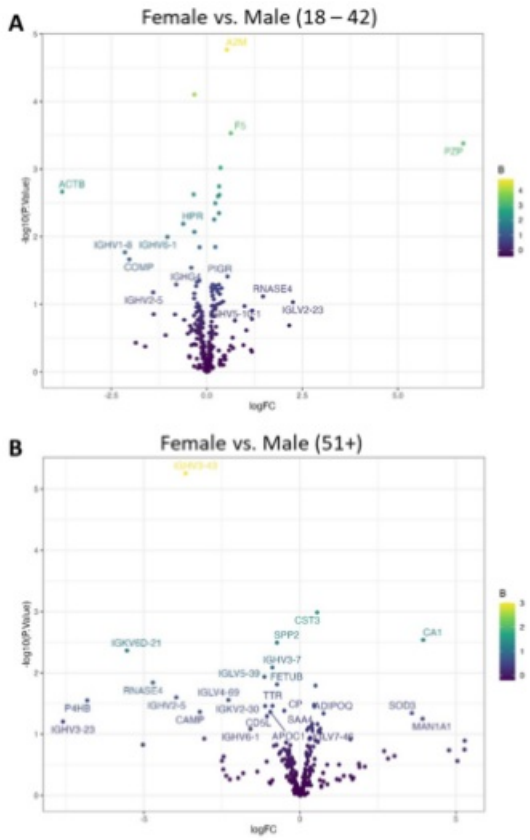

*Figure 1. Differential expression of serum proteins between **A**) 18 – 42 year old and **B**) 51 year and older female and male patients with severe psoriasis (PASI≥10) respectively. Volcano plots processed using R Limma (Bioconductor version: Release 3.18) show –log10 transformed P-value cut-off of 1 on the y-axis and log FoldChange (FC) cutoff of ±0.5 on the x-axis. Protein names indicate significantly differentiated candidates (B-statistic > 0.3).*

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Abstract N°: 6227

Prevalence and factors associated with the use of dermocosmetics inpatients with psoriasis: a worldwide study : The results of ALL project

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Introduction & Objectives:

Dermocosmetics (DC) are products formulated to enhance the softness and suppleness of the stratum corneum by boosting its hydration levels. In the treatment of psoriasis, DC play a crucial role as adjuncts to traditional therapies, aiding in the reduction of scale buildup in affected individuals. This study aimed to examine the prevalence of DC utilization among dermatology patients and explore the prevalence of conventional treatments, such as topical and systemic medications, among DC users.

Materials & Methods:

This online survey was conducted among a representative sample of the population aged 16 years or older from 20 countries. The questionnaire focused on patient experience. It collected information on demographics, any dermatological conditions in the past 12 months, type of physician and therapeutic management. The primary analysis of this study was the prevalence of use of one or more dermocosmétiques disponible en pharmacie sans ordonnance alone or in combination with standard psoriasis therapies in the 12 months prior to the survey. The secondary analysis was a comparison of emollient and non-emollient users to evaluate predictors: socio-demographic, clinical parameters and treatments used to treat psoriasis. Descriptive analyses were performed using absolute and percentage frequencies. The significance test was two-tailed and set at 5% ($p \leq 0.05$). Student's t-test and Pearson's chi-squared were used to compare subjects who reported using DC with those who did not

Results:

A population of 991 psoriasis patients was selected, including 541 (54.5%) males and 451 (45.5%) females (mean age 47.8 +/- 15.5). min 16-85 years. Among the responders, 172 (17.4%) use DC as part of the therapeutic management of psoriasis. 79 (8%) DC users use a DC only for the treatment of psoriasis. 91 (52.9%) were prescribed a DC by their doctor, 35 (20.3%) on the sole advice of a pharmacist and 3 (1.7%) on the advice of a nurse. 43 (25%) chose their own DC without consulting a health professional. 25 (14.5%) use a systemic treatment in combination with a CD, including 5 (2.9%) injectable treatments for psoriasis. 68 (39.5%) use a CD in combination with local dermocorticoid treatment. 56.4% use a CD daily, 31.4% twice a day (morning and evening) and 12.2% three or more times a day. 92 (53.5%) stated that the cost of dermocosmetics prevented them from using them more frequently.43 25% also used hygiene products and skincare products adapted to psoriasis, 36.6% only skincare products and 11% only hygiene products. Age (49.1 vs 47.9 years, p NS), male gender (47.1% vs 56.2%, pNS) and occupation were not predictive of DC use. Of the 819 respondents who did not use DC, 42.9% reported that the cost of DC had prevented them from using it.

Conclusion:

This study represents the first inaugural investigation into the frequency of forest therapy (FT) usage among

individuals with dermatological issues. However, further mechanistic research is warranted to delve into the reasons behind individuals' adoption of FT and its effects on the well-being and quality of life of those with skin conditions.

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Abstract N°: 6239

Real-world durability of effectiveness through 24 months of anti-interleukin (IL)-17A biologics and other approved biologics in treating patients with moderate-to-severe psoriasis in the Psoriasis Study of Health Outcomes (PSoHO)

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Introduction & Objectives:

Patients with psoriasis (PsO) report that a quick and enduring response are key treatment goals [1]. As such, more studies are needed to evaluate the treatment response of different biologics over long observation periods. To address this research gap, this analysis uses three different outcomes to evaluate the durability of treatment effectiveness of different biologics for patients with moderate-to-severe PsO from week 12 through 2 years in a real-world setting.

Materials & Methods:

The Psoriasis Study of Health Outcomes (PSoHO) is an ongoing, 3-year, international, prospective, non-interventional cohort study comparing the effectiveness of the anti-interleukin (IL)-17A cohort of ixekizumab (IXE) and secukinumab (SEC) to other approved biologics in patients with moderate-to-severe PsO initiating or switching to a new approved biologic [2,3]. The other biologics cohort includes adalimumab (ADA), brodalumab (BROD), certolizumab, etanercept, guselkumab (GUS), infliximab, risankizumab (RIS), tildrakizumab (TILD), and ustekinumab (UST).

The first durability of effectiveness outcome was defined as the proportion of patients who achieved the primary endpoint of PASI90 and/or an sPGA score of 0 or 1 at week 12, and who maintained a PASI75 score and/or an improvement of 2 points or more in sPGA from baseline at months (M)6, M12 and M24. Two further analyses evaluated the proportion of patients who achieved PASI100 or PASI90 at week 12 and maintained this result at M6, M12 and M24. This study shows descriptive data using non-responder imputation (NRI) for the two cohorts, as well as for individual treatments with over 50 patients at baseline. Regardless of treatment changes, patient data correspond to the assigned treatment at baseline. Unadjusted response rates are reported as proportions for each outcome and include 95% confidence intervals (CIs). Cohort comparisons used p-values from Fisher's Exact tests.

Results:

Of the 1981 patients, 39.0% of patients were in the anti-IL-17A cohort and 61.0% received other biologics at baseline. Figure 1a shows that a significantly higher proportion of patients in the anti-IL-17A cohort achieved each

of the three outcomes measuring durability of effectiveness (p≤0.001). For the individual treatments, figure 1b shows that 47.9% of IXE-treated patients, 46.3% of RIS-treated patients and 41.9% of SEC-treated patients achieved the first durability of effectiveness outcome. In figure 1c, over 14% of patients treated with BROD, RIS or IXE achieved a PASI100 response at week 12 and maintained complete skin clearance through month 24. Similarly in figure 1d, over 30% of patients treated with these biologics achieved the PASI90 durability response. As a non-interventional study, the number of patients varied across treatment groups and the small sample size of some biologics led to broader CIs.

Conclusion:

Evaluating PSoHO data at week 12 and months 6, 12, and 24, this analysis showed that the durability of treatment effectiveness in patients with moderate-to-severe PsO was significantly higher with anti-IL-17A biologics than other biologics in a real-world setting. Overall, this study highlights the importance of considering the durability of responses to treatments for patients with moderate-to-severe PsO.

References:

\1. Blome et al. Arch Dermatol Res. 2016; 308(2): 69–78.

\2. Pinter et al. JEADV. 2022; 36(11), 2087-2100.

\3. Pinter et al. Derm Ther. 2023; 1-15.

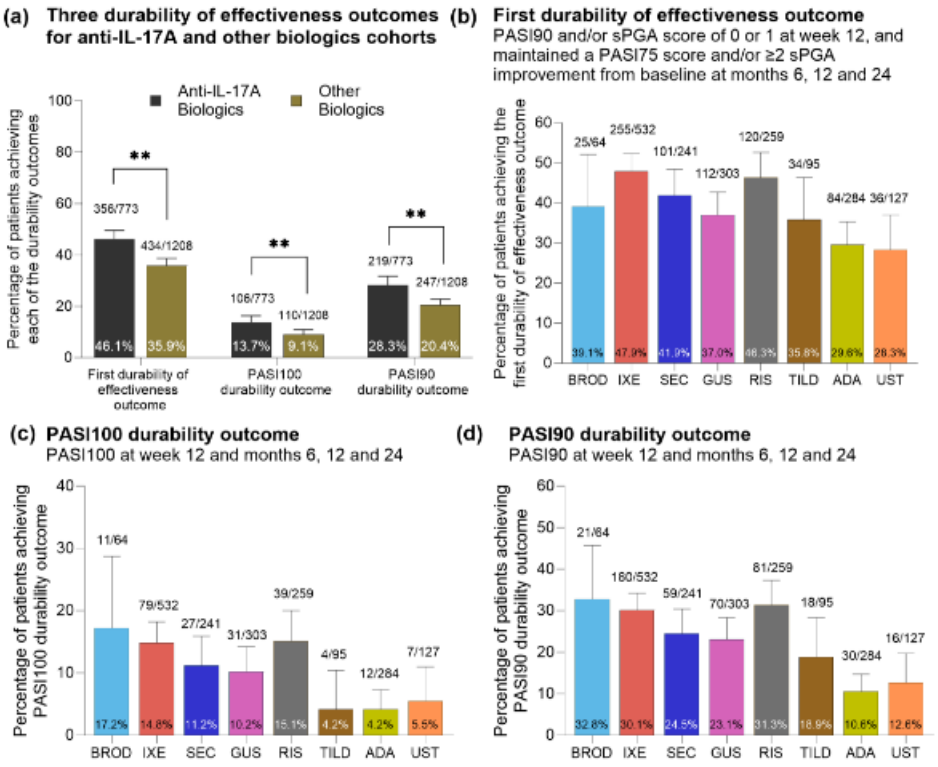

Figure 1: The proportion of patients who achieved the (a) three outcomes of durability of effectiveness in the anti-IL-17A and Other Biologics cohorts, (b) durability of effectiveness outcome in the individual treatment groups, (c) PASI100 at week 12 and subsequently at months 6, 12 and 24 in the individual treatment groups and (d) PASI90 at week 12 and subsequently at months 6, 12 and 24 in the individual treatment groups. The first durability of effectiveness outcome was defined as the proportion of patients who achieved PASI90 and/or an sPGA score of 0 or 1 at week 12 and maintained a PASI75 score and/or an improvement of 2 points or more in sPGA from baseline at M6, M12 and M24. The PASI100 durability outcome is defined as the proportion of patients who achieved PASI100 at week 12 and then maintained PASI100 at months 6, 12 and 24. The PASI90 durability outcome is defined as the proportion of patients who achieved PASI90 at week 12 and then maintained PASI90 at months 6, 12 and 24. Data only shown for treatments with at least 50 patients. Regardless of treatment changes, patient data correspond to the assigned treatment at baseline. Cohort comparisons used p-values from Fisher's Exact tests. ** denotes p≤0.001. Bar graphs show unadjusted upper 95% confidence intervals. Confidence intervals were constructed using the Normal approximation. Abbreviations: ADA adalimumab; BROD, brodalumab; GUS, guselkumab; IL, interleukin; IXE, ixekizumab; RIS, risankizumab; SEC, secukinumab; TILD, tildrakizumab; UST, ustekinumab.

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Abstract N°: 6293

Secukinumab retention and effectiveness in patients with moderate to severe plaque psoriasis: Five-year results from the SERENA study

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Introduction & Objectives:

Secukinumab has shown sustained efficacy across multiple clinical trials across various domains of psoriatic disease.1–7 Real-world evidence studies provide additional valuable data on the long-term retention of secukinumab in routine clinical practice. SERENA was a large, longitudinal, observational study conducted at 438 sites across Europe for up to 5 years in adult patients with moderate to severe plaque-type psoriasis (PsO), psoriatic arthritis, and ankylosing spondylitis. Here, we report final 5-year results of secukinumab treatment retention and efficacy in patients with PsO.

Materials & Methods:

The SERENA study design has been reported previously.8 Patients received ≥16 weeks of secukinumab treatment before enrolment in the study. Data were collected both retrospectively and prospectively. Secukinumab retention rate was defined as the percentage of patients who had been treated with secukinumab for years 1, 2, 3, 4 and 5. Patients in the current analysis were enrolled in the study between October 2016 and August 2018.

Results:

Overall, 1740 patients with moderate to severe PsO were included in the analysis. The mean age at inclusion was 48.3 years; 67.5% were male, mean body mass index was 28.8 kg/m2, and 94.2% were Caucasian. Mean (SD) time since diagnosis of PsO was 17.3 (13.2) years. The mean (SD) time since first secukinumab treatment to study inclusion was 1.1 (0.7) years. Overall, 59.6% of patients had documented PsO treatment, including 34.8% of patients who had taken biologic treatment prior to secukinumab. The secukinumab treatment retention rates after 1, 2, 3, 4 and 5 years in the study were 88.3%, 75.5%, 66.9%, 60.4% and 55.0%, respectively **(Figure 1).** Overall, 913 (52.5%) of patients did not complete the study; the most common reasons for discontinuation included lack of efficacy (25.4%), patient decision (7.6%), physician decision (5.5%), lost to follow-up (4.8%) and adverse event (4.7%). The proportion of patients achieving a PASI 90 response was 58.6% at year 1 and 59.5% at year 5; the proportion of patients with a PASI 100 response was 32.7% at year 1 and 20.4% at year 5 **(Table 1).**

Conclusion:

Secukinumab retention rates were high with sustained effectiveness in patients with moderate to severe PsO during 5-year follow-up in a real-world setting.

1. Thaci D, et al. *J Am Acad Dermatol.* 2015;73:400-409.
2. Langley RG, et al. *N Engl J Med.* 2014;371:326-338.
3. Bissonnette R, et al. *J Eur Acad Dermatol Venereol.* 2018 Sep;32(9):1507-1514.
4. Bagel J, et al. *J Am Acad Dermatol.* 2017;77(4):667-674.
5. Reich K, et al. *PGC* 2017;Poster 021.
6. Gottlieb AB, et al. *Br J Dermatol.* 2020;182(4):889-899.
7. McInnes IB, et al. *Rheumatol* 2017;56:1993-2003.
8. Kiltz U, et al. *Adv Ther.* 2020;37(6):2865-2883.

Figure 1. Retention rate of secukinumab from year 1 through year 5

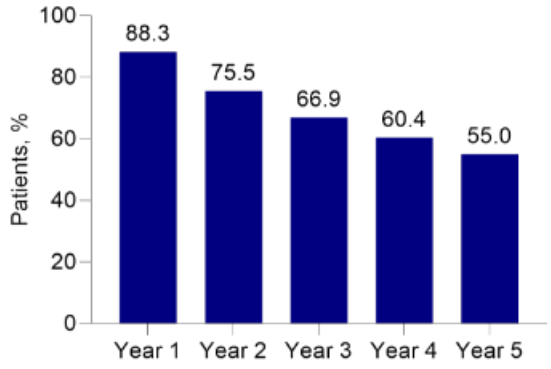

Table 1. Proportion of patients* achieving PASI 90 and PASI 100 after Initiation of secukinumab in patients with a PASI assessment at treatment start (N=1509)

	Year				
	Year 1	Year 2	Year 3	Year 4	Year ≥5
PASI 90 response, n %	884 (58.6)	867 (57.5)	847 (56.1)	942 (62.4)	898 (59.5)
PASI 100 response, n %	493 (32.7)	459 (30.4)	383 (25.4)	345 (22.9)	308 (20.4)

*59.6% of patients had documented PsO treatment (34.8% with Biologic) prior to secukinumab.
Note: Analysis employed imputation, which was conducted using a regression model with age, sex, country, PASI score and presence of PsA as covariates, assessed at the start of secukinumab.
PASI, Psoriasis Area Severity Index; PsA, psoriatic arthritis; PsO, plaque-type psoriasis.

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Abstract N°: 6308

Clinical Characteristics and Treatment Patterns of Psoriasis in Asia and Switzerland: results of the multicentre Global Healthcare Study on Psoriasis (GHSP)

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Introduction & Objectives:

Psoriasis is a chronic inflammatory dermatosis for which multiple treatment options exist from topical medications, phototherapy, non-biologic systemic therapies, to biologic drugs. Insight into regional differences in clinical characteristics and treatment patterns between countries in Asia and Switzerland are important to help improve global equity and access to treatment.

Materials & Methods:

A multicentre, longitudinal observational study collecting cross-sectional data as part of the Global Healthcare Study on Psoriasis (GHSP) in Asia and Switzerland was performed from January 2020 to 31 March 2024. A 48-item questionnaire was utilized to study clinical characteristics, comorbidities, severity, impact on quality of life, and both current and previous treatment patterns.

Results:

In total, 1415 psoriasis patients across Singapore (136), China (239), Thailand (163), Philippines (86), and Switzerland (791) were included with mean Psoriasis Area and Severity Index (PASI) score of 4.9, 9.8, 6.2, 10.6, and 5.7, respectively, and mean Dermatology Life Quality Index (DLQI) score of 4.7, 9.6, 8.8, 9.3, and 8.5 respectively. Of these patients, plaque psoriasis was the most common phenotype (90.5%) followed by guttate (7.8%), pustular (7.6%), and inverse psoriasis (7.1%). Topical therapy formed the backbone of treatment in Asia (79.8%) and Switzerland (96.7%). Majority of patients in Switzerland (59.0%) and Singapore (65.4%) received phototherapy in contrast with China (27.6%), Thailand (49.1%), and Philippines (40.7%) where less than half did with personal preference, lack of affordability and availability limiting greater uptake. Methotrexate was the most prescribed oral systemic agent in all countries except China where retinoids were the preferred agent. Biologic treatment uptake was higher in Switzerland (59.5%, p-value <0.001), where cost is reimbursed if criteria for severity are met, and in Singapore (31.6%) in contrast with China (23.0%), Philippines (5.8%), and Thailand (18.4%) where affordability, availability, and personal preference were cited as barriers. Singapore and Switzerland shared similarly high biologic, oral systemic drug, and phototherapy prescribing practices in part due to financial coverage. Greater diversity of biologic drug types was also seen in Switzerland compared to Asia where interleukin-17A inhibitors were the main biologic class used. Biosimilar drug uptake was notably low at 3.0%.

Conclusion:

Our results highlighted a stark difference in biologic treatment uptake between Switzerland and Asian countries, excluding Singapore, in part due to financial coverage. Strategies to improve availability and affordability of these drugs are necessary with a possible role for encouraging access to less costly biosimilar drugs, and medical assistance funding. Future longitudinal studies are needed in Asia with serial severity and quality of life scores which can map these regional differences in treatment patterns and its impact on psoriasis severity and quality of life.

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Abstract N°: 6322

Psoriatic lesions in human skin xenotransplants in vivo are triggered by perceived stress and can be suppressed by the neurokinin-1 receptor antagonist aprepitant

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Introduction & Objectives:

There is as yet insufficient scientific evidence for the widely held belief that psychoemotional (perceived) stress can trigger or exacerbate the development of psoriatic skin lesions. Here, we have probed the validity of this concept in the humanized psoriasis mouse model *in vivo*.

Materials & Methods:

Psoriatic lesions were induced in healthy human skin xenografts on SCID/beige mice (n=25) by intradermal injection of autologous, in vitro IL-2-preactivated PBMCs one month after grafting. Five days after psoriasis lesion had developed, the xenografts were treated with topical dexamethasone (DEX) to induce lesion remission. 3 days after psoriasis lesions had disappeared, the mice were exposed to either sound (sonic) or sham stress for 24h, which induces neurogenic skin inflammation. 14 days later, the xenografts were harvested and a battery of inflammatory and neurobiological markers was assessed by quantitative (immuno)histomorphometry.

Results:

Sonic stress induced relapse of psoriatic lesion in all of the human skin xenografts within 14 days. This corresponded to significant changes in psoriasis-associated skin phenomena after sound stress exposure: increased epidermal thickness, K16 expression, keratinocyte proliferation, anti-microbial peptide expression(S100A7, hβ2-defensin), immune activation of intraepidermal cells (increased HLA-DR, ICAM-1, CD1d, MICA-NKG2D expression).Sonic stress also significantly increased epidermal and/or dermal immune cell numbers (CD3+, CD8+, CD11c+, CD56+, ILC3, c-KIT+ or tryptase+ cells) as well as the expression of psoriasis-associated pro-inflammatory mediators (CXCL10, IL-22, IL-15, IL-17A/F, IFN-γ and TNFα). Lastly, biomarkers of neurogenic skin inflammation (NGF, NK1-R and substance P) were also significantly upregulated in the xenografts on mice exposed to perceived stress. Treatment with the FDA-approved, anti-emetic neurokinin-1 receptor antagonist, aprepitant, prevented the stress-induced relapse of psoriatic lesions in 4 out of 5 mice and normalized most of the read-outs described above.

Conclusion:

Our data provide the first conclusive evidence that perceived stress can indeed trigger psoriatic lesions in human skin in vivo, and point to a keyrole of substance P-dependent neurogenic inflammation in this process. Aprepitant and other NK-1R antagonists may help to limit stress-induced psoriasis relapses/exacerbations.

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Abstract N°: 6325

Effectiveness of Biologics in Clinical Practice: Month 12 Absolute PASI Outcomes from an International Observational Psoriasis Study of Health Outcomes (PSoHO).

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Introduction & Objectives:

Absolute Psoriasis Area and Severity Index (PASI) may be an alternative to relative PASI for treatment comparisons because it reflects both clinically meaningful improvements in disease activity and informs treatment decisions based on actual disease severity, regardless of baseline score**1,2**. The Psoriasis Study of Health Outcomes (PSoHO) is a 3-year, international, prospective, non-interventional study comparing the effectiveness of anti-IL-17A biologics [ixekizumab (IXE) and secukinumab (SEC)] to other approved biologics in patients with moderate-to-severe psoriasis (PsO) undergoing routine medical care. While relative PASI effectiveness has been reported at 12 months, absolute PASI responses have not yet been shown**3**. This analysis aims to report the effectiveness measured by absolute PASI through 12 months.

Materials & Methods:

PSoHO included patients with moderate-to-severe plaque PsO, initiating or switching to a new approved biologic treatment (including biosimilars). This analysis reports the percentage of patients receiving EMA-approved on-label dosing (n=1678), who achieved absolute PASI scores ≤1, ≤2 and ≤3 at months 6 and 12. Unadjusted response rates for absolute PASI scores are reported as percentages for each outcome and time-point. Non-responder imputation (NRI) was used for missing outcomes and reported here.

Results:

At month 6, higher response rates for absolute PASI ≤1, ≤2 and ≤3 were achieved by 62.2%, 72.1% and 77.8% of patients in the anti-IL-17A cohort compared to 47.4%, 61.3% and 69.7% of patients in the other biologics cohort respectively (Fig 1). At month 12, higher response rates for absolute PASI ≤1, ≤2 and ≤3 were achieved by 56.5%, 66.2% and 71.2% of patients in the anti-IL-17A cohort compared to 50.3%, 62.6% and 69.0% in the other biologics cohort respectively (Fig 2). At month 6, across individual treatments, IXE provided the highest response rates in absolute PASI ≤1, ≤2 and ≤3 with 65.2%, 74.0% and 79.2% respectively (Fig 1). At month 12, IXE showed the highest response rates in absolute PASI ≤1 with 59.6%, followed by risankizumab, guselkumab, tildrakizumab, secukinumab, brodalumab, adalimumab, and ustekinumab with 57.5%, 51.5%, 51.2%, 50.0%, 46.7%, 44.8%, and 42.4% respectively (Fig 2).

Conclusion:

This analysis indicates that the anti-IL-17A cohort of the EMA approved on-label population had a higher response rate in absolute PASI through month 12, in a real-world setting. Across individual drug treatments, IXE

indicated the highest percentage of patients achieving key endpoints at both 6 and 12 months.

References:

1. Puig et al. Acta Derm Venereol. 2019; 99:971-977.
2. Gerdes et al. J Dermatol Treat. 2020; 31:470-475.
3. Pinter et al. Dermatol Ther. 2023.

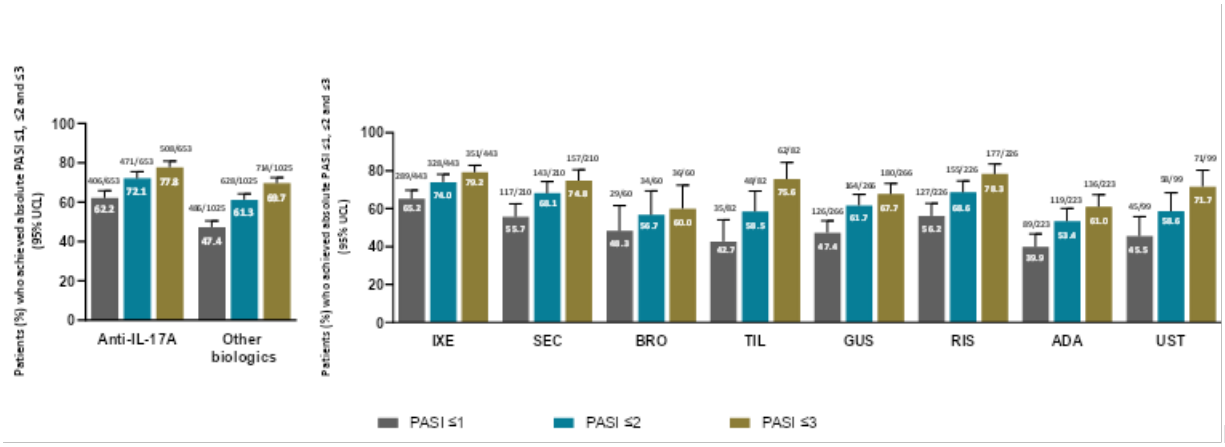

Fig 1: Percentage of patients receiving EMA-approved on-label dosing who achieved absolute PASI ≤1, ≤2, and ≤3 at Month 6 for anti-IL-17A vs other biologics cohort, and IXE vs. individual drug treatments (95% UCL).

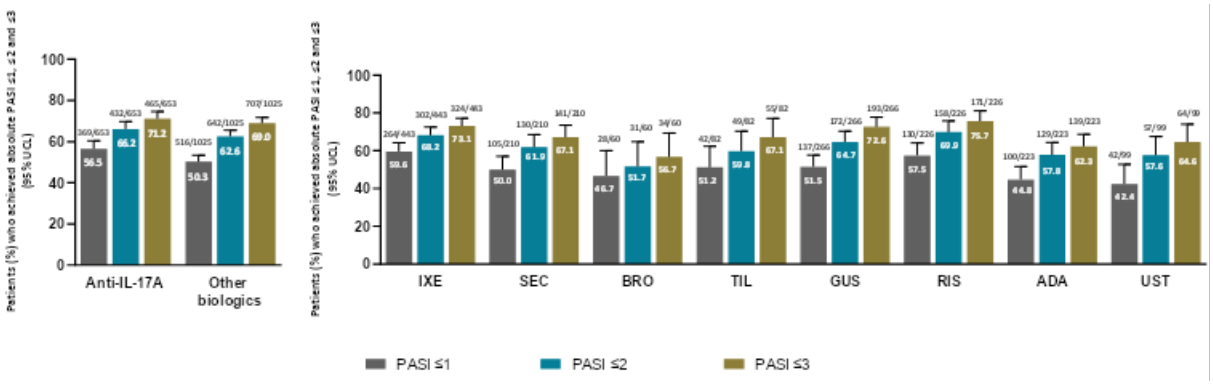

Fig 2: Percentage of patients receiving EMA-approved on-label dosing who achieved absolute PASI ≤1, ≤2, and ≤3 at Month 12 for anti-IL-17A vs other biologics cohort, and IXE vs. individual drug treatments (95% UCL).

Abbreviations: European Medicines Agency (EMA), Upper confidence limit (UCL), Psoriasis Area and Severity Index (PASI), anti-interleukin-17A (anti IL-17A), ixekizumab (IXE), secukinumab (SEC), brodalumab (BRO), tildrakizumab (TIL), guselkumab (GUS), risankizumab (RIS), adalimumab (ADA), and ustekinumab (UST).

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Abstract N°: 6331

Psoriasis and health related quality of life: Towards a patient oriented approach

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Introduction & Objectives

Psoriasis is a chronic inflammatory disease with significant psychosocial implications. The persistent itching, pain, and discomfort associated with the condition can negatively affect health related quality of life (HRQL) and contribute to the onset of depression, anxiety, or stress related symptoms and vice versa. Understanding the psychosocial impact of the disease and how clinical severity or disease management associated to HRQL is essential for guiding treatment decisions and improving patient outcomes. This study aims to investigate the relationship between dermatological variables, the potential mediating role of depression, anxiety, and stress symptoms, and HRQL affection, among patients with psoriasis.

Materials & Methods

A prospective observational study of adult patients with psoriasis from a Dermatology referral center in Chile's public health sector. Patients underwent evaluation during routine psoriasis follow-ups, with data recorded on demographic factors, PASI score, years since diagnosis, and use of systemic treatment and/or phototherapy. For the psychosocial burden of the disease the DQLI and the DASS-21 were assessed. Patients with a history of any psychiatric comorbidities were excluded. Descriptive analysis of variables was conducted, and Spearman's correlation matrix examined significant correlations between clinical and psychological variables. Additionally, a multinomial regression model was employed to explore associations between HRQL impact and clinical/psychological dimensions. Patients were categorized based on the DLQI scores into none to very severe levels of HRQL affection, and predictive variables were evaluated for their role in differentiating the unaffected and affected populations across severity levels.

Results

A total of 55 patients were included in the analysis. Demographics and clinical characteristics are presented in **Table 1.** Significant associations between PASI and DLQI scores ($r=0.356$, $p < .01$), and DLQI scores and all dimensions of the DASS-21 questionnaire (Depression [$r=0.310$, $p < .05$]; Anxiety [$r=0.502$, $p < .001$]; Stress [$r=0.433$, $p < .01$]) were evidenced **(Table 2).** The multinomial regression model for HRQL affection demonstrated a good fit ($\chi^2 = 94.0$, $p < 0.001$), with a McFadden adjusted coefficient of determination of 0.451. Significant predictive variables for HRQL affection are summarized in **Table 3.**

Conclusion

In adult patients with psoriasis in Chile, PASI score, depressive, anxiety, and stress symptoms are directly associated with HRQL impairment. However, age and systemic treatment do not show significant correlations with HRQL affection.

From a clinical standpoint, PASI score correlates with moderate to very severe HRQL impairment, gaining significance as HRQL affection worsens. Years since diagnosis predict moderate to severe HRQL impairment but

lack significance in mild and very severe subgroups. Phototherapy is significant in severely affected individuals only, suggesting a potential benefit for those with very severe HRQL impairment if phototherapy is initiated.

In the psychological dimension, depressive and stress symptoms predict mild to moderate HRQL impairment, while depressive and anxiety symptoms drive the predictive dimension in severely affected individuals. In the very severely affected subgroup, only anxiety symptoms show a predivtive dimension on HRQL impairment, while depressive and stress symptoms lose significance.

Table 1: Demographic and clinical characteristic of patients

Sex	
Male	30 (54.5%)
Female	25 (45.5%)
Average Age	55.5 ± 13.8 Years [Range 23-83]
Average years since diagnosis	16.1 ± 12.9 years [Range 1-50]
Systemic Treatment	
Yes	26
No	29
Phototherapy	
Yes	13
No	42
Average PASI score	6.3 ± 6.4 [Range 0-25]
Average DLQI score	9.3 ± 7.9 [Range 0-26]
Average DASS-21 score	
Depressive symptoms	7.7 ± 7.0 [Range 0-21]
Anxiety symptoms	6.9 ± 5.8 [Range 0-19]
Stress symptoms	9.2 ± 6.2 [Range 0-21]

Table 2: Matrix correlation for clinical and psychosocial variables

	PASI	DLQI	Depression	Anxiety	Stress	Years since diagnosis	Systemic treatment	Phototherapy
PASI	-							
DLQI	0.356 **	-						
Depression	0.130	0.310 *	-					
Anxiety	0.099	0.502 ***	0.803 ***	-				
Stress	0.126	0.433 **	0.848 ***	0.868 ***	-			
Years since diagnosis	0.206	0.023	-0.015	0.067	0.121	-		
Systemic treatment	0.203	-0.060	-0.041	-0.058	-0.031	0.294 *	-	
Phototherapy	0.053	-0.183	-0.073	-0.119	-0.063	0.263	0.245	-

Note. * $p < .05$, ** $p < .01$, *** $p < .001$

Table 3: Multinomial regression model for the predictive dimension of clinical and psychological variables in the affection of the quality of life in patients with psoriasis

DLQI Classification according to HRQL affection	Predictive Variable	p Value
Low	Age	0.959
	PASI	**0.116**
	Depression	**0.024***
	Anxiety	0.957
	Stress	**0.053***
	Years since diagnosis	0.762
	Systemic treatment	0.305
	Phototherapy	0.190
Mild	Age	0.070
	PASI	**0.010***
	Depression	**0.003***
	Anxiety	0.143
	Stress	**0.042***
	Years since diagnosis	**0.009***
	Systemic treatment	0.756
	Phototherapy	0.721
Severe	Age	0.178
	PASI	**0.005***
	Depression	**0.006***
	Anxiety	**0.033***
	Stress	0.097
	Years since diagnosis	**0.031***
	Systemic treatment	0.292
	Phototherapy	0.968
Very Severe	Age	0.152
	PASI	**0.003***
	Depression	0.181
	Anxiety	**0.046***
	Stress	0.505
	Years since diagnosis	0.594
	Systemic treatment	0.366
	Phototherapy	**<0.001***

*Significant variables with a predictive dimension in the differences between the population that report no affection in the HRQL and the specific affected subgroup

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Abstract N°: 6337

Safety of psoriasis biologic therapies in multiple sclerosis: treatment strategies

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Introduction & Objectives:

Psoriasis and multiple sclerosis (MS) are medical conditions affecting millions of people worldwide. While psoriasis is an inflammatory skin disease, MS is characterized by central nervous system demyelination due to aberrant autoimmune response.

This study aims to investigate the safety profile of psoriasis biological treatments in individuals with MS. By evaluating the outcomes and adverse events, we aim to contribute to the understanding of optimal therapeutic approaches.

Materials & Methods:

We conducted a retrospective analysis by extracting patient cases of psoriasis and MS from the digital records of our clinic. A comprehensive review of published cases was performed to augment our dataset. Relevant literature was identified through electronic databases such as PubMed, Embase, and Google Scholar. Keywords including “psoriasis,” “multiple sclerosis,” and their variants were utilized to retrieve pertinent articles. Data extraction from both clinic records and published literature encompassed demographic information, clinical manifestations, disease severity, treatment modalities, and outcomes.

Results:

Our study cohort comprised 4 individuals, 3 females and 1 male, with ages ranging from 53 to 57 years. Two patients were undergoing treatment with anti-IL-17agents, Secukinumab and Ixekizumab, with one of them additionally receiving dimethyl fumarate. Another patient was treated with Risankizumab, while the fourth patient with Ustekinumab. The mean duration of treatment with biological agents was 36 months. Remarkably, all four patients exhibited no clinical progression of neurological disease during treatment. Notably, none of the patients reported any adverse events associated with the administration of biologic therapies.

Our literature review yielded 10 cases of concurrent psoriasis and MS, 6 treated with Secukinumab, 2 with Ustekinumab, and one with Ixekizumab. Among patients treated with Secukinumab, 3 were receiving combination therapy with dimethyl fumarate, fingolimod, and natalizumab, respectively.

In all cases, patients experienced stability in their demyelinating disease without any new episodes.

Psoriasis and MS share, at least partially, similar immunopathogenic mechanisms, particularly the overexpression of the Th17 pathway. Th17 cells demonstrate a greater propensity to traverse the choroid plexus in MS compared to other CD4+ subsets. In psoriasis, neutrophil extracellular traps play a role in enhancing Th17 induction. Recently, Li et al. conducted a meta-analysis revealing an elevation in the proportion of peripheral blood Th17 cells, as well as increased levels of IL-17 and IL-23, in MS patients compared to healthy controls. This fact, together with the increased risk of incident psoriasis in patients with MS or the existence of drugs approved for both diseases, such as fumarate, suggests that there is a degree of overlap in the immunopathogenic mechanisms of both these diseases. Contrarily, a recent review highlighted two cases of patients treated with anti-IL-17 agents who experienced a case of myelitis and worsening of multiple sclerosis. This underline the importance of carefully

monitoring patients receiving such treatments.

Conclusion:

In conclusion, our study contributes to the expanding body of research exploring the relationship between psoriasis and MS, suggesting a positive outcome with the use of anti-interleukin 17/23 agents.

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Abstract N°: 6345

Psoriasis Scores of Difficult-to-Treat Areas Deserve a Better Place in the Decision to Initiate a Systemic Treatment: Proposal of an Algorithm.

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Introduction & Objectives:

Moderate-to-severe plaque psoriasis is well controlled today by targeted therapies that are indicated according to scores as Psoriasis Area and Severity Index (PASI), Physician's Global Assessment (PGA), Investigator Global Assessment (IGA), Body Surface Area (BSA), and Dermatology Life Quality Index (DLQI). These scores provide sometimes low values that are less objective in quantifying the disease's severity. The scores of difficult-to-treat areas are not often used in the daily practice and are not included in the criteria for the decision to initiate a systemic therapy.

The aim of our lecture is to suggest possible solutions for the optimal integration of the scores for difficult-to-treat areas assessment in current decisional algorithm for systemic therapies indication in moderate-to-severe plaques psoriasis.

Materials & Methods:

The scores of psoriasis difficult-to-treat areas that negatively affect the patient's social life are: a. Psoriasis Scalp Severity Index (PSSI) measuring the extent of psoriasis skin involvement and the severity of the erythema, infiltration, and desquamation of the scalp [1]. b. Nail Psoriasis Severity Index (NAPSI) assess the severity of nail bed and matrix psoriasis by the area of involvement of the nail unit, identifying the pitting, leukonychia, red spots, crumbling onycholysis, splinter hemorrhages, subungual hyperkeratosis, "oil drop" (score 0 to 160 fr all nails) [1]. c. Erythema, Scaling, Induration, and Fissuring (ESIF) assess palms and soles psoriasis and is calculated by adding the scores for the 4 signs for the soles of the feet (0 to 24 [2]. We made a comprehensive analysis of databases PubMed, Google Scholar and Web of Science, using several keywords for "psoriasis scores", focusing on treatment goals definitions for patients with moderate-to-severe psoriasis and on definitions of treatment response and/or failure and treatment modifications for patients with moderate to severe psoriasis [3].

Results:

European guidelines of systemic therapy for plaque psoriasis as also different European countries guidelines all are focusing on PASI and / or PGA and/or IGA and/or DLQI precise scores as main criteria for the decision of the initiation of a systemic therapy for moderate-to-severe plaque psoriasis. The scores PSSI, NAPSI and ESIF are not part of main decision criteria for the initiation of a systemic treatment. We propose an algorithm with the systematic inclusion of scores of difficult-to-treat-areas in the assessment of plaques psoriasis severity and indication of initiation of a systemic treatment: associating PSSI and/or NAPSI and/or ESIF with the PASI score even in situations when PASI / BSA / PGA / IGA / DLQI have low values.

Conclusion:

Psoriasis severity and an indication of the initiation of a systemic treatment could made according to the highest calculated score (PASI or PSSI or NAPSI or ESIF) or by adding a correction factor in the calculation of PASI for

special areas.

Keywords: psoriasis scores, difficult-to-treat areas

References

\1. Wozel, G. Psoriasis treatment in difficult locations: scalp, nails, and intertriginous areas. Clin Dermatol 2008, 26(5), 448–59.

\2. Egeberg, A.; See, K.; Garrelts, A.; Burge, R. Epidemiology of psoriasis in hard-to-treat body locations: data from the Danish skin cohort. BMC Dermatology 2020, 20, 3.

\3. Mrowietz, U. Implementing treatment goals for successful long-term management of psoriasis. JEADV 2012, 26 (Suppl. 2), 12–20.

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Abstract N°: 6367

Real-world effectiveness of risankizumab in biologic-naïve and biologic-experienced patients with psoriasis at 2 years of treatment: an interim analysis from VALUE, a multicountry, postmarketing observational study

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Introduction & Objectives:

Risankizumab (RZB) is a biologic interleukin 23 inhibitor approved to treat moderate-to-severe plaque psoriasis (PsO) in adults. Herein, we assess the effectiveness of RZB vs other biologic therapies among biologic-naïve (bio-naïve) and biologic-experienced (bio-experienced) patients with PsO at year 2 of treatment from an interim analysis of the real-world, postmarketing observational study, VALUE.

Materials & Methods:

Adults with moderate-to-severe PsO who were prescribed RZB or another biologic therapy were prospectively enrolled in VALUE (NCT03982394) at a 2:1 ratio. All treatment decisions were made independently of study enrollment by the treating physician, and patients received biologic therapies as prescribed. Psoriasis Area and Severity Index (PASI), Dermatology Life Quality Index (DLQI), and Treatment Satisfaction Questionnaire for Medication version 1.4 (TSQM) global satisfaction scores were assessed throughout the study. Results at year 2 (month 25) of treatment are reported from an interim database lock on 07 Dec 2023. Patients who were treated with RZB or another biologic therapy at least once were included in this analysis. Results are reported by modified nonresponder imputation (mNRI) where patients who discontinued or switched biologic therapy due to lack of effectiveness or intolerability were considered treatment failures for subsequent visits. Propensity score match (PSM) with 1:1 ratio using greedy algorithm and exact match for bio-naive/bio-experienced status was employed to account for imbalance between treatment groups. Nominal *P* values are presented.

Results:

Among 2639 patients (RZB, 1765; other biologic therapies, 874) included in this analysis, bio-naïve patients comprised 50.7% (895/1765) of patients receiving RZB and 62.9% (550/874) of patients receiving other biologic therapies. At year 2, bio-naïve patients receiving RZB vs other biologic therapies had significantly lower mean [SD] PASI (0.9 [2.0] vs 2.3 [4.2]; $P < .0001$) and DLQI (1.4 [3.3] vs 3.5 [6.0]; $P < .0001$) scores, higher mean [SD] treatment satisfaction scores (88.3 [16.8] vs 81.1 [20.5]; $P < .0001$), and higher rates of achieving ≥ 90% improvement in PASI (PASI 90, 79.3% vs 57.4%; $P < .0001$) and 100% improvement in PASI (PASI 100, 62.5% vs 42.9%; $P < .0001$; **Table**). Bio-experienced patients receiving RZB also had significantly lower mean [SD] PASI (1.8 [3.6] vs 3.1 [5.1]; $P = .002$)

and DLQI (2.2 [4.0] vs 4.0 [5.1]; *P* < .0001) scores, higher mean [SD] treatment satisfaction scores (83.6 [19.4] vs 74.9 [25.5]; *P* < .0001), and higher rates of achieving PASI 90 (62.0% vs 41.8%;*P* < .0001) and PASI 100 (44.0% vs 30.6%; *P* = .001) vs those receiving other biologic therapies. Similar results were observed for the PSM analysis (**Table**).

Conclusion:

After 2 years of treatment, both bio-naïve and bio-experienced patients receiving RZB experienced significantly better PASI, DLQI, and treatment satisfaction scores than patients receiving other biologic therapies.

Table. Efficacy Outcomes at Year 2 (Interim Analysis) of Treatment Among Biologic-Naïve and Biologic-Experienced Patients

			Biologic Naïve		Biologic Experienced	
Outcome			RZB (N = 895)	Other Biologics (N = 550)	RZB (N = 870)	Other Biologics (N = 324)
PASI	mNRI	Mean (SD)	0.9 (2.0)***	2.3 (4.2)	1.8 (3.6)**	3.1 (5.1)
		n_{valid}	558	323	526	196
	PSM	Mean (SD)	0.8 (1.9)***	2.1 (3.8)	1.9 (3.7)*	3.0 (5.2)
		n_{valid}	299	285	171	177
DLQI	mNRI	Mean (SD)	1.4 (3.3)***	3.5 (6.0)	2.2 (4.0)***	4.0 (5.1)
		n_{valid}	531	312	515	189
	PSM	Mean (SD)	1.7 (3.4)***	3.4 (5.9)	2.1 (3.9)***	3.7 (4.9)
		n_{valid}	282	274	167	171
TSQM GSS	mNRI	Mean (SD)	88.3 (16.8)***	81.1 (20.5)	83.6 (19.4)***	74.9 (25.5)
		n_{valid}	519	291	491	179
	PSM	Mean (SD)	88.4 (15.2)***	82.2 (19.7)	82.6 (20.2)**	75.7 (24.9)
		n_{valid}	273	256	160	165
PASI 90	mNRI	%	79.3***	57.4	62.0***	41.8
		n/n_{valid}	444/560	186/324	326/526	81/194
	PSM	%	78.3***	59.8	62.0**	44.6
		n/n_{valid}	234/299	171/286	106/171	78/175
PASI 100	mNRI	%	62.5***	42.9	44.0**	30.6
		n/n_{valid}	350/560	140/326	233/529	60/196
	PSM	%	62.5***	44.9	45.0*	32.8
		n/n_{valid}	187/299	129/287	77/171	58/177

DLQI, Dermatology Life Quality Index; mNRI, modified nonresponder imputation; n_{valid}, patients with valid data for visit/parameter; PASI, Psoriasis Area and Severity Index; PASI 90/100, ≥ 90%/100% improvement in Psoriasis Area and Severy Index; PSM, propensity score match; RZB, risankizumab; TSQM GSS, Treatment Satisfaction Questionnaire for Medication global satisfaction score.

mNRI was used to analyze PASI 90 and PASI 100 responses. For continuous outcomes, the last measurement immediately before the treatment change was carried forward.

*P < .05, **P < .01, ***P < .001 vs other biologics based on t test (PASI, DLQI, TSQM GSS) or Chi-squared test (PASI 90/100).

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Abstract N°: 6376

Gender influence and bimekizumab treatment in moderate-to-severe psoriasis: a short term real-life multicenter experience

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Introduction & Objectives: Psoriasis is a lifelong chronic inflammatory disease affecting 2-3% of the worldwide population. Major determinants of psoriasis severity include the extent of skin involvement; localization areas such as scalp, palms, and soles; pruritus; presence of comorbidities including psoriatic arthritis; and impairment in quality of life. About one-third of patients have moderate to severe psoriasis and biologic treatments are

increasingly being used in the management of these forms. Bimekizumab is a selective inhibitor of both interleukin (IL)-17A and IL-17F approved for the treatment of moderate to severe plaque psoriasis. To assess whether gender differences in demographic and clinical characteristics of psoriatic patients can affect treatment response to standard-dose of Bimekizumab, during the first 16 weeks of treatment.

Materials & Methods: 318 patients with plaque psoriasis were treated with standard doses of bimekizumab (320 mg at weeks 0, 4, 8, 12, and 16, and every 8 weeks thereafter). In this population, gender differences were assessed by performing two consecutive assessments. First, the following demographic and clinical variables were assessed at baseline: BMI, age, affected body part at first disease manifestation, comorbidities, use or non-use of previous systemic therapy (cyclosporine, methotrexate, fumaric acid esters, PUVA or acitretin), failure of previous biological treatment, PASI at T0 and DLQI at T0. In a second step, the effect of drug treatment was assessed by considering the PASI and DLQI index scores for each patient at baseline (T0), after 4 weeks, and after 16 weeks. Finally, a mixed-effects model was used for each index to analyse the interactions of gender with disease duration, presence of arthritis, involvement of special areas, presence of metabolic syndrome, use or non-use of previous systemic therapy, and possible failure of previous biological treatment

Results: A population of 318 patients, 229 males (median age 35 years; [23-47]) and 89 females (median age 33 years; [20; 48]) were treated for 16 weeks. Statistically significant difference only in BMI and PASI were evident at baseline between male and female patients, as expected. Specifically, females showed significantly lower BMI [19.7 (18.2-23.3)] than males [23.1 (21.6-26.4)] ($p < 0.001$) and a lower disease burden as assessed by the PASI index [PASI in female population: 13.0 (10.0; 18.0)], in male population 16.0 (12.0; 22.0); p=0.019]. Analysis of the effect of drug treatment showed that the reduction in disease severity, evaluated through PAS, was significantly greater in female population after 16 weeks of treatment (b:-1.612; IC95%:-2.621;-0.602; p =0.002), although it does not translate into a different improvement in DLQI between the two populations (b:-1.12-3.2; IC 95% 0.961; p=0.299).

Conclusion: Based on our results, gender differences in patients with plaque psoriasis, may drive response to bimekizumab during the first 16 weeks of treatment. Further prospective studies are needed to confirm the role of gender in long-term response to bimekizumab.

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Abstract N°: 6377

Effectiveness of Ixekizumab on Skin, Itch and Quality of Life through 24 weeks from the Second Interim Analysis of a US Observational Psoriasis Study.

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Introduction & Objectives:

Ixekizumab (IXE) is a highly selective, IL-17A monoclonal antibody with demonstrated efficacy in treating moderate-to-severe plaque psoriasis1, including in challenging body areas such as nails and scalp2,3. Real-world (RW) data compliments clinical trial data, providing information on different study populations and outcomes in routine clinical practice, providing a RW perspective that is different from clinical trials. To gain more RW insights, we provide descriptive data on a second interim analysis from the prospective Psoriasis in Special Areas (PSoSA) study.

Materials & Methods:

PSoSA is a US-based, multicenter, single-arm, prospective, observational study enrolling adult patients with a confirmed diagnosis of moderate-to-severe psoriasis (PsO) and nail involvement, with or without scalp involvement, whose HCP/physician has prescribed IXE for the first time. As part of the second interim analysis of the PSoSA study, we assess the effectiveness of IXE treatment at weeks 4, 12 and 24, through evaluation of the Psoriasis Area and Severity Index (PASI), Itch Numeric Rating Scale (NRS) and Dermatology Life Quality Index (DLQI) and present a descriptive analysis of results obtained. Continuous and categorical variables are reported.

Results:

At the time of this second interim analysis (December 2023), 187 patients were assessed. Use of at least one concomitant PsO therapy other than IXE was reported by 19.3% of patients at baseline (0.5% phototherapy and 18.7% topical). Biologic systemic agents were discontinued by 67.3% of patients within 12 months prior to enrollment. As early as Week 4, improvements in PsO, itch and quality of life were experienced by patients treated with IXE and continued up to Week 24. Specifically, mean (±SD) baseline PASI score (10.4±11.69) improved by 6.3 points by Week 4 (4.1±5.04), an additional 2.3 points by Week 12 (1.8±3.32) and a further 0.8 by Week 24 (1.0±1.87). Mean PASI change from baseline and percentage change from baseline are outlined in Table 1. PASI90 was achieved by 18.8% of patients by Week 4, by Week 12 this increased to 54.0% of patients and by Week 24, to 69.6% of patients (Figure 1). PASI100 was achieved by 10.9% of patients by Week 4, 27.4% of patients by Week 12 and 43.5% of patients by Week 24 (Figure 1). An Itch NRS score of 0 (no itch) was reported by 17.8% of patients by Week 4, 29.7% of patients by Week 12 and 41.8% of patients by Week 24. At Week 4, 41.9% of patients reported a ≥4-point improvement from their baseline recorded Itch NRS score of ≥4. By Week 12, this increased to 45.0% of patients and by Week 24, 57.6% of patients. DLQI (0,1) was reported by 22.2% of patients by Week 4, 42.9% of patients by Week 12 and 61.2% of patients by Week 24.

Conclusion:

This second interim analysis of the PSoSA study demonstrates improvement in PASI, itch and DLQI scores as early

as week 4 and up to week 24 in patients initiating IXE treatment.

References:

\1. Blauvelt A, et al. Br J Dermatol. 2021;184:1047-1058.

\2. Reich K, et al. J Dermatolog Treat. 2017;28:282-287.

\3. Dennehy EB, et al. J Drugs Dermatol. 2016;15:958-961.

Table 1: PASI change from baseline and percentage PASI change from baseline at Weeks 4, 12 and 24

	Week 4 mean ± SD [Nx]	Week 12 mean ± SD [Nx]	Week 24 mean ± SD [Nx]
PASI change from baseline*	-6.6 (9.61)	-9.4 (11.23)	-10.8 (13.88)
95% CI	-8.17, -5.01	-11.45, -7.35	-14.05, -7.55
PASI % change from baseline	-52.6 (43.67)	-74.7 (37.75)	-82.3 (39.23)
95% CI	-59.89, -45.31	-81.66, -67.74	-91.56, -73.04

**p*-value at each week = <.0001. *p*-value is calculated based on a two-tailed t-test where the null hypothesis is population mean=0 and the alternative hypothesis is population mean ≠ 0. Percentage change from baseline is not derived for subjects with baseline value of 0. Abbreviations: CI, confidence interval; Nx, number of patients with non-missing data in each category; PASI, Psoriasis Area and Severity Index; SD, standard deviation.

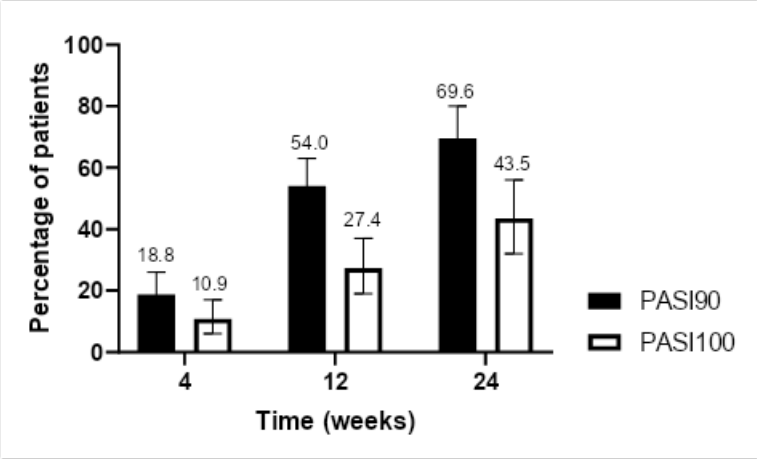

Figure 1: Percent of patients who achieved PASI90 and PASI100 at weeks 4, 12 and 24.

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Abstract N°: 6379

Time to treatment change in patients receiving risankizumab vs other biologic therapies after 2 years of treatment: interim analysis from the multicountry real-world postmarketing observational VALUE study in patients with psoriasis

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Introduction & Objectives:

Risankizumab (RZB) is an interleukin 23 inhibitor approved for the treatment of moderate-to-severe plaque psoriasis (PsO) in adults. In an interim analysis, we assessed the time to treatment change for patients treated with RZB vs other biologic therapies in the ongoing 3-year real-world postmarketing observational study, VALUE.

Materials & Methods:

Patients with moderate-to-severe PsO were enrolled in VALUE (NCT03982394) at a 2:1 ratio for RZB vs other biologic therapies. Treatment decisions were made independently of study enrollment, and all patients received their biologic treatment as prescribed. Results are reported from an interim database lock on 07 December 2023. Treatment changes (defined as discontinuation of treatment, dose escalation, dosing interval shortening, or change of biologic treatment per the treating physician) were assessed through month 25 of treatment among patients receiving RZB vs other biologic therapies. The probability of treatment change was estimated from a Kaplan-Meier curve for time to first treatment change that accounted for censoring and follow-up time. Propensity score matching (PSM) with a 1:1 ratio using greedy algorithm and exact match for biologic-naive/biologic-experienced status was used to account for imbalances between groups.

Results:

This analysis included 2639 patients (1765 receiving RZB and 874 receiving other biologic therapies). Patients receiving RZB were significantly less likely to require a treatment change compared with patients receiving other biologics (15.9% vs 27.0%; $P < .0001$) by month 25 of treatment. The probability of treatment change (95% CI) at month 25 based on the Kaplan-Meier curve for time to first treatment change was 0.16 (0.14, 0.18) for patients receiving RZB vs 0.29 (0.26, 0.32) for patients receiving other biologic therapies (**Table**). For patients who experienced treatment change, the mean time to treatment change was numerically longer among patients receiving RZB compared with those receiving other biologic therapies (11.2 months vs 10.8 months; $P = .64$). Similar patterns were observed for biologic-naïve patients (RZB, n = 895; other biologics, n = 550). Biologic-naïve patients receiving RZB were significantly less likely to require a treatment change by month 25 of treatment compared with those receiving other biologics (12.0% vs 26.2%; $P < .0001$); the probability of treatment change at month 25 based on the Kaplan-Meier curve for time to first treatment change was 0.12 (0.10, 0.14) for those receiving RZB vs 0.28 (0.24, 0.32) for those receiving other biologic therapies. Among biologic-naïve patients who

experienced treatment change, those receiving RZB vs other biologic therapies also had a numerically longer time to first treatment change (13.2 months vs 11.2 months; *P* = .10). Similar results were reported for the PSM population.

Conclusion:

In the ongoing real-world VALUE study comparing cohorts treated with RZB or other biologic therapies, patients receiving RZB were less likely to require treatment changes during up to 2 years of treatment than were patients receiving other biologic therapies. Additionally, when treatment changes were required, these changes occurred numerically later among patients receiving RZB vs other biologics.

Table. Treatment Survival

	Total Population		Bio-naïve Population	
	RZB (n = 1765)	Other Biologic Therapies (n = 874)	RZB (n = 895)	Other Biologic Therapies (n = 550)
Time to first treatment change, month, mean (SD)				
All patients	n = 285	n = 249	n = 117	n = 158
	11.2 (9.7)	10.8 (9.2)	13.2 (10.9)	11.2 (9.4)
PSM	n = 124	n = 218	n = 58	n = 134
	12.4 (10.6)	10.9 (9.6)	12.4 (9.8)	11.3 (9.8)
Cumulative treatment change probability at month 25 (95% CI)[a]				
All patients	n = 1765	n = 874	n = 895	n = 550
	0.16*** (0.14, 0.18)	0.29 (0.26, 0.32)	0.12*** (0.10, 0.14)	0.28 (0.24, 0.32)
PSM	n = 786	n = 786	n = 484	n = 484
	0.15*** (0.12, 0.17)	0.27 (0.24, 0.31)	0.12*** (0.09, 0.15)	0.27 (0.23, 0.31)
Proportion of patients experiencing a treatment change up to month 25, % (95% CI)[b]				
All patients	n = 1765	n = 874	n = 895	n = 550
	15.9*** (14.2, 17.7)	27.0 (24.1, 30.1)	12.0*** (9.9, 14.3)	26.2 (22.6, 30.1)
PSM	n = 786	n = 786	n = 484	n = 484
	14.2*** (11.9, 16.9)	26.1 (23.0, 29.3)	11.6 (8.9, 14.8)	24.8 (21.0, 28.9)

PSM, propensity score matched; RZB, risankizumab.
[a]Results based on based on the Kaplan-Meier curve for time to first treatment change that accounted for censoring and follow-up time. *P* values are based on logrank test comparing 2 treatment groups using all data up to the database lock date.
[b]Results describe the proportion of patients experiencing a treatment change. *P* values based on Chi-squared test.
***$P < .0001$ vs other biologic therapies.

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Abstract N°: 6386

Bimekizumab in routine clinical practice: Baseline characteristics and treatment history of patients with moderate to severe plaque psoriasis from the second interim analysis of ELEVATE

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Introduction & Objectives:

Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A,1,2 is authorised for treatment of moderate to severe plaque psoriasis.3

ELEVATE is a multicentre, prospective, observational study aiming to describe patient (pt)-reported outcomes (PROs) of effectiveness in pts with psoriasis receiving BKZ in routine practice, stratified by treatment history (TxH). A first interim analysis (IA1) described baseline (BL) characteristics and TxH of 196 pts newly initiating BKZ in the first year of use in German routine practice.4

Here, BL characteristics and TxH are presented for pts enrolled up to the second IA (IA2).

Materials & Methods:

Eligible pts for ELEVATE are adults previously naïve to and newly initiating BKZ (per the locally approved label) in France, Germany, Greece, Italy and the United Kingdom.

PROs (e.g. Dermatology Life Quality Index [DLQI], Psoriasis Symptoms and Impacts Measure [P-SIM], and treatment satisfaction) are surveyed via an app and clinical assessments (e.g. Psoriasis Area and Severity Index [PASI], Physician's Global Assessment [PGA], and affected body surface area [BSA]) are made at multiple observation points over approximately 12 months (via app: ~Weeks 0, 2, 4, 8, 12, 26, 39, and 52; via clinical assessment: ~Weeks 0, 12, 26, 39, and 52).

IA2 was performed once 300 patients had completed 6 months of BKZ treatment in Germany (data lock: 25 October 2023). Here, BL characteristics and TxH are presented for pts enrolled up to the data lock. Data are summarised for the safety set (pts who received ≥1 BKZ dose).

Results:

At the data lock, 505 pts in Germany had consented to participate; the safety set included 497 pts.

The **Table** summarises demographics and BL disease severity for pts in the safety set. At BL, 329 (66.2%) pts were male; mean age (standard deviation [SD]) was 45.2 (14.4) years. Age and sex distribution varied by TxH. Mean (SD) PASI and DLQI scores were 13.6 (8.7) and 14.5 (7.7), respectively. Mean P-SIM scores were >5 for 13 of 14 items and ≥7 for skin redness, scaling, and dryness. 92.2% of pts had presence of psoriasis in ≥1 high-impact

psoriasis area (nail, scalp, and palmoplantar; **Table**).

The **Figure** summarises TxH split by recent (≤12 months before BKZ first dose) and past (>12 months before BKZ first dose) systemic therapy (Sx). Most pts (N=371; 74.6%) had TxH of any Sx, of which 177 (47.7%) had received biologic therapy (Bx). TxH was unavailable for 3 pts (0.6%). 123 (24.7%) were naïve for any Sx, and overall BKZ was the first line Bx for 317 (63.8%) pts.

Among pts with recent Bx TxH, the most common prior modes of action were tumour necrosis factor-alpha inhibition (N=54; 30.5%), IL-23p19 inhibition (N=51; 28.8%), and IL-17A inhibition (N=47; 26.6%).

Conclusion:

In pts newly initiating BKZ in German routine practice in ELEVATE, BL scores measuring disease severity and quality of life confirmed moderate to severe psoriasis disease state. Almost all pts had presence of psoriasis in ≥1 high-impact area.4

Most pts had a Sx TxH and for 63.8%, BKZ was their first Bx for psoriasis.** The profile of pts enrolled remained consistent with IA1.

References:

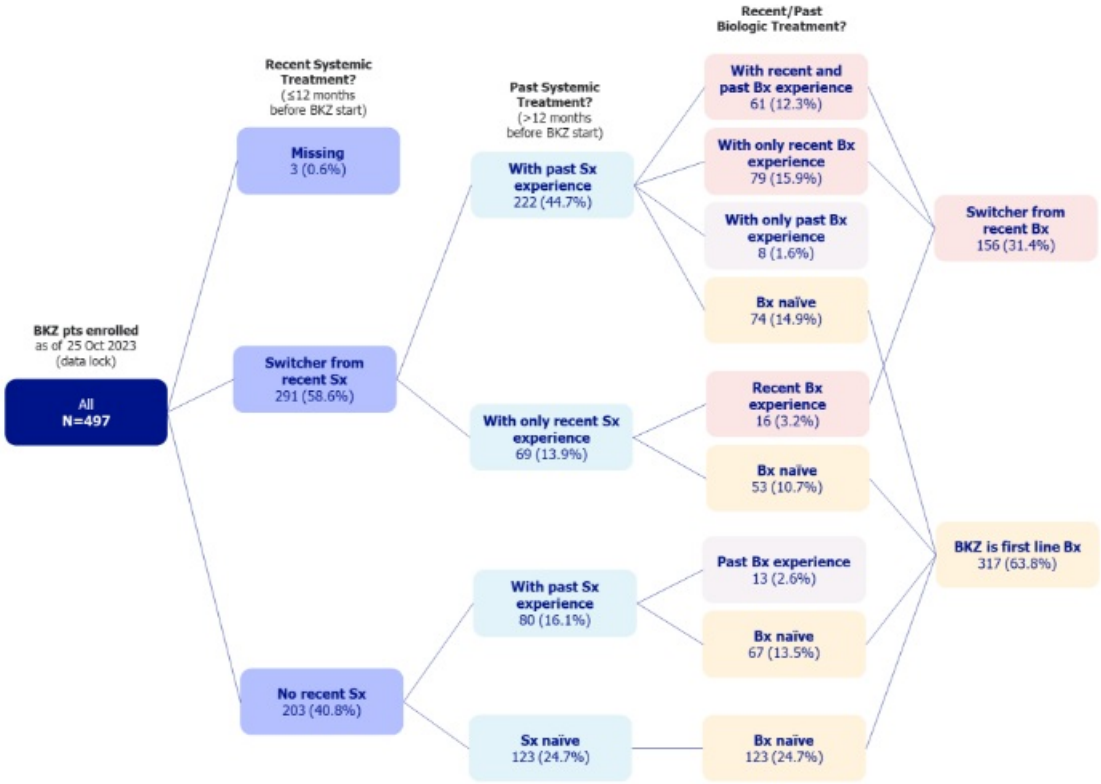
1. Glatt S. Ann Rheum Dis. 2018;77:523–32; **2.** Adams R. Front Immunol. 2020;11:1894; **3.** EMA: https://www.ema.europa.eu/en/documents/overview/bimzelx-epar-medicine-overview_en.pdf [Accessed April 2024]; **4.** Asadullah K. Presented at EADV 2023;P2594.

Table. Demographics and baseline characteristics for patients enrolled at the IA2 data lock in Germany (safety set)

	Recent and past systemic TxH N=222	Recent but no past systemic TxH N=69	No recent but past systemic TxH N=80	No recent and no past systemic TxH N=123	Total N=497
Male, n (%)	150 (67.6)	51 (73.9)	50 (62.5)	75 (61.0)	329 (66.2)
Age (years), mean (SD)	47.7 (14.2)	41.4 (13.7)	44.4 (14.3)	43.3 (14.8)	45.2 (14.4)
BMI (kg/m²), mean (SD)	30.1 (6.8)	28.0 (6.2)	29.0 (5.8)	28.1 (5.6)	29.2 (6.3)
Disease duration (years), mean (SD)	20.2 (14.6)	12.5 (12.1)	18.2 (12.2)	12.3 (11.9)	16.8 (13.7)
PASI score, mean (SD)	11.9 (8.1)	14.3 (9.1)	15.9 (8.3)	14.5 (9.6)	13.6 (8.7)
PASI score ≥10, n (%)	116 (52.3)	44 (63.8)	61 (76.3)	77 (62.6)	300 (60.4)
DLQI total score, mean (SD)	12.6 (7.3)	17.4 (7.5)	16.7 (7.4)	14.9 (7.9)	14.5 (7.7)
DLQI score ≥11, n (%)	123 (55.4)	45 (65.2)	53 (66.3)	77 (62.6)	301 (60.6)
Comorbidities[a]					
Suspected/confirmed PsA and/or spondyloarthritis, n (%)	33 (14.9)	2 (2.9)	0	3 (2.4)	38 (7.6)
Anxiety and depression, n (%)	19 (8.6)	4 (5.8)	2 (2.5)	10 (8.1)	35 (7.0)
Major adverse cardiac event, n (%)	13 (5.9)	2 (2.9)	7 (8.8)	8 (6.5)	30 (6.0)
Metabolic syndrome, n (%)	13 (5.9)	2 (2.9)	5 (6.3)	6 (4.9)	26 (5.2)
P-SIM score[b]					
Skin redness, mean (SD)	6.4 (2.7)	7.7 (2.4)	7.9 (2.2)	7.3 (2.3)	7.1 (2.6)
Skin scaling, mean (SD)	6.5 (2.7)	7.7 (2.3)	7.5 (2.4)	7.1 (2.8)	7.0 (2.7)
Skin dryness, mean (SD)	6.8 (2.5)	7.5 (2.4)	7.5 (2.4)	7.1 (2.6)	7.1 (2.5)
PGA score ≥2[c]					
f-PGA, n (%)	78 (35.1)	27 (39.1)	42 (52.5)	60 (48.8)	208 (41.9)
sc-PGA, n (%)	143 (64.4)	50 (72.5)	62 (77.5)	99 (80.5)	355 (71.4)
pp-PGA, n (%)	68 (30.6)	22 (31.9)	31 (38.8)	44 (35.8)	165 (33.2)

Recent systemic therapy is defined as previous systemic therapy received in ≤12 months before the first BKZ dose. Past systemic therapy is defined as previous systemic therapy received >12 months before the first BKZ dose. [a] MedDRA-based terms; [b] Only P-SIM items with a total mean score ≥7 are included in this table; [c] PGA score ≥2 indicates pts were mildly to severely impacted in the relevant area. BMI: body mass index; DLQI: Dermatology Life Quality Index; f-PGA: fingernail-PGA; IA2: second interim analysis; MedDRA: Medical Dictionary for Regulatory Activities; PASI: Psoriasis Area and Severity Index; PGA: Physician's Global Assessment; pp-PGA: palmoplantar-PGA; P-SIM: Psoriasis Symptoms and Impacts Measure; sc-PGA: scalp-PGA; PsA: psoriatic arthritis; SD: standard deviation; TxH: treatment history.

Figure. Patient stratification based on treatment history for patients enrolled at the IA2 data lock in Germany (safety set)



Percentages are calculated as a proportion of all patients enrolled at the data lock (N=497). Recent systemic therapy is defined as previous systemic therapy received in ≤12 months before the first BKZ dose. Past systemic therapy is defined as previous systemic therapy received >12 months before the first BKZ dose. BKZ: bimekizumab; Bx: biologic therapy; Sx: systemic therapy.

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Abstract N°: 6391

Demographics, Disease Characteristics and Time to Effective Treatment of Psoriasis Patients in the Ghent PsoPlus Cohort of 2021

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Introduction & Objectives: Psoriasis is a chronic immune-mediated skin disease with several comorbidities and a significant impact on quality of life. Undertreatment is common, often resulting in prolonged disease duration before initiating biologic therapy. To address this, Ghent University Hospital established the PsoPlus consultation, rooted in Value-Based Health Care principles. Patients initially consult a specialty-trained psoriasis nurse who conducts the anamnesis, addresses lifestyle and psychosocial factors and screens for comorbidities. Subsequently, a dermatologist conducts clinical examinations, assesses comorbidities, and collaborates with the patient on disease management. This is guided by the treat-to-target (T2T) paradigm, utilizing 9 criteria. Follow-up intervals depend on goal attainment: every 3 months if <8/9 goals met, and every 6 months if ≥8/9 goals met. This study aims to analyze patient and disease characteristics and time to effective treatment in PsoPlus. Additionally, the impact of the T2T approach on treatment decisions and disease progression is examined.

Materials & Methods: Through a single center, exploratory, retrospective study, 170 patients in the PsoPlus dedicated clinic were compared to identify differences at moment of enrollment in PsoPlus and at the last recorded consultation in 2021.

Results: Median disease duration at the first PsoPlus consultation was 16.0 years. A significant difference in Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality Index (DLQI) between the first and the last recorded PsoPlus consultation (PASI 6.0 vs. 0.6; DLQI 11 vs. 2; $p<0.001$) was found. A weak positive Spearman correlation (rs) was found between disease duration and PASI at the first PsoPlus consultation ($rs=0.175$; $p=0.034$), while a weak negative correlation ($rs=-0.2$; $p=0.013$) was found at the last registered PsoPlus consultation. Patients with a disease duration of more than 20 years, had significantly more switches of treatment than those with a shorter disease duration ($p<0.001$). Median time from psoriasis onset until PASI ≤ 2 was 16.0 years. Median time from the first PsoPlus consultation until PASI ≤ 2 was reached, was 7.0 months. Upon enrollment in PsoPlus, 61.2% of patients were diagnosed with comorbidities. The most prevalent comorbidities were psoriatic arthritis (13.5%), metabolic disorders (34.1%), cardiovascular disorders (21.2%) and mental health disorders (26.5%). At the last PsoPlus consultation in 2021, comorbidities rose to 65.3%; psoriatic arthritis diagnoses increased to 15.4%, metabolic disorders to 37.3% and about one-quarter had cardiovascular and mental health disorders.

Conclusion: By portraying the long journey of patients with psoriasis, we reconfirm that psoriasis is a systemic disease that needs a personalized and holistic approach. The T2T approach facilitates timely intervention, leading to improved disease severity and quality of life.

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Abstract N°: 6398

Bimekizumab treatment history and quality of life outcomes in patients with moderate to severe plaque psoriasis in routine clinical practice: Results from the second interim analysis of ELEVATE

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Introduction & Objectives:

Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.1 BKZ is authorised in multiple regions for the treatment (Tx) of moderate to severe plaque psoriasis.2 ELEVATE aims to describe patient (pt)-reported outcomes (PROs) in adults with psoriasis receiving BKZ in routine clinical practice, stratified by Tx history (TxH). Here, results are presented from the second interim analysis (IA2) in pts enrolled in Germany.

Materials & Methods:

ELEVATE is a multicentric, prospective observational study ongoing in France, Germany, Greece, Italy, and the UK. Eligible pts are aged ≥18 years with moderate to severe plaque psoriasis newly initiating BKZ Tx, as per the local label; pts with prior BKZ TxH are excluded. Pts are followed up for ~12 months after starting BKZ Tx, electronically completing PRO measures (Dermatology Life Quality Index [DLQI], Psoriasis Symptoms and Impacts Measure [P-SIM], and Tx Satisfaction Questionnaire for Medications 9 [TSQM-9]) at 8 observational periods (OP): Week 0 (baseline) and ~Weeks 2, 4, 8, 12, 26, 39, and 52. The co-primary outcomes are to describe the TxH of pts with psoriasis and the proportion of pts achieving DLQI 0/1 (no impact of skin disease on a pt's life)3 at Week 26 (OP6).

IA2 was initiated once 300 pts completed 6 months of BKZ Tx in Germany (data lock: 25 October 2023). PROs are summarised in the full analysis set (FAS), and results are reported for the overall group and by TxH subgroups: systemic naïve (no prior systemic treatment [ST]), biologic naïve (prior ST, but no prior biologic treatment [BT]), and biologic experienced (prior BT). Analyses included only pts enrolled in Germany and were descriptive and based on observed cases.

Results:

At the data cut-off, 497 pts received ≥1 dose of BKZ (safety set) and 289 completed Week 26; 453 pts were included in the FAS (66.9% male; mean [standard deviation, SD] age: 45.5 [14.6]; mean [SD] DLQI: 14.3 [7.7]). TxH of any systemic therapy was reported in 342 (75.5%) pts, with 163 (47.7%) having received a biologic.

At Week 26 (OP6), 55.9% of pts with reported DLQI achieved a DLQI of 0/1 (**Table**). DLQI 0/1 achievement was comparable across pt subgroups stratified by TxH. The proportion of pts with no/small impact on quality of life (QoL), defined by DLQI severity categories, increased from baseline through Week 26 (OP6), with a corresponding

decrease in those with a very/extremely large impact on their QoL (**Figure 1**). The proportion of pts with P-SIM item scores of 0 (indicating no symptoms), including for skin itching, scaling, redness, and pain, rapidly increased from baseline to Week 2 (OP2) and continued to increase through Week 26 (OP6) across all TxH subgroups (**Figure 2**). At Week 26 (OP6), pts reported good Tx satisfaction according to mean (SD) TSQM-9 scores (scored 0–100) in the effectiveness (74.2 [32.1]), convenience (82.3 [18.6]), and global satisfaction domains (82.1 [21.1]).

Conclusion:

Overall, >50% of pts in this interim analysis self-reported no impact of skin disease on health-related QoL after 26 weeks of BKZ Tx, with symptom improvements observed as early as Week 2. Despite the broad Tx profile, BKZ resulted in consistent and rapid improvements in QoL and symptoms, independent of TxH.

References:

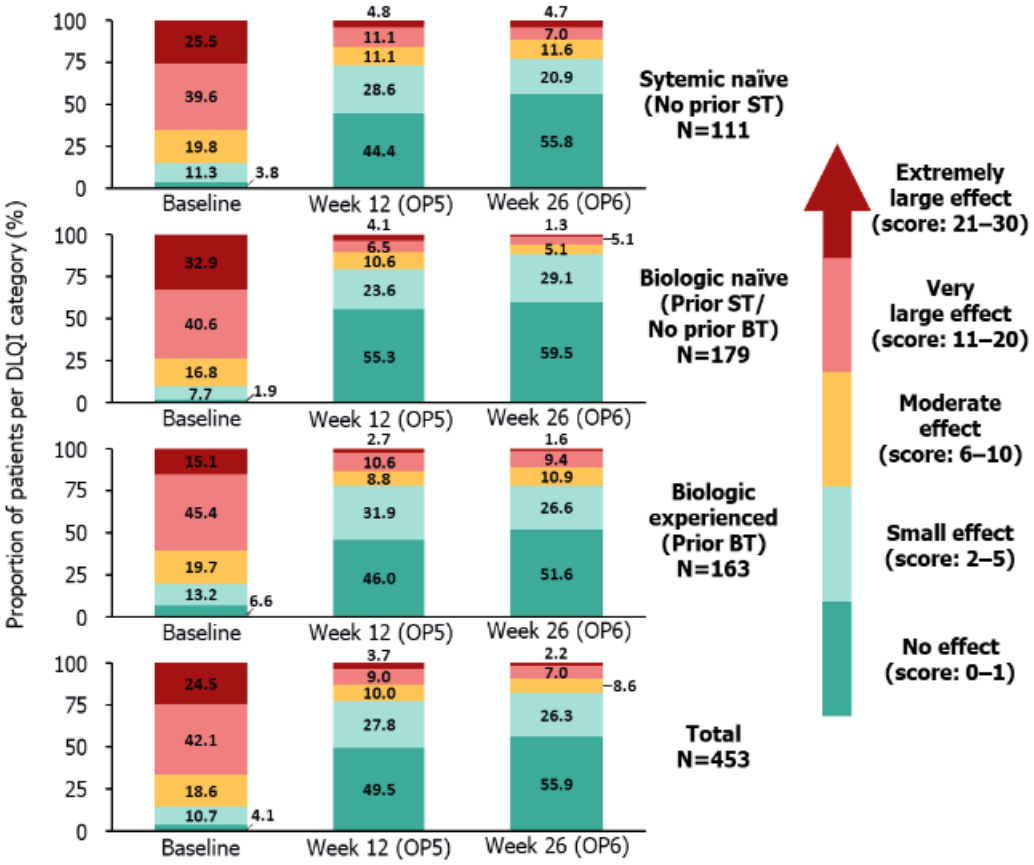
1. Glatt S. Ann Rheum Dis. 2018;77:523–32; **2.** EMA: https://www.ema.europa.eu/en/documents/overview/bimzelx-epar-medicine-overview_en.pdf [Accessed April 2024]; **3.** Hongbo Y. J Invest Dermatol. 2005;125(4):659–64.

Table. Proportion of patients with DLQI 0/1 at Week 26 (OP6) by treatment history (OC)

	Treatment history			
	Systemic naïve (No prior ST) N=111	**Biologic naïve (Prior ST/ No prior BT) N=179**	**Biologic experienced (Prior BT) N=163**	**Total N=453**
DLQI 0/1, n/Nobs (%)[a]	24/43 (55.8)	47/79 (59.5)	33/64 (51.6)	104/186 (55.9)
95% CI	39.9, 70.9	47.9, 70.4	38.7, 64.2	48.5, 63.2

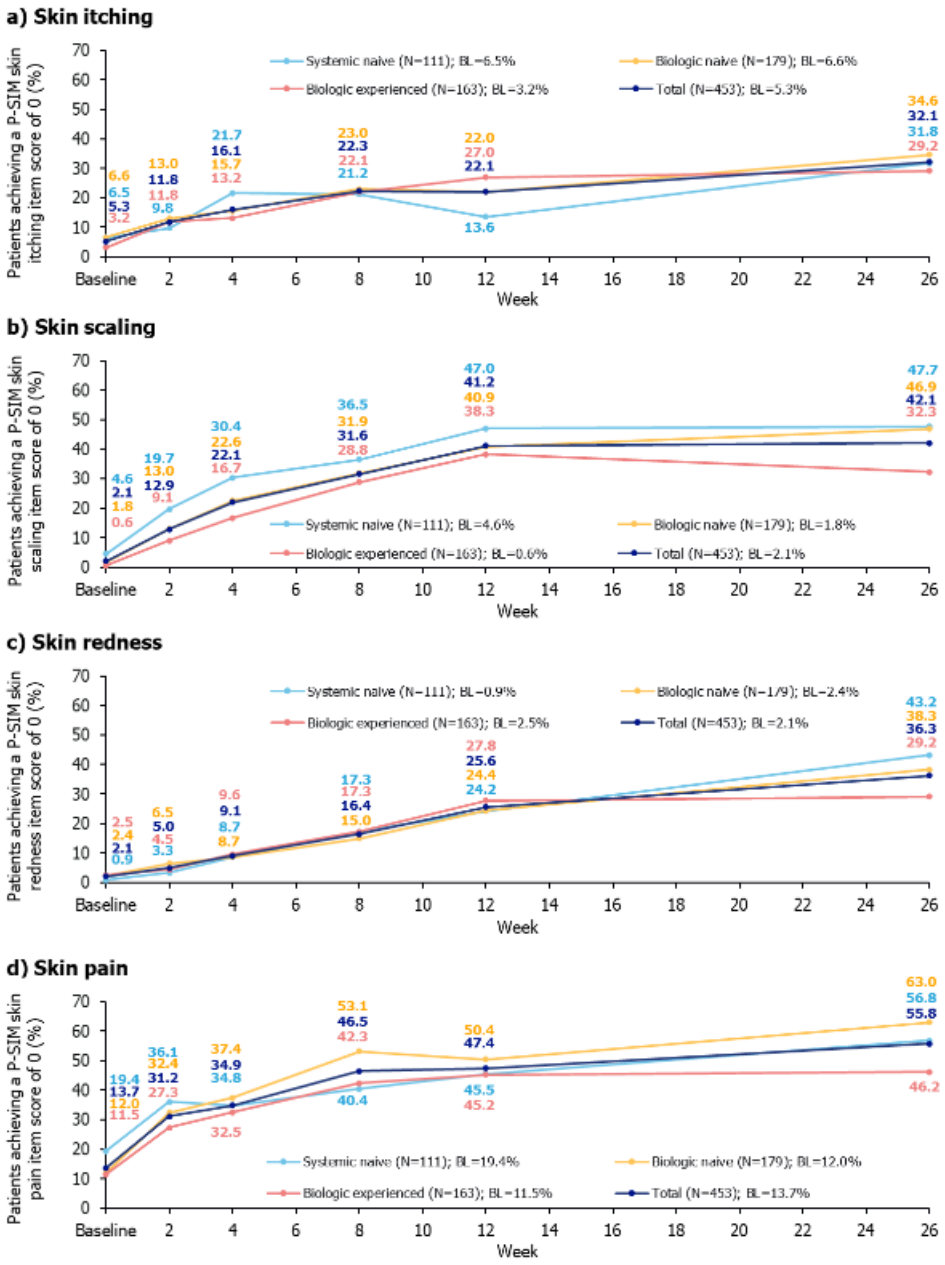
Full analysis set: patients with ≥1 baseline and post-baseline assessment; a valid baseline assessment should have occurred prior to the first BKZ dose, or up to 5 days after the first BKZ dose. [a] OC: Nobs represents the number of patients with a non-missing measurement for the given responder variable at Week 26 (OP6), with percentages calculated accordingly. BKZ: bimekizumab; BT: biological treatment; CI: confidence interval; DLQI: Dermatology Life Quality Index; OC: observed case; OP: observational period; ST: systemic treatment.

Figure 1. Proportion of patients per DLQI category from baseline through Week 26 (OP6) by treatment history (OC)



Full analysis set: patients with ≥1 baseline and post-baseline assessment; a valid baseline assessment should have occurred prior to the first BKZ dose, or up to 5 days after the first BKZ dose. BKZ: bimekizumab; BT: biologic treatment; DLQI: Dermatology Life Quality Index; OC: observed case; OP: observational period; ST: systemic treatment.

Figure 2. Proportions of patients reporting P-SIM item scores of 0 (symptom clearance) from baseline through Week 26 (OP6) by treatment history (OC)



Full analysis set: patients with ≥1 baseline and post-baseline assessment; a valid baseline assessment should have occurred prior to the first BKZ dose, or up to 5 days after the first BKZ dose. P-SIM items were scored from 0 (no signs/symptoms/impacts) to 10 (very severe signs/symptoms/impacts). Patients who were biologic naïve had prior systemic treatment history. BKZ: bimekizumab; BL: baseline value; BT: biological treatment; OC: observed case; OP: observational period; P-SIM: Psoriasis Symptoms and Impacts Measure; ST: systemic treatment.

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Abstract N°: 6407

Bimekizumab treatment history and clinical outcomes in patients with moderate to severe plaque psoriasis in routine clinical practice: Results from the second interim analysis of ELEVATE

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Introduction & Objectives:

Bimekizumab (BKZ), a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A, is authorised in multiple regions for the treatment (Tx) of moderate to severe plaque psoriasis.1,2 Here, results from the second interim analysis (IA2) of ELEVATE on the clinical outcomes of patients (pts) with psoriasis who initiated BKZ Tx in Germany are presented.

Materials & Methods:

ELEVATE is a multicentric, prospective, observational study ongoing in France, Germany, Greece, Italy, and the UK. Eligible pts are aged ≥18 years with moderate to severe plaque psoriasis newly initiating BKZ Tx, as per the local label; pts with prior BKZ treatment history (TxH) are excluded. Pts are observed for ~12 months following initiation of BKZ Tx. Clinical assessments (e.g. Psoriasis Area and Severity Index [PASI], Physician's Global Assessment [PGA]) occur at 5 observational periods (OP); Week 0 [baseline] and approximately Weeks 12, 26, 39 and 52. Secondary outcomes include the proportion of pts with PASI 0, ≤2, ≤3, ≤5, and a PGA score of 0/1 (clear/almost clear). Tx-emergent adverse events (TEAEs) are recorded via passive pharmacovigilance surveillance, summarised using the Medical Dictionary for Regulatory Activities, version 26.0.

IA2 was initiated once 300 pts had completed 6 months of BKZ Tx in Germany (data lock: 25 October 2023). TEAEs are summarised in the safety set and pt demographics and clinical outcomes in the full analysis set (FAS). Results are reported for the overall pt group and by TxH subgroups: systemic naïve (no prior systemic treatment [ST]), biologic naïve (prior ST, but no prior biologic treatment [BT]), and biologic experienced (prior BT). Analyses include only pts enrolled in Germany and were descriptive and based on observed cases.

Results:

At the data cut-off, 497 pts had received ≥1 dose of BKZ. In total, 453 pts (FAS) had ≥1 baseline and post-baseline assessment (66.9% male; mean [standard deviation, SD] age: 45.5 [14.6]; mean [SD] PASI: 13.6 [8.7]; PGA ≥2: 96.2%), with 289 pts having completed Week 26 (OP6). 342 (75.5%) reported TxH of any systemic therapy, of which 163 (47.7%) had TxH of any biological therapy. In pts with PASI >1, mean (SD) PASI decreased from 13.9 (8.6) at baseline to 1.6 (2.9) at Week 12 (OP5), and 1.3 (2.7) at Week 26 (OP6). Decreases in mean PASI observed by Week 26 (OP6) were generally similar across TxH subgroups (**Figure**). Absolute PASI ≤2 was achieved by 82.0% of pts at Week 26 (OP6).

At Week 26 (OP6), >80% of pts achieved PGA 0/1 in high impact areas of the fingernail, scalp, or palmoplantar area, with similar high response rates observed across TxH subgroups (**Table 1**). TEAEs by TxH are summarised in **Table 2**. Common TEAEs by preferred term included: oral candidiasis (n=28/497; 5.6%), nasopharyngitis (n=12/497; 2.4%), COVID-19 (n=10/497; 2.0%), and eczema (n=8/497; 1.6%).

Conclusion:

IA2 demonstrated substantial improvement in clinical outcomes following 26 weeks of BKZ Tx in pts with psoriasis, which is consistent with other IA2 data showing substantial improvements in quality of life and pt-perceived symptoms. Response rates were generally consistent across TxH subgroups.

References:

1. Glatt S. Ann Rheum Dis. 2018;77:523–32; **2.** EMA: https://www.ema.europa.eu/en/documents/overview/bimzelx-epar-medicine-overview_en.pdf [Accessed February 2024].

Table 1. Proportion of patients with PGA 0/1 in high impact areas at Week 26 (OP6) by treatment history (OC)

	Treatment history			
	Systemic naïve (No prior ST) N=111	Biologic naïve (Prior ST/ No prior BT) N=179	Biologic experienced (Prior BT) N=163	Total N=453
f-PGA 0/1, n/Nobs (%)[a]	20/26 (76.9)	44/52 (84.6)	27/32 (84.4)	91/110 (82.7)
sc-PGA 0/1, n/Nobs (%)[a]	43/48 (89.6)	73/88 (83.0)	44/56 (78.6)	160/192 (83.3)
pp-PGA 0/1, n/Nobs (%)[a]	17/21 (81.0)	28/36 (77.8)	22/26 (84.6)	67/83 (80.7)

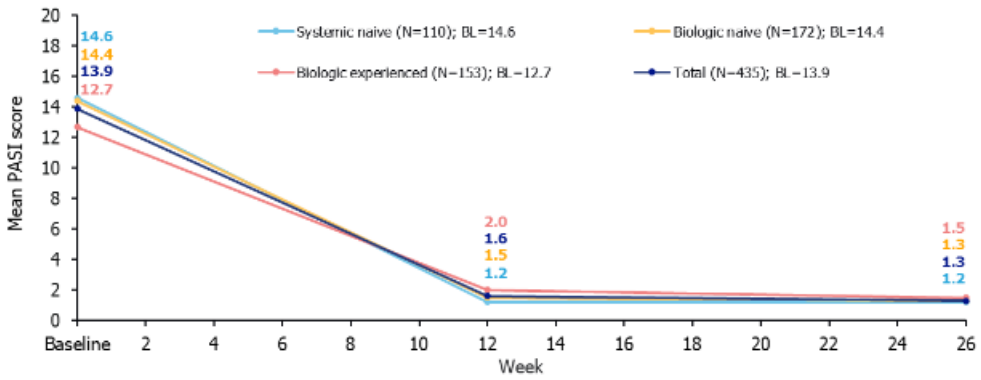
Full analysis set: patients with ≥1 baseline and post-baseline assessment; a valid baseline assessment should have occurred prior to the first BKZ dose, or up to 5 days after the first BKZ dose. [a] OC: Nobs represents the number of patients with a non-missing measurement for the given responder variable at Week 26, with percentages calculated accordingly. BT: biological treatment; f-PGA: finger nail-specific Physician's Global Assessment; OC: observed case; OP: observational period; PGA: Physician's Global Assessment; pp-PGA: palmoplantar-specific Physician's Global Assessment; sc-PGA: scalp-specific Physician's Global Assessment; ST: systemic treatment.

Table 2. TEAEs by systemic and biological treatment history

	Treatment history			
Category, n (%)	Systemic naïve (No prior ST) N=123	Biologic naïve (Prior ST/ No prior BT) N=194	Biologic experienced (Prior BT) N=177	Total N=497
Any TEAEs	26 (21.1)	65 (33.5)	55 (31.1)	146 (29.4)
Severe TEAEs	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.2)
Serious TEAEs	6 (4.9)	14 (7.2)	19 (10.7)	39 (7.8)
ADRs	13 (10.6)	36 (18.6)	25 (14.1)	74 (14.9)
Serious ADRs	2 (1.6)	5 (2.6)	8 (4.5)	15 (3.0)

Safety set: patients who received ≥1 dose of study treatment. ADR: adverse drug reaction; BT: biological treatment; ST: systemic treatment; TEAE: treatment-emergent adverse event.

Figure. Mean absolute PASI through Week 26 (OP6) by treatment history (OC)



Full analysis set: patients with ≥1 baseline and post-baseline assessment; a valid baseline assessment should have occurred prior to the first BKZ dose, or up to 5 days after the first BKZ dose. Only patients with baseline PASI >1 were included. Patients who were biologic naïve had prior systemic treatment history. BKZ: bimekizumab; BL: baseline; OC: observed case; OP: observational period; PASI: Psoriasis Area and Severity Index.

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Abstract N°: 6408

eHealth literacy among adults living with psoriasis: a multinational study in 20 countries. The results of ALL study

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Introduction & Objectives:

The internet has emerged as a significant resource for accessing health-related information. The notion of eHealth literacy is introduced and defined as the capacity to search for, locate, comprehend, and assess health information from electronic sources, and to utilize the acquired knowledge to address or manage health issues. Limited information exists regarding eHealth literacy among individuals with psoriasis. The primary objective of this study was to evaluate eHealth literacy levels among psoriasis patients and investigate the factors linked to eHealth literacy.

Materials & Methods:

Patients with psoriasis were selected through an online survey of the general population over the age of 16 in 20 countries worldwide. Psoriasis was self-reported by patients on the basis of a physician's diagnosis. The questionnaire was developed in partnership with patient organisations and continues to focus on the patient's experience. The questionnaire collected information on the patient's demographic and socio-demographic profile. Patients who reported using the internet to find reliable information about psoriasis were used to assess eHealth literacy (eHl). A comparison between those who did and did not use the Internet to obtain information about their disease was made to assess predictors of (eHl), such as socio-demographic and clinical characteristics, type of treatment, fear of adverse effects, feelings of discouragement to continue treatment and satisfaction with the treating physician.

Results:

A population of 992 respondents was selected, including 541 (54.5%) men and 451 (45.5%) women (mean age 47.8 +/- 15.5, min 16-85 years). 245 (24.5%) had used the internet to find information about their disease. 191 (19.3%) visited specialist websites, 77 (7.8%) branded websites. 86.5% of those who used the internet said they trusted the content. Average age (46.3 vs 48.3 years NS) and male gender (51% vs 66.7%, p NS) were not associated with eHl. Factors predictive of eHl were discomfort in personal life (52.2% vs 41.9%, $p \leq 0.05$) and in professional life (40.1% vs 33%, $p \leq 0.05$), feeling less productive at work (35.8% vs 25.6%, $p \leq 0.05$), feeling that sex life was disturbed (38.2% vs 24.3%, $p \leq 0.05$) and difficulties in their relationship (35.6% vs 24.7%, $p \leq 0.05$) because of psoriasis. Taking oral treatments (34.9% vs 18.6%, $p \leq 0.05$) and worrying about side effects (47.4% vs 39.9%, $p \leq 0.05$) and feeling discouraged about continuing treatment (54.7% vs 46.6%, $p \leq 0.05$) were associated with eHi. Dissatisfaction with the healthcare professional's explanations (40.8% vs 41.1%, $p \leq 0.05$), the length of the consultation (42.4% vs 40.2%, p NS), and the care provided by the doctor (45.3% vs 43.8%, p NS) were not associated with eHi.

Conclusion:

The accessibility and utilization of online resources by individuals with psoriasis can impact their health behaviors and overall health outcomes. Healthcare providers should take into account the eHealth literacy levels of psoriasis patients and guide them towards trustworthy and relevant online sources. The findings from our studies will facilitate the creation of interventions aimed at improving eHealth literacy skills and enhancing the usability of web-based information for adults with psoriasis.

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Abstract N°: 6441

Effectiveness, safety and survival of tildrakizumab in patients with moderate-to-severe psoriasis after 78 weeks, in real clinical practice.

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Introduction & Objectives: Tildrakizumab (TIL) is a humanized IgG1/κ type monoclonal antibody that binds specifically to the p19 subunit of the cytokine interleukin 23 (IL-23), without binding to IL-12, and inhibits its interaction with the IL-23 receptor. It is approved for the treatment of moderate-to-severe plaque psoriasis. Real-world evidence on the effectiveness and safety of tildrakizumab is limited.

OBJECTIVE: To evaluate the effectiveness, safety and survival of Tildrakizumab in the treatment of moderate-to-severe psoriatic patients over 78 weeks in routine clinical practice.

Materials & Methods: This is an observational, retrospective study of real clinical practice in adult patients with moderate-to-severe PSO treated with TIL 100mg subcutaneous every 12 weeks. The study was performed in 2 hospitals in Andalusia (Spain). A total of 64 patients with moderate-to-severe PSO were included in this study. Disease severity and treatment response was assessed by PASI, BSA, IGA and DLQI over 78 weeks. Data are presented as mean ± standard deviation for continuous variables, and number and percentage for categorical variables. Wilcoxon tests were performed to analyze possible differences between periods of time in PASI, BSA, IGA and DLQI scores (0 vs 12-16; 12-16 vs 24; 24 vs 48-52; 48-52 vs 78). Treatment survival was calculated using Kaplan–Meier survival analysis. All analyses were performed using GraphPad Prism version 8.3.0 for Windows (GraphPad Software, San Diego, California USA, www.graphpad.com").

Results: Our population composed by 64 patients with moderate-to-severe plaque psoriasis. They presented with a mean age of 51 years, 70.3 % were male, had a mean PSO evolution of 18.1 (11.5) years, a mean BMI of 32.0 (7.1). They also presented with other comorbidities: dyslipidemia (32.8%), arterial hypertension (40.6%); diabetes (18.8 %); psoriatic arthritis (17.2%); metabolic Syndrome (21.9%) and Non-alcoholic fatty liver disease (NAFLD) (25%). 9 psoriatic patients had diagnosis of neoplasia At baseline, disease parameters were: PASI=9.6 (4); BSA=14.3 (8.1); IGA=3.8 (0.6); DLQI=15.9 (5.9) .

After 12-16 weeks all disease parameters decreased showing statistically significant differences versus baseline: PASI = 3.2 (4.3) (p<0,0001); BSA = 3.4 (5.5) (p<0,0001); IGA= 1 (0.9) (p<0,0001) and DLQI = 3.6 (6.0) (p<0,0001). After 78 weeks of treatment, disease parameters still improved to: PASI=1.4 (1.6), BSA=1.7 (2.1), IGA=0.6 (0.6), DLQI=1.6 (1.4) . At week 78, the percentage of patients achieving PASI 75, 90 and 100 was 86.7%, 53.3% and 40% respectively . Furthermore, 93.3% patients were PASI <5, 73.3% were PASI <3 and 53.3% PASI <1 at 78 weeks . After 78 weeks of treatment, global treatment survival was 80.1% (included discontinuation by any cause) and 81.6% for survival due to lack of effectiveness or safety issues . There were 15/64 discontinuations (4 primary failure, 9 secondary failures), 2 discontinuations for reasons different than lack of effectiveness or safety). The treatment with tildrakizumab was safe, neoplasia progressions reported were not related to treatment.

Conclusion: Tildrakizumab showed effectiveness, safety and survival results in a cohort of patients with moderate-to-severe plaque psoriasis treated in a real clinical practice setting.

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Abstract N°: 6475

Bimekizumab, a novel anti -IL17A/17F agent for the treatment and long-term management of Generalized pustular psoriasis, two cases report

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Introduction & Objectives: Pustular psoriasis (PP) is a rare chronic inflammatory entity with sterile pustules that can be localized or generalized. Subtypes of pustular psoriasis include generalized pustular psoriasis (GPP), palmoplantar pustular psoriasis (PPP) and acrodermatitis continua of Hallopeau (ACH). PP often occurs with concurrent plaque psoriasis. While key inflammatory cytokines in plaque psoriasis are TNF-a/IL-23/IL-17/IL-22, recent data demonstrate that IL-36 pathway is a central axis driving the pathogenic inflammatory mechanism of PP. However, it appears that these two pathways cross-talk to each other and contribute to the pathophysiological mechanism of pustule formation. Up to date there is a lack of GPP treatment guiding. In Japan and other Asian countries several biologics are approved for the treatment of the disease including anti-TNFa agents, anti-IL-23 and IL17/IL17R inhibitors. Considering the advances into the pathophysiology, and the presence of preliminary data suggesting that Bimekizumab reduces IL-36 levels in the serum by simultaneously blocking IL-17A/17F, arises the question whether Bimekizumab could lead to clinical improvement in GPP.

Materials & Methods: We present two female patients -62 and 53 years old -with GPP for one and three years respectively. Both had more than four flares/year. Former had failed both MTX/ acitretin while later CyA/ acitretin. Both had GPPGA:4 (severe) and Bimekizumab was initiated along with topical steroids. Tolerance and potential adverse events were noted.

Results: Both patients had achieved a GPPGA total score of 0/1 by the end of week 3. Currently they are undergoing the sixth and tenth month of therapy respectively and still reserve great response while therapy is well tolerated as no side effect is detected.

Conclusion: Pustular form of psoriasis are chronic, inflammatory, debilitating disorders which are refractory or resistant to various treatments. GPP is a rare subtype that poses management challenges. Considering the nature of the disease there is a need of treatment that can rapidly and completely resolve symptoms with an acceptable safety profile. Some biologic agents that target key cytokines involved in the activation of inflammatory pathways have been used as treatments for GPP and are approved in Japan and other Asian countries. Recently spesolimab, an IL-36R antagonist has been approved for treatment of GPP flares in adults but still there is an unmet need for sustained treatment and long-term management. As IL-36 axis and IL23/IL17 axis may interconnect and act synergistically in the pathophysiological mechanism of pustule formation, IL-17 inhibition could be a therapeutic option. Bimekizumab is a novel anti-IL17A/F agent that has shown great efficacy in plaque psoriasis with a quick onset of action. As preliminary data suggest that Bimekizumab reduces IL-36 levels in the serum by simultaneously blocking IL-17A/17F, our cases suggest that agent could be an appealing approach for long-term management of GPP but more data are needed

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Abstract N°: 6492

Long-Term Real-World Achievement of Skin Clearance Treatment Targets With Persistent 24-Month Risankizumab Use in Patients With Moderate-Severe Psoriasis, With and Without Prior Biologic Experience, From the CorEvitas Psoriasis Registry

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Introduction & Objectives:

Risankizumab (RZB) is an interleukin-23 inhibitor that demonstrated efficacy in treating moderate-severe plaque psoriasis in phase 3 trials. This real-world study assessed the long-term effectiveness of 24-month RZB treatment, stratified by biologic experience, in patients with moderate-severe plaque psoriasis from the CorEvitas Psoriasis Registry, an independent, observational, prospective registry of patients with psoriasis in North America.

Materials & Methods:

This study included adult patients with moderate-severe plaque psoriasis (Investigator's Global Assessment ≥3) in the United States and Canada who initiated RZB at a baseline visit between April 2019–February 2022 and had persistent use after 24 (±3) months. Outcomes included the mean (standard deviation [SD]) improvement from baseline in Psoriasis Area and Severity Index (PASI) and body surface area (BSA); achievement of absolute PASI thresholds of 0, ≤1, and ≤3; achievement of National Psoriasis Foundation (NPF)-defined acceptable (BSA ≤3% or BSA improvement ≥75% from baseline) or target (BSA ≤1%) responses; and a Dermatology Life Quality Index (DLQI) score of 0/1 at 24 months. Analyses were stratified by prior biologic use (bio-naïve and bio-experienced). Maintenance of response at 24 months was assessed among patients with PASI 90 at 6 and/or 12 months and a follow-up visit.

Results:

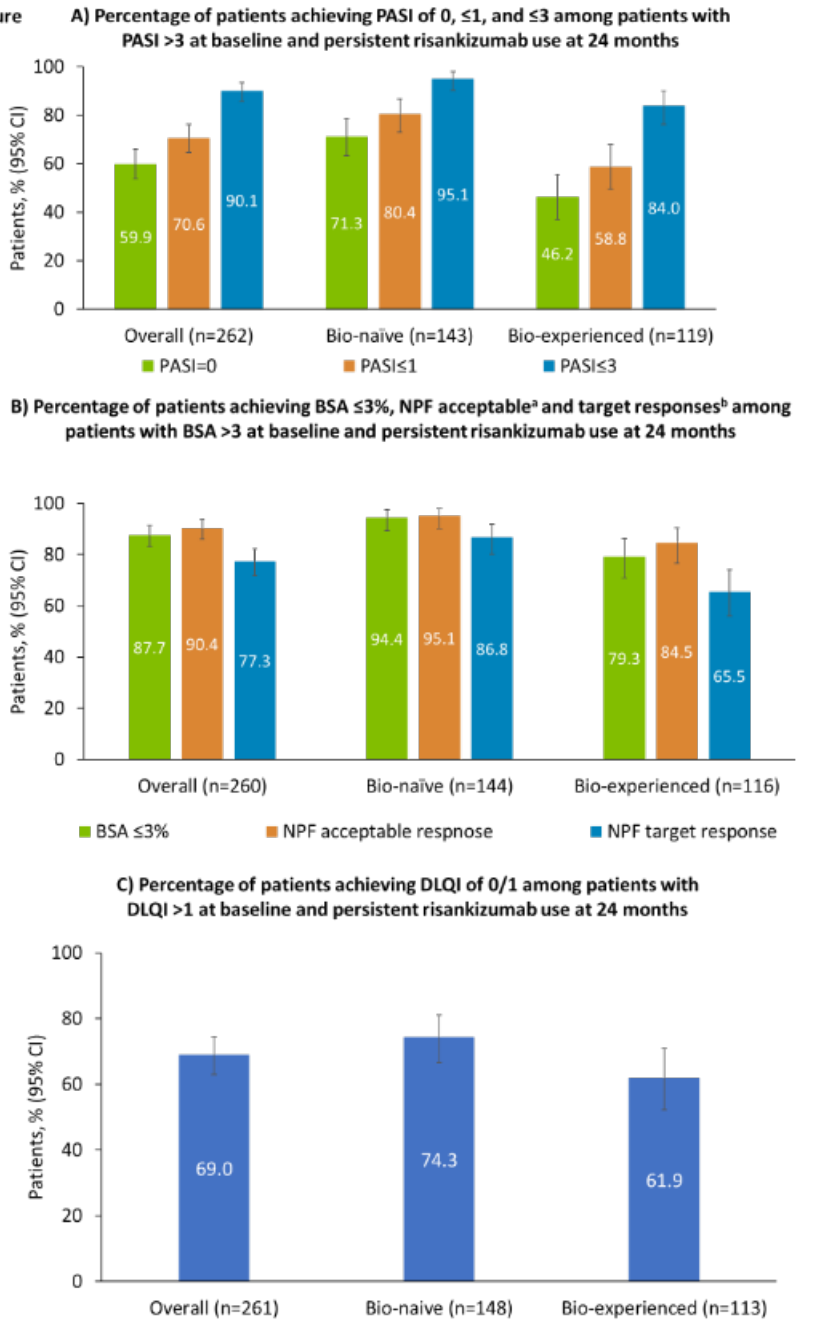
In total, 297 patients, mean (SD) age 48.1 (14.7) years and 43.1% female, were included in this analysis. At baseline, the mean (SD) psoriasis duration was 17.4 (14.0) years and 46.8% (n=139) were bio-experienced, with mean (SD) PASI of 10.2 (8.0) and mean (SD) BSA % involvement of 14.8 (15.3). At 24 months, RZB treatment significantly improved PASI (mean improvement (SD): 9.3 (7.7), p <0.001) and BSA (mean improvement (SD): 13.6 (15.1), p <0.001) from baseline, regardless of prior biologic use (all p<0.001); 24-month mean (SD) PASI was 0.9 (1.8) and mean BSA % was 1.2 (2.4). Among 262 patients with baseline PASI >3, 157 (59.9%), 185 (70.6%), and 236 (90.1%) achieved PASI thresholds of 0, ≤1, and ≤3 with 24-month RZB use, respectively (**Figure**). Similarly, among 260 patients with baseline BSA >3, 228 (87.7%), 235 (90.4%), and 201 (77.3%) achieved BSA ≤3, and NPF acceptable and target responses, respectively. In patients with DLQI>1 at baseline, 180/261 (69.0%) achieved DLQI of 0/1 at 24 months. Among 143 bio-naïve patients with PASI data, 102 (71.3%), 115 (80.4%), and 136 (95.1%) achieved PASI=0, ≤1, and ≤3, respectively; among 119 bio-experienced patients, 55 (46.2%), 70 (58.8%), and 100 (84.0%) achieved PASI=0, ≤1, and ≤3, respectively (**Figure**). BSA ≤3 and NPF acceptable and target responses were achieved by 136 (94.4%), 137 (95.1%), and 125 (86.8%) bio-naïve patients with BSA data (N=144), respectively, and 92 (79.3%), 98 (85.4%), and 76 (65.5%) of bio-experienced patients with BSA data (n=116). DLQI

0/1 was achieved by 110/148 (74.3%) and 70/113 (61.9%) of bio-naïve and bio-experienced patients, respectively (**Figure**). Finally, ≥85% of patients who achieved PASI 90 at 6 and/or 12 months and remained on RZB treatment for 24 months maintained their response.

Conclusion:

In a real-world setting, continuous 24-month RZB use was highly effective in achieving skin clearance and improved quality of life, regardless of prior biologic use, among patients with moderate-severe plaque psoriasis.

Figure



BSA, body surface area; CI, confidence interval; DLQI, Dermatology Life Quality Index; NPF, National Psoriasis Foundation; PASI, Psoriasis Area and Severity Index.
[a]BSA ≤3% or 75% improvement. [b]BSA ≤1%.

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AMSTERDAM 25-28 SEPTEMBER 2024
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Abstract N°: 6504

A rare cutaneous revelation : pustular psoriasis and its potential association with Fahr's syndrome. A case report

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Introduction & Objectives: Fahr's Syndrome (FS) is a rare entity characterized by bilateral and symmetrical intracerebral calcifications, often associated with disorders of phosphocalcic metabolism. The manifestations of this syndrome vary depending on its etiology, exceptionally with cutaneous involvement. We report a case of this syndrome secondary to postoperative hypoparathyroidism revealed by pustular psoriasis, emphasizing the diversity of symptoms associated with this condition.

Materials & Methods: This concerns a 63-year-old female, operated for a goiter 20 years ago, and currently managed for hypothyroidism with levothyroxine. She presents with pruritic, diffuse erythematous-squamous plaques associated with neurological manifestations, evolving for 7 months. Dermatological examination reveals erythematous plaques with thick whitish scales, non-infiltrated, and topped with pustules on the trunk. Biological tests show severe hypocalcemia (corrected calcium: 58 mg/L [88–105]), hypoparathyroidism along with deficiency in 25-OH-vitamin D2D3. Electrocardiogram showed electrical signs of hypocalcemia.** Given the association of pustular lesions, neurological signs, and hypocalcemia, Fahr's syndrome is suspected. Brain computed tomography scan supported this diagnosis. The patient urgently received intravenous calcitotherapy with vitamin D supplementation. After 2 weeks of treatment, there was a complete resolution of all symptoms, and normalization of corrected calcium in follow-up testing. Oral treatment was made of calcitotherapy at 3 g/day , alfacalcidol at dose of 3 µg/day, and vitamin D deficiency substitution at 25,000 IU/week, leading to a favorable outcome.

Results: Fahr's syndrome, a rare entity characterized by clinical variability, manifests with intracranial calcifications and neuropsychiatric disorders such as mental debility, intellectual deterioration, and behavioral disturbances. Diagnosis primarily relies on imaging studies, particularly brain scans, revealing symmetrical calcifications in the central gray nuclei and dentate nuclei of the cerebellum. **Dermatologically, Fahr's syndrome often exhibits skin manifestations linked to hypoparathyroidism and hypocalcemia. A rare association reported in the literature involves Fahr's syndrome and a pustular disorder resembling psoriatic pustulosis, though the precise connection between these entities remains incompletely understood. Studies suggest that calcium plays a crucial role in keratinocyte regulation, highlighting a significant relationship between Fahr's syndrome and pustular psoriasis. Our clinical observation underscores this important connection, the clinical symptoms disappeared once her calciumia levels normalized.** Conclusion:** Our patient developed iatrogenic hypoparathyroidism, leading to severe hypocalcemia that revealed Fahr's syndrome, manifested by pustular psoriasis. This emphasizes the importance of considering Fahr's syndrome in the presence of pustular psoriasis.

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Abstract N°: 6563

Development of a Novel Multidisciplinary Care Model for Screening and Managing Patients with Psoriatic Arthritis: Consensus Guidance for Primary Care Providers in Canada

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Introduction & Objectives: There is a significant unmet need for the timely assessment and diagnosis of psoriatic arthritis (PsA) in patients with psoriasis (PsO), and in confidently assessing therapy efficacy and safety. Pharmacists are uniquely positioned to help address this need; however, there is currently a lack of standardized clinical guidance for primary care providers following a PsO diagnosis and subsequent treatment initiation by rheumatologists and/or dermatologists. Therefore, our study aimed to develop consensus guidance for screening and managing patients for PsA and identify potential roles for pharmacists within the multidisciplinary care team to facilitate timely specialist access and improve patient outcomes.

Materials & Methods: We used a modified DELPHI process to gather insights on screening practices, quality of life (QoL) monitoring, and lifestyle counselling from 11 Key Opinion Leaders across Canada, which included pharmacists, rheumatologists, and dermatologists. Consensus was reached for each criterion when 75% agreement was achieved, and clinical guidance was developed to facilitate best practices in PsA screening and management.

Results: Dermatologists and family physicians were identified as the healthcare providers (HCPs) best positioned to screen PsO patients with a confirmed dermatologist diagnosis for PsA. It was recommended that screening be performed every 6-12 months through in-person or virtual/telephone appointments, with self-reporting questionnaires providing an opportunity to streamline the screening process. Dermatologists and Rheumatologists were identified as the most appropriate HCP for monitoring QoL in patients with PsO and PsA, respectively. It was recommended that methods for PsA screening and QoL monitoring should ultimately be at the discretion of the responsible HCP, though PEST was identified as a preferred tool for PsA screening. Pharmacists were identified as being best positioned to monitor drug safety, assist with reimbursement, and counsel patients on health and lifestyle considerations including smoking, alcohol consumption, maintaining a healthy body weight, and remaining up to date on vaccinations.

Conclusion: Effective screening and management of PsA in patients previously diagnosed with PsO requires a multidisciplinary approach. The consensus-derived guidance provides a valuable and novel framework for the multidisciplinary management of PsA in Canada, with pharmacists being uniquely positioned to help address some of the current gaps in care. Implementing these best practices has the potential to reduce delays in diagnosing and initiating treatment for PsA in patients with PsO and improve overall patient outcomes.

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Abstract N°: 6603

Effectiveness and safety of bimekizumab in psoriatic disease: monocentric retrospective observational study in real clinical practice.

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Introduction & Objectives: Bimekizumab is the first selective dual IL-17 A and F inhibitor approved for the treatment of psoriasis, psoriatic arthritis, and axial spondyloarthritis. Bimekizumab has demonstrated efficacy and safety both in the treatment of psoriasis, demonstrating superiority to the inhibition of IL-17 A alone, and in psoriatic arthritis, both at the peripheral and axial level. The objective of this study is to evaluate the effectiveness and safety of bimekizumab in our patients with psoriatic disease

Materials & Methods: We present a monocentric retrospective observational study in patients with moderate-severe psoriasis treated with bimekizumab under routine clinical practice conditions. Demographic and clinical characteristics were collected at baseline and PASI response at weeks 4 and 12-16 was analyzed, as well as reported adverse effects.

Results: A total of 13 patients were included, 69% men, with an average age of 52.9 (± 13.4) years and a BMI of 29.0 (± 6.6) kg/m2. 39% had concomitant psoriatic arthritis. At baseline, the average PASI was 11.8 (± 7.2), BSA 10.3 (± 9.0), and DLQI 21.3 (± 2.2). At week 4, after a single dose of bimekizumab, the mean PASI was reduced to 2.4 (± 1.5) and at week 12-16 to 1.0 (± 1.4). Skin clearance was achieved regardless of patient characteristics or psoriasis location. Patients with concomitant psoriatic arthritis experienced rapid and clinically relevant improvements already from the first dose. Bimekizumab was well tolerated and no adverse effects were reported.

Conclusion: The effectiveness of bimekizumab observed in our patients confirms or even exceeds that reported in clinical trials, without new safety alerts. Speed in treatment is crucial especially when psoriasis has a high impact on quality of life, and in case of joint involvement, where there is a risk of structural progression. We highlight the speed of action of bimekizumab, both at the skin and joint level. Bimekizumab is presented as a highly effective therapeutic alternative, providing rapid and clinically relevant improvements that significantly reduce the impact of psoriatic disease on patients' quality of life.

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Abstract N°: 6691

Prevalence and predictive factors of Self-Medication in people with psoriasis: a worldwide study. The results of ALL project

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Introduction & Objectives:

The World Health Organization (WHO) defines self-medication (SM) as the "utilization of medicinal products by individuals to address self-identified ailments or symptoms, or the occasional or ongoing use of medication prescribed by a healthcare provider for chronic or recurrent conditions or symptoms." However, there is insufficient data regarding the prevalence of SM among individuals with psoriasis. This study aimed to examine the occurrence of SM among people living with psoriasis and assess the factors that might predispose individuals to engage in SM practices.

Materials & Methods:

This online survey was conducted on a representative sample of the population of psoriasis patients from 20 countries, aged 16 years or more. The questionnaire gathered information about demographics, about any dermatological condition that occurred in the past 12 months and about any feelings of stigma. . Responders were considered to be self medication user if they reported that they managed very well on their own.. A comparison of SM and non-SM patients was used to evaluate SP predictors: socio-demographic, clinical parameters, psychological impact on self-perception, relationships, daily life and social or professional life. Statistical analysis was performed using EasyMedStat (version 3.34; www.easymedstat.com).

Results:

A population of 992 psoriasis sufferers was selected, including 541 (54.5%) males and 451 (45.5%) females (mean age 47.8 +/- 15.5, min 16-85 years). 76 (7.7%) are SM users, of which 47.4% are men, with a mean age of 50.18 (± 14.88) years. None of the SM users had consulted a doctor in the last 12 months. Regarding the last doctor they consulted for their psoriasis, they were more likely to consider that the time spent was not sufficient (60.5% vs 39.1%, $p \leq 0.05$), that the explanations given were not satisfactory (61.8% vs 39.3%, $p \leq 0.05$) and that the care offered was not satisfactory (65.8% vs 42.4%, $p \leq 0.05$). Predictive factors for SM are retirement (42.1% vs. 31.5%, $p \leq 0.05$), absence of symptoms (43.4% vs. 24.3%, $p \leq 0.05$), belief that psoriasis is not severe enough (39.47% vs. 21.16%, $p \leq 0.05$). Lack of time (6.58% vs. 3.28%, NS) and lack of financial means (3.95% vs. 2.95%, NS) are not predictive factors for SM. SM users tend to search more often on specialised health sites. (11.84% vs 0.0%, $p \leq 0.05$), regularly browse blogs dedicated to my skin condition (9.21% vs 0.0%, $p \leq 0.05$) and regularly read health magazines (6.58% vs 0.0%, $p \leq 0.05$).

SM users were less likely to use a psoriasis treatment (40.8% vs 75.3%, $p \leq 0.05$). They are less likely to use topical treatments based on dermo corticoids (39.5% vs 64.3%, $p \leq 0.05$) and alternatives (6.4% vs 24%, $p \leq 0.05$). On the other hand, they were more likely to use dermo cosmetic creams (products applied to the skin and available in

pharmacies without prescription) (26.3% vs. 16.6%; , p ≤ 0.05).

Conclusion:

Self-medication represents a significant but often overlooked issue among individuals with psoriasis, stemming from various contributing factors. Engaging in self-medication practices may hinder the timely implementation of effective medical interventions for psoriasis. Therefore, it is crucial to mitigate its adverse effects by educating patients, enhancing the quality of doctor-patient interactions, and employing the most effective treatment strategies available.

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Abstract N°: 6696

Importance of engaging with psoriasis-related social media influencers and bloggers for patients with psoriasis under treatment.

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Introduction & Objectives:

Social networks have emerged as crucial platforms for accessing dermatological and therapeutic information. Social media influencers now wield significant influence in disseminating health-related content and shaping health behaviours. Particularly noteworthy is the impact of interacting with social media figures, such as influencers and bloggers, during periods of heightened susceptibility to influence. However, there is limited understanding of the significance of engaging with psoriasis-related social media influencers (PSMIs) among patients undergoing treatment for psoriasis. Thus, this study aimed to evaluate the prevalence of PSMI engagement among psoriasis patients, analyse the effects of PSMIs on patient concerns and treatment adherence, and assess patient satisfaction with dermatological care.

Materials & Methods:

Patients with psoriasis were selected through an online survey of the general population over the age of 16 in 20 countries worldwide. As the study used anonymous data and did not involve clinical examination, institutional review board approval was not required. Psoriasis was self-reported by patients on the basis of a doctor's diagnosis. The questionnaire was developed in partnership with patient organisations and continues to focus on the patient's experience. A comparison was made between those who did and did not use the Internet to obtain information or discuss their condition with PSMI to assess predictors of engagement with PSMI such as socio-demographic and clinical characteristics, type of treatment, fear of side effects, feelings of discouragement to continue treatment and satisfaction with the treating physician.

Results:

A population of 721 patients with psoriasis receiving conventional treatment was selected, including 395 (54.8%) men and 326 (45.2%) women (mean age 48.5+/- 15.2. min 16-85 years). 73 (10.1%) were receiving injectable medications, 200 (27.7%) were receiving oral medications and 619 (85.9%) were receiving topical medications administered by a healthcare professional [HCP] . 52 (7.2%) of the 721 respondents who had received conventional treatment were PSMI users: 8 (11%) with injectable treatment, 25 (12.5%) with oral medication and 44 (7.1%) with topical medication. PSMI users were younger (40.58 vs 49.1%, $p \leq 0.05$). There was no male predominance (59.6% vs 54.4%, p NS). PSMI users were more likely to report concerns about adverse effects (63.5% vs 43.5%, $p \leq 0.05$), 57.5% of PSMI users with injectable treatment, 56% with oral treatment and 40.4% with topical treatment. PSMI users were not more likely to experience treatment fatigue (59.6% vs 51.3%, p NS). PSMI users were no less likely to think that the time spent by the health professional was insufficient (36.5% vs 27.9%, p NS), that the explanations given were unsatisfactory (34.6% vs 28.1%, p NS) and that the treatment proposed was satisfactory (69.2% vs 67.9%, p NS).

Conclusion:

This study marks the inaugural exploration of engagement with PSMIs among patients receiving treatment for psoriasis. Our findings reveal heightened levels of concern among psoriasis patients who engage with PSMIs. However, we did not observe any correlation between interaction with psoriasis-related social media influencers, including bloggers, and satisfaction with HCPs. It is noteworthy that influencers possess a unique capacity to influence the emotions, thoughts, and behaviors of their followers, both knowingly and unknowingly.

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Abstract N°: 6762

The myriad manifestations of psoriatic erythroderma : A case series

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Introduction & Objectives:

Erythroderma is a rare condition characterised by exfoliation and erythema involving more than 90% of the body surface area. Eczema and psoriasis are the two common dermatological conditions presenting with erythroderma. We present here a series of ten cases of psoriatic erythroderma to highlight the wide variety of presentations and possible differentials.

Materials & Methods:

This series comprises of ten cases of psoriatic erythroderma who were admitted and treated at the dermatology department of a tertiary care hospital.

Results:

Six of our patients were male and the other four, female with ages ranging from 13 years to 70 years. All the patients presented with extensive scaling and erythema with systemic features like fever. Plaques suggestive of psoriasis were seen only in one patient, extensive pustular psoriasis was seen in two patients while the other patients did not have any specific clinical signs suggestive of psoriasis. Nail involvement was seen in all the patients but the changes were non specific in some cases. Scalp involvement was seen in all the patients. Of this series, 3 patients had recurrent episodes of erythroderma, with similar complaints in the past. None of the patients was on systemic treatment at the time of presentation. All the patients had used topical steroids for varying durations prior to presentation. All the patients with one exception were diabetic and hypertensive and 6 had features suggestive of metabolic syndrome. The patients with more severe co morbidities had frequent episodes of erythroderma. Frequently the erythroderma was precipitated by infection and in one case, by herbal medicine. Biopsy showed features suggestive of psoriasis in all cases.

Eight of the patients were treated with Cyclosporine while two patients in whom Cyclosporine was contraindicated were managed with oral steroids and Azathioprine. Most of the patients had partial clearance within two weeks of treatment and all of them are on regular follow up with maintenance therapy (Methotrexate, Azathioprine, Acitretin).

Conclusion:

Psoriatic erythroderma is clinically challenging to manage based on the morphology alone and most of these patients were referred to our centre with various other diagnoses. The confounding clinical features lead to misdiagnosis and delay in initiation of appropriate therapy. Biopsy is a useful tool to confirm the diagnosis. Cyclosporine had high efficacy in the management of this condition.

References :

1. Askin O, Altunkalem RN, Uzuncakmak TK, Toplu FŞ, Engin B. Erythroderma: A clinicopathological study of 47 cases from 2018 to 2020. Dermatologic Therapy. 2020 Nov;33(6):e14342.

2. Miyashiro D, Sanches JA. Erythroderma: a prospective study of 309 patients followed for 12 years in a tertiary center. Scientific reports. 2020 Jun 17;10(1):9774.
3. Ghalamkarpour F, Pourani MR, Abdollahimajd F, Zargari O. A case of severe psoriatic erythroderma with COVID-19. Journal of Dermatological Treatment. 2022 Feb 17;33(2):1111-3.
4. Reynolds KA, Pithadia DJ, Lee EB, Liao W, Wu JJ. A systematic review of treatment strategies for erythrodermic psoriasis. Journal of Dermatological Treatment. 2021 Jan 2;32(1):49-55.

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Abstract N°: 6765

Expression of IL-7 receptor on Th1,Th17 lymphocytes from peripheral blood in psoriatic arthritis.

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Introduction & Objectives:

Psoriatic arthritis (PsA) is a chronic immune-mediated inflammatory disease of the joints, spine and entheses that can occur in patients with psoriasis. The pathogenesis of PsA is based on the activation of Th1, Th17 cells. Pro-inflammatory cytokines produced by the cells are involved in the cascade of reactions leading to the joint deformation and bone destruction. For some autoimmune diseases associated with the Th1/Th17 response, IL-7 has been found to be involved in pathogenetic mechanisms. At the same time, IL-7 is assumed to support autoreactive T lymphocytes. Effect of the cytokine on cells is provided by the binding to a specific receptor thus causing a signal transmission into the cell and inducing the processes of differentiation, proliferation, and production of cytokines. In animal models of autoimmune diseases, it was shown that usage of blocking antibodies to α-chain of the IL-7 receptor (IL-7R) caused the reduction of inflammation in target tissues and the decrease in number of infiltrating T lymphocytes.

The aim of this study was to investigate the contents of Th1, Th17 lymphocytes and expression of IL-7 receptor subunits on cells from those T lymphocyte subpopulations in patients with psoriatic arthritis and heathy individuals.

Materials & Methods:

The study included patients with psoriatic arthritis (PsA, n = 13) with low, moderate and high disease activity according to indexes DAPSA and PASI, and healthy individuals (n = 9). Flow cytometry was used to determine the expression of IL-7 receptor subunits (CD127, CD132) and to assess cell phenotypes from peripheral blood samples. Th1 cells was phenotyped as CD3+CD4+CD183+ cells and Th17 cells - CD3+CD4+CD161+ cells.

Results:

We have found no differences in the amount of Th17 cells between investigated groups. But In PsA, an increase in CD127+CD132- and CD127+CD132+ cells among Th17 lymphocytes was detected compared to donors. We have shown that patients with high activity of PsA by DAPSA have a decreased number of Th1 lymphocytes compared to patients with modearate activity of PsA and healthy donors. However, among Th1 lymphocytes of patients with PsA, it was found an increase of cells expressing IL-7 receptor subunits: CD127+CD132-, CD127-CD132+, CD127+CD132+. There was no sighnificant difference between content of Th1, Th17 cells, the expression of IL-7 receptor subunits by Th1, Th17 cells and disease severity indexing by PASI.

Conclusion:

Thus, our study showed that in patients with PsA, the expression of CD127 and CD132 on the populations of Th1 and Th17 lymphocytes from peripheral blood is increased relative to that of healthy individuals.

These results may contribute to the better understanding of the pathogenesis of psoriatic arthritis, and also serve as a basis for selecting the IL-7 receptor as a target in the development of new treatment for psoriatic arthritis.

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Abstract N°: 6831

Best responders to calcipotriol and betamethasone dipropionate PAD-cream: post-hoc analysis from pooled MC2-01-C2 and MC2-01-C7 phase III trials at week 4 and week 8

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Introduction & Objectives: A calcipotriol (CAL) and betamethasone dipropionate (BDP) cream based on polyaphron dispersion (PAD) technology emerged as a novel formulation for a more convenient topical treatment of psoriasis. Individual endpoints from two phase III clinical trials revealed high efficacy, a favourable safety and tolerability profile and convenience for CAL/BDP PAD-cream compared to CAL/BDP gel.1 This *post-hoc* analysis aimed to assess the proportion of best responders to CAL/BDP PAD-cream at week (W) 4 and W8 and to identify the key baseline (BL) characteristics associated with best response among CAL/BDP PAD-cream users.

Materials & Methods: *Post-hoc* pooled analysis of adult patients with mild-to-moderate psoriasis from two multicentre, randomized, investigator-blind, active and vehicle-controlled trials: MC2-01-C2 and MC2-01-C7. Patients were randomly assigned in a 3:1:3 ratio to CAL/BDP PAD-cream, PAD-cream vehicle or CAL/BDP gel once daily. Detailed methodology has previously been published.1 Best responders at W4 and W8 were defined as those achieving the following composite endpoint: Physician's Global Assessment (PGA) controlled disease (i.e., any improvement in PGA to score of 0-1 from BL), with modified Psoriasis Area and Severity Index (mPASI) success (i.e., mPASI <2) and Dermatology Life Quality Index (DLQI) satisfaction (i.e., DLQI 0-1). Comparison of best response rates between treatment arms were performed by logistic regression models using multiple imputation. Additionally, a Classification and Regression Tree (CART) model based on observed cases was used to identify the key BL characteristics associated with best response at W4 and W8 only among the CAL/BDP PAD-cream arm and totally independent of data in other arms. All analyses were performed for the modified intention-to-treat (mITT) population, which includes all randomized patients who were treated and had at least one efficacy assessment after starting treatment.

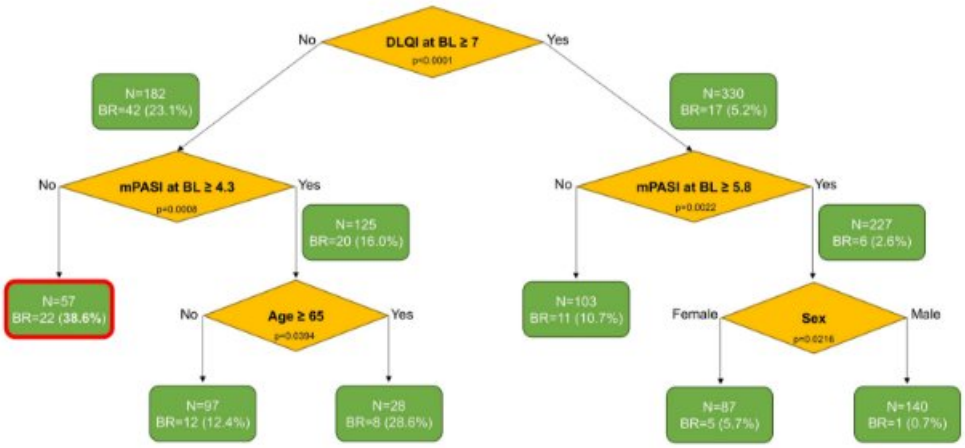
Results:* The mITT included 1271 patients (551 patients on CAL/BDP PAD-cream, 542 on CAL/BDP gel and 178 on vehicle). A statistically significant higher proportion of best responders were observed in the CAL/BDP PAD-cream group (11.0%) compared to both CAL/BDP gel (6.2%; p=0.0048) and vehicle (0.0%; p=0.0004) as early as W4. Differences between groups were further accentuated at W8, with a statistically significant higher proportion of best responders in the CAL/BDP PAD-cream group (27.6%) compared to CAL/BDP gel (16.1%; p<0.0001) and vehicle (3.9%; p<0.0001). Regarding the BL profile of CAL/BDP PAD-cream best responders, 22 out of 57 patients (38.6%) with a BL DLQI <7 and mPASI <4.3 achieved best response at W4 (Figure 1A), while 28 out of 44 patients (63.6%) with a BL DLQI <7 and mPASI <4.0 achieved best response at W8 (Figure 1B).

Conclusion: A higher percentage of best response was seen for CAL/BDP PAD-cream compared to both CAL/BDP gel and vehicle in adults with mild-to-moderate psoriasis. At W8, approximately one out of three patients treated with CAL/BDP PAD-cream achieved the restrictive composite endpoint of best response (i.e., PGA controlled disease + mPASI <2 + DLQI 0-1), which represents a status of minimal/no disease activity. BL DLQI and mPASI scores may predict which patients are most likely to achieve the best response to CAL/BDP PAD-cream.

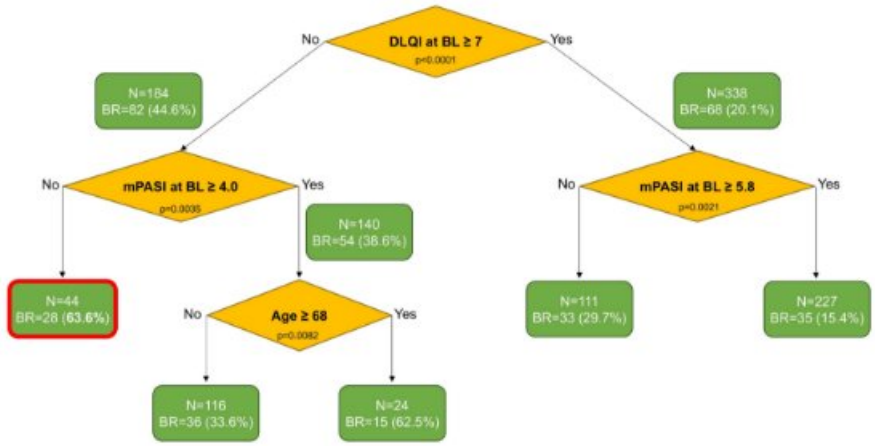
References: 1Pinter A, et al. J Eur Acad Dermatol Venereol. 2022;36(2):228-236.

Figure 1. Decision tree of CART model applied on the CAL/BDP PAD-cream arm to identify the key baseline characteristics associated with best response at Week 4 (A) and Week 8 (B)

A)



B)



Note: CART model is based on observed cases from the CAL/BDP PAD-cream arm at W4 (n=512) and W8 (n=522). The subgroup with the highest best response rate is marked with a red square. P-values represent Chi-square test results of binary or dichotomized parameters, where the parameter with the smallest p-value defines the split.

BDP, betamethasone dipropionate; BL, baseline; BR, best responders; CAL, calcipotriol; CART, Classification and Regression Tree; DLQI, Dermatology Life Quality Index; mPASI, modified Psoriasis Area and Severity Index; PAD, polyaphron dispersion.

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Abstract N°: 6858

Psoriasis Patient perspectives on Cardiovascular Risk, Screening and Management

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Introduction & Objectives:

Patient perspectives on psoriasis as a systemic disease, with it's heightened risk of cardiovascular (CV) disease is unclear. Approaches to CV risk factor screening and management vary in this cohort. This study aimed to ascertain knowledge, perceptions, practice and preference of patients with respect to psoriasis and CVD, CV risk factor screening and management.

Materials & Methods:

This cross-sectional study consisted of a self-administered questionnaire capturing demographic characteristics, knowledge of association between psoriasis and CVD and perspectives on CV screening and management. This was distributed to psoriasis patients in public and private clinic settings and those affiliated with patient support groups. The survey data was assessed with the use of descriptive statistics.

Results:

A total of 103 psoriasis patients were surveyed. The majority of respondents were male (52%), 46-60 years (40.4%), with longstanding psoriasis (>20 years), 42.2.%. Most patients nominated a dermatologist in a public hospital setting as the primary clinician responsible for their psoriasis management (87.4%). Only 20.6% psoriasis patients surveyed indicated knowledge of the association between CVD and psoriasis and 22.5% of patients agreed that psoriasis was associated with worse CV outcomes compared to the general population. 63.7% indicated they had undergone CV risk factor screening in the last year, with most nominating GPs 17.6%, followed by Cardiologists 14.1%, then Dermatologists 6.9%, as the clinician who performed this CV screening. 68.6% indicated they were not known to a Cardiologist for their heart health. 34.3% nominated a Cardiologist as their preferred clinician to facilitate CV risk factor screening and management, 23.5% indicated preference for a multidisciplinary team, 17.6% nominated GPs, and 6.9% nominated the Dermatologist.

Conclusion:

There is need for improved patient education regarding the relationship between psoriasis and CVD. Heightened awareness around incumbent cardiovascular risk may serve as impetus for patients to seek relevant cardiovascular risk factor screening, management and pursue healthy lifestyle behaviours. Despite a lack of awareness regarding CV risk, psoriasis patients nominated a preference for sub-speciality cardiology input and multidisciplinary care with respect to screening and management of CVD risk.

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Abstract N°: 6861

Efficacy of Ixekizumab in patients of psoriasis with treatment failure in South Asian population

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Introduction & Objectives: Psoriasis vulgaris is a chronic, remitting and relapsing, autoimmune papulosquamous inflammatory disorder. It affects about 1-3% of human population. It has been recognized to be a systemic disorder and is associated with arthritis, cardiovascular disorders, obesity, metabolic syndrome, depression, etc. Conventional mode of treatment includes cytotoxic and immunomodulatory molecules like methotrexate, cyclosporin, acitretin, apremilast, tofacitinib, etc. Many of them are associated with end organ damage and require regular periodic monitoring. The newer mode of treatment includes biologic drugs which are more targeted and block vital steps in the pathogenesis of psoriasis and are safer as compared to the conventional drugs. Currently available biologics and biosimilars in our country include Etanercept, Infliximab, Adalimumab, Secukinumab and Ixekizumab. Ixekizumab was introduced last year in 2023 and is the newest biologic available. The efficacy of Ixekizumab is believed to be the highest amongst the available biologics. Treatment failure is a distinct possibility with any of the treatment modalities, which can be both primary and secondary. The purpose of this observational study was to evaluate the efficacy of Ixekizumab in patients who had experienced treatment failure with other therapies.

Materials & Methods: Over a period of 9 months from April 2023 to December 2023, 6 patients (5 male and 1 female) were initiated into Ixekizumab therapy who had failed previous treatments, both conventional and biologics. 2 patients were of chronic plaque psoriasis, 2 of palmo-plantar psoriasis and 2 of scalp psoriasis. 3 patients were on Methotrexate, 2 on Secukinumab and 1 on cyclosporine before they failed therapy. 2 patients had primary failure and 4 had secondary failure. No additional tests were done since they were already under treatment. The standard protocol of Ixekizumab was followed. Ixekizumab is available as 80mg pre-filled syringes for subcutaneous use. On day 0, a loading dose of 160mg was given. Later at weeks 2, 4, 6, 8, 10 and 12 a dose of 80mg was given. Since the patients were of different clinical types of psoriasis, no single scoring system could be used for evaluation. Instead, both, the physician and the patients were asked to evaluate the efficacy on a scale of 1 to 5 with 1 (0-20%), 2 (21-40%), 3 (41-60%), 4 (61-80%) and 5 (81-100%) improvement, at the end of 16 weeks of treatment.

Results: All the patients showed considerable improvement with both the clinician’s and patient’s score in the range of 3 to 5 at the end of 16 weeks of treatment. All the patients who had previously failed treatment, responded to Ixekizumab

Type of psoriasis	Physician efficacy score	Patient (self) efficacy score
P1 Chronic plaque	4	4
P2 Chronic plaque	4	4
P3 Palmoplantar	4	3
P4 Palmoplantar	3	4
P5 Scalp	4	4
P5 Scalp	4	3

Conclusion: Ixekizumab is a humanised monoclonal IgG4 antibody against Il-17A receptor. It is approved for the treatment of patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Compared to the other biologics available in our country, it has a faster onset of action and provides rapid relief to the patients. In our study, where all the patients had failed on previous treatments, it showed an excellent improvement. Ixekizumab is an efficacious option for not only starting treatment naive patients into biologic therapy but also, for patients with treatment failure.

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Abstract N°: 6911

Interleukin-23 Inhibition in Obese Patients with Plaque Psoriasis: A 2-Year, Real-World, Single-Center Retrospective Study

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Introduction & Objectives: Obesity, defined as body mass index (BMI) ≥ 30 kg/m2, is one of the most prevalent comorbidities of psoriasis and has been identified both as a risk factor for the development of the disease and as a marker of greater disease severity. Previous studies have demonstrated that obesity may negatively affect the response of psoriasis patients to biological therapies such as those targeting tumor necrosis factor (TNF) and interleukin (IL)-17, while the exact pathophysiological mechanisms behind this phenomenon are not fully understood. However, the impact of obesity on the effectiveness of other biologics, such as IL-23 inhibitors, has not been thoroughly investigated and the available literature is still limited. The aim of this study was to evaluate the effectiveness and safety of two IL-23 inhibitors, risankizumab and guselkumab, in obese patients with psoriasis in a real-world setting.

Materials & Methods: We conducted a retrospective, single-center study and reviewed medical records of all patients with moderate-to-severe plaque psoriasis that had received at least one dose of either risankizumab or guselkumab. Patients with a BMI ≥ 30 kg/m2 at the time of drug initiation were included in the study. Data on the effectiveness and safety were reviewed for each available visit and for up to 2 years (104 weeks).

Results: We identified and included 114 (80 risankizumab, 34 guselkumab) patients in total, with 30.7% of them being female. The mean age at the time of drug initiation was 53.18 years and the average disease duration was 20.03 years. The mean BMI was 35.11 kg/m2 with 75.4% of the cohort suffering from at least one medical comorbidity. Metabolic disorders affected 59%, cardiovascular disorders 43% and psychological/psychiatric disorders 16.7% of patients. Concerning difficult-to-treat areas, 64% of patients suffered from scalp psoriasis, 53.5% from nail psoriasis and 31.6% had genital area involvement. Psoriatic arthritis was present in 21.1% of patients. The mean baseline psoriasis area severity index (PASI) (SD) was 8.97 (7.02). At weeks 12/24/52/104, the mean PASI (SD) was reduced to 0.86 (1.39)/0.73 (2.07)/0.7 (1.7)/0.67 (1.89), respectively. At 12 weeks of treatment, PASI75/PASI90/PASI100 responses were achieved by 83.3/66.7/58.9% of patients, at 24 weeks by 89.3/84.5/77.4%, at 52 weeks by 88.6/81.0/72.2% and at 104 weeks by 89.7/84.6/74.4% of patients, respectively. At 52 weeks 89.9% and at 104 weeks 92.3% had a PASI score ≤2. During the observation period, no serious adverse events were reported.

Conclusion: Our findings are in accordance with the limited available literature and suggest that IL-23 inhibitors are effective and safe therapeutic options for obese patients suffering from psoriasis. Nevertheless, prospective studies with large number of patients are needed in order to draw stronger conclusions.

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Abstract N°: 7015

Towards an international consensus on outcomes that matter to patients with psoriasis: a modified Delphi study

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Introduction & Objectives:

Measuring outcomes that matter to patients is key in the concept of Value-Based Healthcare (VBHC) and international consensus on which outcomes that should be measured in the field of dermatology is still lacking, also in the context of psoriasis. Psoriasis is a chronic inflammatory skin disease, known to have a high impact on patients' physical, psychological, and social functioning. In recent work, we have proposed a 'value-based outcome set' aiming to define which outcomes that matter to patients. However, the relevance of these outcomes and the feasibility of using the outcome set in clinical practice may vary across countries, which is why international validation is needed. The aim is to define a standardized value-based outcome set for patients with psoriasis through international expert consensus.

Materials & Methods:

A Delphi study will be conducted in accordance with the ICHOM guidelines to reach consensus. Patient-relevant outcomes will be identified through a systematic review first. An international working group consisting of patient representatives and healthcare professionals will be set up and meet on regular basis to obtain relevant input. Experts will be recruited through the International Psoriasis Council (IPC) and the International Federation of Psoriasis Associations (IFPA) to obtain a mix of patients and healthcare professionals. Consensus will be obtained for the following dimensions: outcomes and definitions, outcome measures and case-mix variables. The exercise will run from September 2024 to February 2025.

Results:

Results from the input meetings with the working group will serve as a basis to conduct the Delphi survey. Consensus is expected after two rounds and will be reached when the working group votes surpass the threshold of 80% agreement.

Conclusion:

This international value-based outcome set will be the first in the field of dermatology and will empower the use and measurement of standardized outcomes in daily clinical practice, which is essential when adopting the principles of VBHC. The use of this outcome set will allow international benchmarking and support continuous improvement of patient value in the context of psoriasis care.

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Abstract N°: 7053

Infantile generalized Blaschkolinear psoriasis

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Introduction & Objectives:

Blaschkolinear psoriasis (BLP) is a rare form of psoriasis first described in 1951. It is characterized by a linear distribution of psoriatic lesions along Blaschko's lines. BLP is exceedingly rare in children, with only a handful of pediatric cases reported in the literature so far.

Materials & Methods:

We describe a new observation of an infantile BLP with an unusual generalized distribution.

Results:

An otherwise healthy 3-year-old boy presented with generalized scaly erythematous plaques in a linear pattern. The lesions appeared at seven months on his right leg and rapidly spread over his trunk and limbs. By the age of one year, he had generalized involvement including face and scalp. There was no pruritus or other symptoms. The patient did not take any medications and his medical history was unremarkable. There was no family history of psoriasis or similar skin lesions. Dermatologic examination revealed generalized scaly erythematous plaques distributed along Blaschko's lines, arranged in transverse S-shaped lines on the trunk and as longitudinal lines on the extremities. Scalp and face were involved. There were numerous linear hypopigmented scar lesions. In continuation with linear plaques, the toenails presented onycholysis with xanthonychia and fingernails had pitting with central depression. Palms and soles, as well as mucous, were normal. Dermoscopic examination showed whitish scales and dotted vessels in uniform distribution. Histopathology examination revealed psoriasiform pattern, with epidermal parakeratosis, acanthosis, regular elongation of rete ridges, suprapapillary thinning, Munro's microabcesses and hypogranulosis. In the dermis, capillaries were dilated and a lymphocytic inflammatory infiltrate was present. On the basis of clinical, dermoscopic and histopathological findings, the diagnosis of BLP was made. The eruption was poorly controlled by topical steroids and vitamin D analogues. Treatment was started with acitretin 0.7 mg/kg daily with beginning of improvement within four weeks.

Conclusion:

Epidemiological data of BLP are scarce, particularly for children. Only thirteen cases of pediatric patients have been reported in the literature so far. BLP was mainly localized with unilateral involvement. Generalized presentation has only been described in a single case of a 10-year-old girl. The pathogenesis remains unclear, but it could be explained as a result of the migration of cells carrying a somatic mutation following Blaschko's lines during early embryogenesis. BLP can coexist with non-segmental plaques of psoriasis; this is termed superimposed linear psoriasis. It can also occur as the only manifestation of psoriasis, where there are no psoriatic lesions presenting outside of the Blaschko distribution, as in our case. The diagnosis is usually challenging for dermatologists and should be differentiated from other linear dermatoses with Blaschkoid distribution. For this reason, some cases of BLP probably go unreported. The main differential diagnosis is inflammatory linear verrucous epidermal nevus. There are no specific therapeutic recommendations in BLP. Topical steroids and vitamin D analogues are the mainstream treatment for localized BLP. Phototherapy, systemic antipsoriatic agents, and biologics should be considered in extensive and recalcitrant cases. This case reminds dermatologists to consider psoriasis in the

differential diagnosis of generalized Blaschkoid dermatoses.

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Abstract N°: 7128

A Digital Tool Connecting Patients with the HealthCare System Through Psoriasis Virtual Community

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Introduction & Objectives:

Virtual communities in healthcare are part of consumer health informatics and integrate patients' opinions with medical experience and scientific knowledge based on the best available evidence.

We launched the first psoriasis virtual community in October 2019, entirely managed by dermatologists, self-funded and free of charge.

We wanted to know the impact of participating in the psoriasis virtual community.

Although there are many digital tools available, scarce has an evaluation of real-world impact.

The objective was to identify an association between participation in the virtual community and seeking attention related to psoriasis disease from dermatologists and rheumatologists.

Materials & Methods:

We conducted a retrospective cohort study, including patients over 18 years old who completed at least one questionnaire on the platform within the first two years of the psoriasis virtual community´s launch. Follow-up spanned two years.

Results were presented as absolute values and percentages for categorical variables and as mean with standard deviations for continuous variables. We employed a multivariable logistic regression model to analyze the association between visits to dermatologist and rheumatologist, and psoriasis severity and suspicion of psoriasis arthritis, respectively. Statistical significance was set at $p<0.05$.

Results:

We analyzed data from 646 participants, with 49% completing at least one severity questionnaire. The Psoriasis Symptom Inventory (PSI) was completed by 39%, the Dermatology Quality of Life Index (DLQI) by 36% and the Patient Report of Extent of Psoriasis Involvement (PREPI) by 9%. Based on scores, 59% exhibited severe psoriasis.

A psoriatic Arthritis Screening and Evaluation questionnaire (PASE) was completed by 35%, with psoriatic arthritis suspected in 23%. Only 12% filled out all the questionnaires.

Following initial questionnaire completion, 45% and 16% sought attention from dermatologists and rheumatologists, respectively, during the first-year follow up .

Adjusting for age and sex, individuals with severe psoriasis were 1.89 times more likely to attend dermatological consultations during the first-year follow-up compared to those with mild-moderate psoriasis (adjusted OR = 1.89, 95% CI [1.16-3.06], z = 2.56, p = 0.01), though this trend did not persist at the two-year follow-up. Moreover, adjusting for age and sex, those with suspected psoriatic arthritis based on PASE score were 3.43 times more likely to seek attention from rheumatologists during the first-year follow-up compared to those without such suspicion (adjusted OR = 3.43, 95% CI [1.61-7.33], z = 3.19, p = 0.001), with this trend persisting at the two-year follow-up.

Conclusion:

We observed discernible disparities between patients with high self-reported questionnaire scores and their propensity to seek dermatological and rheumatological consultations. We posit that the psoriasis virtual community represents a vital tool in empowering patients and fostering their active engagement in matters concerning their health.

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Abstract N°: 7200

International Consensus Definition and Diagnostic Criteria for Generalized Pustular Psoriasis From the International Psoriasis Council

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Introduction & Objectives:

Generalized pustular psoriasis (GPP) is a rare and potentially life-threatening auto-inflammatory disease characterized by recurrent, sudden flares of widespread painful erythema studded with sterile pustules that may coalesce to form lakes of pus. GPP is a heterogeneous disease with a wide range of clinical presentations, making accurate diagnosis and differentiation from other pustular dermatoses challenging. GPP lacks internationally accepted definitions and diagnostic criteria, impeding timely diagnosis and treatment and hindering cross-regional clinical and epidemiological study comparisons. Establishing an internationally accepted standardized definition of GPP based on agreed-upon diagnostic criteria is essential for prompt diagnosis and effective treatment, and for meaningful research. The objective of this study was to develop an international consensus definition and diagnostic criteria for GPP using the modified Delphi method.

Materials & Methods:

The rarity of GPP presents a challenge in acquiring comprehensive published clinical data necessary for

developing standardized definition and criteria. Instead of relying on a literature search, 43 statements that comprehensively addressed the fundamental aspects of the definitions and diagnostic criteria for GPP were formulated based on expert reviews of 64 challenging GPP cases. These statements were presented to a panel of 33 global GPP experts for voting, discussion, and refinements in 2 virtual consensus meetings. Consensus during voting was defined as at least 80% agreement; the definition and diagnostic criteria were accepted by all panelists after voting and in-depth discussion.

Results:

In the first and second modified Delphi round, 30 (91%) and 25 (76%) experts participated. In the initial Delphi round, consensus was achieved for 53%of the statements, leading to the approval of 23 statements that were utilized to develop the proposed definitions and diagnostic criteria for GPP. During the second Delphi round, the final definition established was, “Generalized Pustular Psoriasis is a systemic inflammatory disease characterized by cutaneous erythema and macroscopically visible sterile pustules.” It can occur with or without systemic symptoms, other psoriasis types, and laboratory abnormalities. GPP may manifest as an acute form with widespread pustules or a subacute variant with an annular phenotype. The identified essential criterion was, “Macroscopically visible sterile pustules on erythematous base and not restricted to the acral region or within psoriatic plaques.”

Conclusion:

This study successfully achieved an international consensus on the definition and diagnostic criteria for GPP through the innovative

use of the modified Delphi method with formal expert collaboration. The resulting definition and diagnostic criteria for GPP are intended

to provide a clear and standardized framework for diagnosis, ultimately leading to improved patient care, enhanced epidemiological research, and a better understanding of the disease’s impact on affected individuals.

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Abstract N°: 7215

Increased dysmetabolic burden is present independent of effective biological treatment of psoriasis

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Introduction & Objectives:

Metabolic disturbances are common in psoriasis patients and contribute significantly to increased cardiovascular risk. Systemic biologic therapy for psoriasis is highly effective in clearing skin lesions, while its effects on metabolic parameters remain uncertain. Our objective was to investigate the dysmetabolic burden in psoriasis patients treated with biologic therapy.

Materials & Methods:

80 patients (26 women, 54 men; age 30-45 years) with psoriasis and without comorbidities or medications, who were in the stable phase of successful treatment (PASI score <5) treated with topical therapy (N=10), methotrexate (N=15), adalimumab (N=14), secukinumab (N=15) or guselkumab (N=15) were recruited. Anthropometric measures (BMI, waist-hip ratio), LDL and HDL cholesterol, triglycerides, blood pressure, HOMA-IR, triglyceride glucose index, and FIB-4 index were measured.

Results:

An increased dysmetabolic load was found in all patients treated with biologic therapy. The dysmetabolic load generally showed a similar expression of the dysmetabolic parameters in patients treated with methotrexate or local treatment. The only significant difference is between patients treated with adalimumab and those treated locally. The overexpression of dysmetabolic factors was similar for all three biologic therapies, although the FIB-4 index was higher in the group treated with adalimumab than in the treatment groups with secukinumab and guselkumab.

Conclusion:

Successfully treated psoriasis patients had an increased, but basically similar, dysmetabolic burden to those treated locally or with methotrexate. It is evident that effective psoriasis treatment with biologic therapy is not associated with a large improvement in dysmetabolic burden. This observation may be a valuable aid in reducing dysmetabolic burden and cardiovascular risk in psoriasis patients.

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Abstract N°: 7256

Rifampicin and Psoriasis. TBC-related type of Psoriasis-does it exists?

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Introduction & Objectives:

Psoriasis is a multifaceted disease in terms of its pathophysiological mechanisms, inducing and aggravating factors, clinical types and clinical severity associated comorbidities and therapeutic modalities. The efficacy of traditional systemic therapies for psoriasis is limited by various side effects, toxicity drug-drug interactions, and the need for frequent laboratory monitoring.

Materials & Methods:

Patients with psoriasis treated with tumor necrosis factor alpha (TNF alpha) inhibitors are in increased risk for reactivation of latent tuberculosis infections as TNF alpha is an important factor in the body's defense against Mycobacterium tuberculosis. Epidemiological studies have shown considerable prevalence of latent tuberculosis both in psoriasis patients and in general population.

In animal models the antibiotic - Rifampicin causes immunosuppression and in conventional doses it suppresses the T-cell function. Rifampicin blocks the DNA-dependent RNA - polymerase of mycobacteria and other microorganisms.

Results:

In a several randomized clinical studies during the last 15 years we demonstrated in more than 70 patients with different clinical forms of psoriasis the good therapeutic response to Rifampicin. Recently, several papers showing the good therapeutic effect of Izoniazid in psoriatic patients with latent Tuberculosis were published.

Conclusion:

For the first time we suggest a specific type of psoriasis which is clinically variable, associated with tuberculosis infection. We hypothesize the existence of a unique tuberculosis-related type of psoriasis that could be treated successfully with Rifampicin.

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Abstract N°: 7286

Clinical characteristics of generalized pustular psoriasis: A large retrospective cohort in China

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Introduction & Objectives: Generalized pustular psoriasis (GPP) is a rare, chronic, and severe inflammatory skin disease. At present, there are still few large-scale epidemiological studies on the disease in China.

Materials & Methods: We retrospectively analyzed the epidemiological characteristics of hospitalized GPP patients in our center from March 2017 to December 2023. All information was obtained from our electronic medical record system and telephone follow-up

Results: A total of 280 patients were included in this study, with 368 hospitalizations, most of which were from northwest China. There were 225 adults and 55 children. The average age of diagnosis was 37.7 ± 19.0 years, the average age of onset was 35.7 ± 19.3 years, and the male and female were 157 / 123. Among GPP + PsV patients, the average age was 40.0 ± 17.2 years, onset was 38.9 ± 17.4 years, and the male-to-female ratio was 107 / 73. In GPP-PsV patients, the average age was 33.4 ± 21.3 years old, the age of onset was 29.8 ± 21.1, and the male-to-female ratio was 50 / 50. Among all patients, the most common possible initial trigger was infection (13.2 %), especially upper respiratory tract infection, followed by systemic herbal treatment (4 %). Among the causes of recurrence, the first is infection, and the second is glucocorticoid reduction. 21.8 % of patients had a history of allergies, mainly antibiotics. Regarding systemic symptoms, the vast majority of patients (264 / 280) had one or more symptoms, including fever, itching, skin or muscle pain. Similarly, we also found that the time of acute attack of GPP was also different due to different seasons. Spring, summer, autumn, and winter accounted for 24.5 %, 27.8 %, 26.6 %, and 21.2 %, respectively. From 2018 to 2023, the GPP treatment model has also undergone a major shift, with the proportion of palliatives for biological agents increasing from 0 in 2017 to 52.3 % in 2023. Compared with traditional oral drugs, the average treatment time was 6.4 ± 3.5 days vs 9.2 ± 3.3 days in the biological agent group ($P < 0.001$). The average regression time of pustules was 5.5 ± 4.4 days vs 6.7 ± 2.9 days ($P < 0.05$).

Conclusion: In recent years, the use of biological agents in GPP patients has increased year by year. Compared with traditional oral drugs, the use of biological agents has reduced the treatment time of GPP and shortened the time of pustule regression.

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Abstract N°: 7333

A case of Hodgkin's lymphoma in the context of pustular psoriasis: Coincidence or association?

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Introduction & Objectives:

Psoriasis patients are admitted to be at increased risk for developing various cancers, especially lymphoproliferative malignancies, although the exact mechanism remains unknown.

This case report illustrates the incidental discovery of Hodgkin's lymphoma in a psoriatic patient, and aims thereby to shed light on this intriguing association.

Materials & Methods:

Results:

Case presentation:

A 41-year-old male patient, diagnosed with psoriasis vulgaris during childhood, previously treated with dermocorticoids with recent introduction of methotrexate only two months ago, presented for a pseudo-erythrodermic cutaneous eruption progressing for more than a year in a context of altered general condition associating asthenia and weight loss of 8kg.

General examination found the patient to be apyretic, hemodynamically and respiratorily stable. As for dermatological examination, it revealed a bright red exanthema covering 70% of the body surface, with persistent intervals of healthy skin, topped in places by thick, white, adherent psoriasiform scales, and in others by more or less confluent non-follicular pustules, some of which had ruptured, leaving a yellowish crust; along with desquamative palmar pustulosis, and slightly fissured plantar keratoderma. It also noted the presence of nail involvement, associating pitting, distal onycholysis and subungual hyperkeratosis. The rest of the clinical examination revealed cervical, axillary and inguinal adenopathies, which were painless, firm and relatively mobile on palpation.

The diagnosis of generalized pustular psoriasis was considered from the outset, and later confirmed by histological findings on skin biopsy. In parallel, the patient underwent an ultrasound scan that confirmed the presence of bilateral adenopathies in the above-mentioned areas, some of which were necrotic, with peripheral and central vascularization. A lymph node biopsy was therefore performed, concluding to a morphological appearance and immunohistochemical profile compatible with Hodgkin's lymphoma, later classified as Ann Arbor stage III after assessment of radiological extension.

The patient was jointly managed with the hematology department, where appropriate polychemotherapy was initiated. As for his psoriasis, it progressed very well under dermocorticoids and acitretin 25mg/day.

Conclusion:

Psoriasis is a chronic auto-inflammatory disease with complex pathophysiology, involving, among other things, hyperactivation of T lymphocytes. The hypothesis of an increased risk of lymphoproliferative disorders in the context of psoriasis has therefore been put forward on this basis. This association could also be explained by

common genetic or environmental risk factors, or simply be the consequence of immunosuppressive treatments such as methotrexate (MTX), cyclosporine and more recently biotherapy. Indeed, long-term MTX treatment is known to potentially induce lymphoproliferative disorders. However, our patient had only been on MTX for two months when he developed generalized lymphadenopathy; and although the initial histopathological analysis concluded to Hodgkin's lymphoma, the diagnosis was later reconsidered in favor of an MTX-associated lymphoproliferative disorder.

To our knowledge, this is the first case of lymphoma occurring after only two months of treatment with MTX; moreover, this association is only rarely described in the setting of pustular psoriasis.

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Abstract N°: 7409

Exploring the Dynamics: Inflammation Markers Evolution Among Diverse Patient Subgroups Under Tildrakizumab Treatment - A Case Series Analysis

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Introduction & Objectives:

Psoriasis, a chronic inflammatory papulosquamous skin condition, which manifests as distinct, scaly, thick and erythematous plaques, significantly impacts individuals across all age groups and both genders. It is well-known that systemic inflammation and several comorbidities are directly linked with psoriasis, and the concept of "psoriatic disease" emphasizes that inflammation extends beyond the skin, to joints, blood vessels, heart and so on. In recent years, progress in immune-mediated mechanisms has conducted to new and effective targeted therapies, such as biologic therapy, and tildrakizumab, a monoclonal antibody with high affinity, designed to target the p19 subunit of interleukin-23, showed great clinical improvements in patients with moderate to severe disease. Our objective was to evaluate risk factors for therapeutic response after 3 months of treatment and the evolution of inflammation markers among our subgroup of patients, for a better understanding of their profiles.

Materials & Methods:

Our case series of 10 patients was conducted in the second Department of Dermatology, at Colentina Clinical Hospital in Bucharest, within a bigger ambispective national study.

Results:

We share our results after 3 months of treatment with 100mg tildrakizumab at 10 patients with moderate to severe forms of plaque psoriasis. Regarding PASI 50 at 3 months (PASI50 T3M), risk factors for nonresponders were the presence of psoriatic arthropathy (0.020), history of therapy switches (<0.001) and an early onset of the disease (0.004). No differences in response were found in terms of PASI50 T3M between those with raised erythrocyte sedimentation rate (ESR), abnormal values of neutrophils to leukocytes rates (NLR) or when we considered body mass index (BMI). In regard to Dermatology Life Quality Index (DLQI), we evaluated a decrease below 5 after 3 months of treatment (DLQI T3M) and observed a difficulty in achiving this value at patients with history of therapy swithes (0.001) and an early onset of psoriasis (0.047) . No differences were found for ESR and NLR. Cardiovascular risk factors were taken into consideration, but no correlations were found between inflammation markers (ESR, NLR) and abnormal values of blood pressure.

Conclusion:

The evaluation of disease course in psoriasis should integrate multiple factors, for a better understanding of patient subgroups and their profiles. In assessing treatment effectiveness, PASI 50, 75 or 90 serve as indicators of improvement degree. However, we think it is essential to integrate other predictive markers for a more objective and precise evaluation in this context. The lack of specificity for NLR and ESR can limit their practical use in this case, but studies with bigger cohorts, follow-up for longer periods of time, and new objective measures should be created for a better understanding of psoriatic disease progression.

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Abstract N°: 7429

Drug initiation and treatment pathway with adalimumab: real-world data from the German Psoriasis Registry PsoBest

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Introduction & Objectives: Psoriasis is a chronic immune-mediated inflammatory disease affecting approx. 2.5% of the population in Germany. It can result in severe disease burden impacting quality of life (QoL). This study with data from the German Psoriasis Registry PsoBest aims to investigate real-world patient profiles and the treatment pathways within the first year after starting treatment with adalimumab (ADA), a human monoclonal anti-TNF antibody.

Materials & Methods: Descriptive cross-sectional and longitudinal data analysis of data from PsoBest. Analyses included data from 17,299 patients reported to the registry between 2008-2022, including 8,572 patients with at least 365 days follow-up time. Treatment course is captured via each registry visit documentation. Systemic treatment was analysed in patients at date of inclusion and month 3, 6 and 12.

Results: Out of 8,572 patients with one-year follow-up, 854 received ADA at inclusion (10.0%, incl. biosimilars). They were predominantly male (60.9%), on average were 48.0 years old (SD 14.0) and reported 19.8 (SD 14.0) years' history of psoriasis. Mean PASI was 15.0 (SD 10.6), mean DLQI 11.9 (SD 7.5). 56.8% showed nail psoriasis, 34.9% with psoriatic arthritis.

11.4% of patients starting ADA had no prior systemic therapy, 68.0% had prior therapy with non-biologics and 20.6% with biologics. At month 3, 728 patients received ADA (96.4%). The few therapy changes up to this time were usually to non-biologics (2.3%) or to other TNF-alpha inhibitors (0.7%). At month 6, the picture was similar: 91.3% of patients received ADA, the few switches were mainly to non-biologics (4.7%) or to other TNF-alpha inhibitors (0.9%). Between month 6 and 12, 6.1% of patients switched to non-biologics and 3.6% to other biologic treatments. 742 patients received ADA at month 12. Within these patients we found patients staying on ADA since month 0 as well as switchers to ADA, predominantly from non-biologic treatments. Sensitivity analysis including patients regardless of follow-up-time revealed comparable results.

A higher proportion of biologic naïve patients starting ADA were male, compared with patients with prior biologic experience: 69.9 vs. 58.6% ($p= 0.007$). They also showed differences compared to second line patients regarding shorter duration of psoriasis (median 16 vs. 24 years, $p< 0.001$) and a higher impairment of health related QoL: median DLQI 12.04 vs. 9.0 ($p< 0.001$). Other patient characteristics were similar in both cohorts. Among all biologic naïve patients (n= 2,621), 678 (25.9%) received ADA as first -line biologic.

Conclusion: ADA is a durable treatment option with high 12-month persistence and often selected as a subsequent therapy. Age, duration of disease and joint involvement appeared as factors influencing the use of ADA as first line therapy. Even with numerous alternatives, ADA is still a valid treatment option and a valuable and

widely used treatment option in patients with psoriasis.

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Abstract N°: 7468

Current status, patient profiles and impact on health care through the German Psoriasis Registry PsoBest

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Introduction & Objectives: The non-interventional German psoriasis registry PsoBest gains long-term evidence on the quality, safety, effectiveness and patient benefit of routine psoriasis care.

Materials & Methods: PsoBest observes adult patients with moderate to severe psoriasis with or without psoriatic arthritis (PsA). Patients are enlisted at the start of any naïve approved systemic treatment and followed for up to 10 years. Data comprises clinical parameters (e.g. the Psoriasis Area Severity Index (PASI)), patient-reported outcomes (e.g. the Dermatological Quality of Life Index (DLQI), patient benefit index and the patients self-rated health (EQ 5-D VAS)), drug-specific treatment and health care data. Drug safety is recorded using forms for pregnancies, serious and non-serious adverse events (SAEs, AEs) including AEs of special interests.

Results: By April 2024, 1,160 sites nationwide were enrolled in the registry (87 outpatient clinics from hospitals, 1,073 dermatological practices), reflecting a large proportion of dermatological care for psoriasis in Germany. N= 23,075 patients were enlisted since 2008. In 2023, 21,546 visits with 2,105 new patients were reported.

As of 30 June 2023, data from 17,355 patients were available after terminating quality checks and data verifications. Of these, 58.8% were male, mean age was 47.6 years. At baseline, 30.2% of patients were diagnosed with PsA and 46.7% showed nail involvement. The average disease duration was 17.2 years, mean PASI 15.2, mean DLQI 11.8, mean EQ 5-D VAS 57.9, indicating a significant burden of disease and a reduction of patients' health-related quality of life.

All antipsoriatic therapies authorised in Germany were observed at the time of inclusion in the registry. As it is possible to switch between drugs during the observation course, a high number of patient years (PY) was observed: 20,467 PY for biologics, 19,854 PY for non-biologics and even 1,236 PY for biosimilar therapy. For AEs and SAEs reported, known and expected differences between the therapies were identified, but no signals of major concern or unexpected adverse events were observed. Data from PsoBest were reported to the guideline groups, the pharmacovigilance institutions, to ministries, the payers, the HTA organisations and to the public.

Conclusion: PsoBest is the largest registry in German dermatology and is still growing steadily. Co-operations with other registries and other projects have been established. Data from PsoBest are a continuous source of real-world evidence on the safety, effectiveness and patient benefits not only for clinicians, regulatory bodies, politics but also for patients. PsoBest contributes to quality assurance and optimisation of care for psoriasis in Germany. The success of the registry derives from the many years of commitment of the project group, continuous financial support from pharmaceutical companies, engagement of the participating centres and the dedication of loyal patients.

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Abstract N°: 7474

Sexual Dysfunction in Women and Men with Psoriasis

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Introduction & Objectives: Psoriasis is recognized not only for its physical manifestations but also for its profound psychosocial impacts, including stigmatization, compromised social interactions, and diminished quality of life. Psoriasis can also affect sexual activity, but there is still little research on this topic. The present study investigated whether and to what extent psoriasis, its severity, location and extent of skin lesions affect sexual dysfunction.

Materials & Methods:

Our study enrolled 109 individuals (45 women and 64 men) aged 18 to 73, hospitalized for psoriasis exacerbation. Psoriasis severity, as assessed by the Psoriasis Area and Severity Index (PASI), ranged from 0.2 to 65 points (mean: 17.0 ± 14.9 points). After collecting demographic and clinical data, each subject was asked to complete the Dermatology Life Quality Index, the 11-item Sexual Life Questionnaire and the International Index of Erectile Function (only men).

Results: Our research revealed that over 90% of surveyed patients experienced some degree of feeling unattractive due to their psoriasis. Skin lesions affected the sex life of approximately 80% of participants at least occasionally, with more than 50% at least sometimes avoiding sexual contact. In approximately 80% of the subjects, the skin lesions at least occasionally affected their sex life, and more than 50% at least sometimes avoided sexual contact. The location of psoriasis, particularly in the genital area ($p = 0.01$), on the face ($p = 0.03$) and hands ($p = 0.05$), also had a significant impact on the level of sexual problems. Psoriasis has a significant impact on the quality of life (QoL), and a deterioration in QoL was strongly correlated with sexual dysfunction ($r = 0.6$, $p < 0.001$), PASI scores ($r = 0.36$, $p < 0.001$), self-assessment of psoriasis severity and location of psoriatic lesions.

Conclusion: Psoriasis leads to various limitations, especially in the sphere of sexual life. Patients with psoriasis feel stigmatized, have lowered self-esteem and consequently experience significant sexual problems. Awareness of the co-occurring psychological aspect of psoriasis and the routine use of validated scales in dermatology practice should contribute to the prompt identification of patients experiencing sexual dysfunction.

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Abstract N°: 7486

The arterial stiffness in patients with psoriasis referred to Imam Khomeini Hospital and Razi Hospital during the years 2021-2022 was investigated using arterial tonometry, and its association with disease severity (PASI) was examined.

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Introduction & Objectives:

Psoriasis is a chronic inflammatory skin disease that affects a significant number of individuals, both young and adults. Serious complications of this disease can impact the overall health of patients, including an increased risk of cardiovascular diseases. The relationship between psoriasis and arterial stiffness, which indicates the rigidity and inflexibility of arteries, is not yet fully understood. This study aimed to investigate this association and the impact of psoriasis on arterial characteristics in patients with this condition. The main objective of this study was to examine the association between psoriasis and arterial stiffness in patients with the disease. The research question was whether patients with psoriasis have higher levels of arterial stiffness compared to healthy individuals.

Materials & Methods:

In this case-control study, 37 confirmed psoriasis patients based on the CASPAR criteria and 37 healthy individuals were included as the control group. The study was conducted from January 2021 to January 2022 at Imam Khomeini Hospital complex and Razi Hospital at Tehran. Demographic data, disease severity assessed by PASI, and arterial stiffness measured using a tonometer were recorded. The data was analyzed and compared between the psoriasis and control groups. Written consent was obtained from all participants.

Results:

In this study, 74 patients were divided into two groups: case and control, with each group consisting of 37 patients. The mean age in the control group was 38.57±13.33 years, while in the case group, it was 47.14±13.48 years. The height ranged from 153 to 195 cm, with a mean of 171±37.10 cm in the healthy group, and from 150 to 188 cm, with a mean of 172±13.10 cm in the patient group. Additionally, the body mass index (BMI) ranged from 17.04 to 31.99 units, with a mean of 25.60±3.78 units in the healthy group, and from 17.72 to 34.08 units, with a mean of 26.45±3.67 units in the patient group.

The arterial stiffness values for healthy individuals ranged from 5 to 6.10 units, with a mean of 1.30±7.36. For the patients included in the study, the arterial stiffness ranged from 5.6 to 5.12 units, with a mean of 1.44±8.87 units. After adjusting for age and gender, the difference in arterial stiffness between the patient and healthy groups decreased from 1.51 units in the unadjusted analysis to 0.98 units in the adjusted analysis. The levels of percentile values for Aortic pulse wave velocity did not show a significant difference between the healthy and patient groups, both with and without adjusting for age and gender.

Conclusion:

According to our study findings, psoriasis can act as a risk factor for cardiovascular diseases, and this mechanism may be mediated through an increase in arterial stiffness. Consequently, psoriasis can contribute to the development of arterial stiffness.

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Abstract N°: 7536

Drug supply for psoriasis in transition: 15 years of experience in the German Psoriasis Registry PsoBest

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Introduction & Objectives:

Over the last two decades, the supply of systemic drugs for psoriasis has undergone an unprecedented dynamic. The question of how the change in drug supply and the choice of systemic therapeutics is reflected in the German Psoriasis Registry PsoBest is examined.

Materials & Methods:

The German national psoriasis registry evaluates clinical outcomes, safety, tolerability and health care use of systemic drugs for psoriasis and psoriatic arthritis in Germany. A descriptive analysis of the utilization of systemic therapeutics at registry inclusion and prior therapies with systemic therapeutics over the course of 2008 to 2023 was performed.

Results:

16,293 patients were analysed - mean age 47.6 years (min-max 18-93), 58.2% male, mean duration of disease 15.4 years, mean PASI at baseline 15.1, mean DLQI 11.8, proportion of psoriatic arthritis (PsA) 18.8%, nail psoriasis 46.8%. Between 458 (in 2008) and 2446 (in 2019) cases were included per year. The proportion of non-biologics included fell from 67.7% to 13.5% between 2008 and 2023. To the same extent, more biologics were used for registry reporting. The proportion of biologics given as the first systemic therapy (biological as first drug) rose from 1.5 % to 32.8 %. The most frequently used biologics groups between 2008 and 2015 were TNF alpha inhibitors (mean value 21.8%), between 2015 and 2018 interleukin 17 antagonists (19.3%) and since 2019 IL-23 inhibitors (33.1%). Adalimumab recorded the strongest growth from 2008 to 2013, ustekinumab from 2014 to 2016, secukinumab from 2017 to 2019 and guselkumab since 2020. The most frequently pre-exposed non-biological systemic therapeutics were fumaric acid esters (20.8% on average) and MTX (20.0%). Drug profiles markedly differed between patients with vs. without PsA, by age, gender and comorbidity. These data are supported by claims data from the statutory health insurance companies in Germany, indicating fair external validity of the PsoBest dataset.

Conclusion:

The use of new drugs in psoriasis shows a strong change and high dynamics between 2008 and 2023. The proportion of biologics is increasing significantly and is in turn undergoing a change due to the biologic generations from TNF blockers to interleukin 17 blockers and interleukin 23 blockers. The steadily increasing number of patients with multiple prior systemic therapies poses a new challenge, as the therapeutic response to all drugs decreases with the number of prior therapies.

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Abstract N°: 7601

Efficacy and safety of moderate to severe palmoplantar psoriasis with bimekizumab: a retrospective, single-center, real-world study up to 24 weeks

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Introduction & Objectives:

Palmoplantar psoriasis (PP) is a diagnostically and therapeutically challenging skin condition causing redness, scaling, and/or persistent sterile pustules persistent. Three immunogenetically overlapping morphologic patterns of palmoplantar psoriasis (PP) have been described: a. pustular (PPP), b. hyperkeratotic (HKPP), and c. mixed (MPP). PP can co-exist with plaque-type psoriasis elsewhere in the body. Intense pruritus and pain due to extensive erosions may cause functional disability and severe psychological burden to the patients suffering from PP.

There are currently no standard therapeutic guidelines for PP treatment. However, Phase III clinical trials of Bimekizumab, a dual inhibitor and humanized bispecific immunoglobulin G1 (IgG1) monoclonal antibody (mAb) simultaneously targeting IL-17A and IL-17F, for moderate to severe plaque psoriasis, have demonstrated its efficacy and safety in PP. Nevertheless, these trials do not differentiate Bimekizumab's effectiveness for different PP subtypes, and there is still need for more real-world data.

Materials & Methods:

We performed a single-center retrospective study to analyze the effectiveness and safety of BMZ in 17 patients with PP.

The primary and secondary endpoints were to evaluate the modified Palmoplantar Psoriasis Area and Severity Index (m-PPPASI), Dermatology Life Quality Index (DLQI), Pruritus (PR) and Pain (P) Visual Analogue Scale (VAS) at baseline, at weeks 4 and 12, and up to 24 of treatment, respectively.

Results:

A total of 17 patients (mean [range] age, 55[40-69] years; 11 females were included. Ten patients had HKPP, and seven had overlapping HKPP and PPP subtype. Thirteen patients were current smokers. Almost all patients had at least one psoriasis -related comorbidity.

Nine patients had prior failure to more than one (up to to four) biologics, whereas eight patients were biologic naïve.

Complete clearance (mPPPASI score, 0) was achieved by 8 of 17 patients at week 4 and, by 11 out of 12 patients reaching week 24 of treatment. Mean DLQI, PR-VAS and P-VAS was reduced by 11.4, 5,3 and 4.7 by week 4 of treatment with bimekizumab, accordingly. Previous exposure to biological treatment, gender, obesity, or comorbidities did not affect treatment outcome. No major safety signals were documented during the study.

Conclusion:

The findings of this case series suggest that bimekizumab could be an appealing approach for treating PPP Prospective randomized placebo-controlled clinical trials are needed to confirm these encouraging initial results.

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Abstract N°: 7604

Trajectories of switching to optimise efficacy and minimising risks in patients with moderate-to-severe plaque psoriasis: results from the PsoReal registry.

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Introduction & Objectives: The introduction of targeted therapies in psoriasis in addition to traditional conventional ones over the past fifteen years, have modified treatment expectations by patients who are looking for an optimal efficacy and safety profile of medication. Moreover, the increasing number of treatment options and the adoption of a treat-to-target approach have increased the attitude to treatment switching with the purpose of maintaining clinical improvement over time [1]. However, information on the best strategies of switching between conventional treatments and biologics in psoriasis is limited.

Materials & Methods: We aimed to prospectively identify the most common trajectories and pattern of switching between conventional and biological therapies in a cohort of 350 adult patients (mean age 52.5±14.2 years, males 70.3%) with moderate-to-severe psoriasis of the Italian PsoReal Registry, during the period 2011-2023. The purpose was to find the trajectories that optimise efficacy and minimise risks in patients treated systemically for psoriasis by employing innovative network representations and spanning trees, through the Edmonds' algorithm.

Results: In our cohort, 107 patients under conventional agents (46.3%) and 40 under biological therapies at baseline (33.6%) switched to other systemic agents during an average follow-up period of 28.4 months. Methotrexate, and partially cyclosporine were main hubs in the switching network of patients starting with a conventional agent. As for biologics, the choices depended on the agents available at the starting of the study in 2011, adalimumab and ustekinumab, with etanercept connecting the two, being main hubs in the switching trajectories of patients (Figure 2). Switching from a conventional to a biologic treatment or from a biologic to another biologic agent were associated with a significant increase in the proportion of patients achieving PASI75 after a 48-month follow-up period, compared to no switching among conventional therapies, with the a relative risk (RR) of achieving Psoriasis Area and Severity Index (PASI)75 after switching being of 1.53 (1.05, 2.22), 1.44 (95% CI: 1.01, -2.07) and, 1.53 (1.05, -2.232) and 1.09 (0.76, 1.54), respectively. Overall, 61 adverse events (AEs) (17.4%) were recorded. Only switching between different classes of conventional therapies significantly increased the risk of AEs (Relative Risk RR= 3.13, 95% CI: 1.35-7.26, p=0.008). The prospective nature of the registry, the use of real-world clinical data, the presence of both conventional and biological systemic agents, as well as the novelty of our methods of analysis represent a strength of this study. Among limitations that included the relatively small sample size and the missing of a cost-benefit analysis of different treatment trajectories, to have considered the more common trajectories used in Italy may not be of great interest for other countries.

Conclusion: Through these innovative methods which may be of example for other countries, we found that switching from a conventional to a biological agent as well as between different biologics, represents the best strategy to optimise efficacy and minimising risks. Certainly, larger studies encompassing different national registries and conducted by applying these original methods, may be required to analyze the specific national trajectories of switching and to confirm the trajectories and patterns of switching detected in our cohort of patients.

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Abstract N°: 7607

Line-field confocal optical coherence tomography for monitoring treatment response in psoriasis

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Introduction & Objectives:

Line-field confocal optical coherence tomography (LC-OCT) is a new diagnostic device developed to provide an in vivo skin evaluation from epidermis to upper dermis at cellular resolution and in three dimensions. It may allow a new non-invasive diagnostic approach for monitoring microscopical changes in different skin diseases as therapy response. The aim of this study was to investigate the role of LC-OCT in monitoring psoriasis response during the treatment with the most common biologic and conventional DMARDs.

Materials & Methods:

We performed LC-OCT imaging of psoriasis lesions from patients before and after 4 and 16 weeks of treatment with biologic drugs (anti-TNF-alpha, IL-17 and IL-23 inhibitors) and conventional DMARDs (cyclosporine, acitretin, methotrexate). Microscopic criteria evaluated by LC-OCT were thickness of the stratum corneum, thickness of the epidermis, undulation of the dermo-epidermal junction and dilatation of blood vessels in papillary dermis.

Results:

All LC-OCT microscopic criteria showed a reduction during the follow-up. At 4 weeks biologics showed faster response than conventional DMARDs. LC-OCT revealed persistence of cytoarchitectural changes in some psoriatic plaques that appeared completely resolved at clinical evaluation after 4 and 16 weeks of treatment.

Conclusion:

LC-OCT may represent a new potential tool to monitor treatment response in psoriasis and to define in vivo and at cellular level the difference between biologic and conventional DMARDs in terms of speed of response and cytomorphological modifications.

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Abstract N°: 7615

Efficacy and safety of moderate to severe palmoplantar psoriasis with bimekizumab: a retrospective, single-center, real-world study up to 24 weeks

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Introduction & Objectives:

Palmoplantar psoriasis (PP) is a diagnostically and therapeutically challenging skin condition causing redness, scaling, and/or persistent sterile pustules persistent. Three immunogenetically overlapping morphologic patterns of palmoplantar psoriasis (PP) have been described: a. pustular (PPP), b. hyperkeratotic (HKPP), and c. mixed (MPP). PP can co-exist with plaque-type psoriasis elsewhere in the body. Intense pruritus and pain due to extensive erosions may cause functional disability and severe psychological burden to the patients suffering from PP.

There are currently no standard therapeutic guidelines for PP treatment. However, Phase III clinical trials of Bimekizumab, a dual inhibitor and humanized bispecific immunoglobulin G1 (IgG1) monoclonal antibody (mAb) simultaneously targeting IL-17A and IL-17F, for moderate to severe plaque psoriasis, have demonstrated its efficacy and safety in PP. Nevertheless, these trials do not differentiate Bimekizumab's effectiveness for different PP subtypes, and there is still need for more real-world data.

Materials & Methods:

We performed a single-center retrospective study to analyze the effectiveness and safety of BMZ in 17 patients with PP.

The primary and secondary endpoints were to evaluate the modified Palmoplantar Psoriasis Area and Severity Index (m-PPPASI), Dermatology Life Quality Index (DLQI), Pruritus (PR) and Pain (P) Visual Analogue Scale (VAS) at baseline, at weeks 4 and 12, and up to 24 of treatment, respectively.

Results:

A total of 17 patients (mean [range] age, 55[40-69] years; 11 females were included. Ten patients had HKPP, and seven had overlapping HKPP and PPP subtype. Thirteen patients were current smokers. Almost all patients had at least one psoriasis -related comorbidity.

Nine patients had prior failure to more than one (up to to four) biologics, whereas eight patients were biologic naïve.

Complete clearance (mPPPASI score, 0) was achieved by 8 of 17 patients at week 4 and, by 11 out of 12 patients reaching week 24 of treatment. Mean DLQI, PR-VAS and P-VAS was reduced by 11.4, 5,3 and 4.7 by week 4 of treatment with bimekizumab, accordingly. Previous exposure to biological treatment, gender, obesity, or comorbidities did not affect treatment outcome. No major safety signals were documented during the study.

Conclusion:

The findings of this case series suggest that bimekizumab could be an appealing approach for treating PPP Prospective randomized placebo-controlled clinical trials are needed to confirm these encouraging initial results.

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Abstract N°: 7639

an observational study on dermatologists' management of cardiovascular risk factors in psoriasis and the association with lifetime risk of atherosclerotic cardiovascular disease

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Introduction & Objectives:

Psoriasis is a chronic inflammatory condition with multiple comorbidities. Recently, there has been a growing awareness of an association between psoriasis and a number of cardiovascular risk factors , such as obesity or dyslipidemia, and consequently with cardiovascular diseases. The recent 2019 American Heart Association guidelines, recognise psoriasis as an enhanced risk-inducing factor for atherosclerotic cardiovascular disease. 2019 NPF guidelines with attention to comorbidities suggest that dermatologists should inform patients regarding this association and ensure the patient is engaged with his or her primary care provider or cardiologist for appropriate screening.

The objectives of this pilot study were:

\1. to assess the risk factors for cardiovascular disease and their cardiovascular risk in our cohort of patients at baseline and after biologics treatment

\2. to assess whether appropriate consultation and management is offered as well as any potential effect of biologics on cardiovascular risk.

Materials & Methods:

All consecutive patients with moderate-to-severe psoriasis who were seen in one of the consultants' biologics specialist clinic at Royal London Hospital, Barts Health NHS Trust, London, in two weeks were enrolled in the study. Basic demographic analysis, current and previous treatments, PASI and DLQI were documented. Cardiovascular risk was calculated using the ASCVD score.

Results: 50 patients were included in the study. Mean age was 41.12. M:F ratio was 1.27. Asian or Asian-British-Bangladeshi was the commonest ethnic group (56%) followed by White British (24%). Mean age of diagnosis was 26.82. The majority of the patients were on an anti-TNF agent – Adalimumab (56.86%) and Certrolizumab (18%). The mean baseline ASCVD score (lifetime risk) was 36.89%. Cardiovascular comorbidities included smoker or ex-smoker (48%), obesity (34%), hyperlipidaemia (28%), hypertension (16%), diabetes (10%). The mean ASCVD score (lifetime risk) post-treatment was 36.89%. Consultation about management of cardiovascular risk was performed in only 6%. Biologics was not found to change the cardiovascular risk, though the mean duration of patients on biologics is 2 years.

Conclusion: Despite the young age of our patients,** multiple risk factors for cardiovascular disease as well as cardiovascular co-morbidities were present. This could be attributed to the inflammation due to psoriasis but also to patients' ethnic background.** As the cardiovascular risk is high, there should be a local pathway to address its management. More studies are required to assess the correlation between psoriasis and cardiovascular disease. It is crucial to raise awareness among dermatologists about the assessment and management of cardiovascular risk, ideally with a multidisciplinary setting with cardiology. There is a need to continue following up the patients to assess the long term outcomes.

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Abstract N°: 7676

Assessment of miR-22-3p, miR-133a-3p, miR-146a-5p, miR-369-3p and Let-7b-5p involved in the cardiovascular disease (CVD) risk in psoriatic patients with overweight/obesity and with normal weight.

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Introduction & Objectives:

Psoriasis is recognized as a multifactorial systemic disease with complex pathogenesis and the increased cardiovascular risk and frequent comorbidities. The immunopathogenesis and genetics of psoriasis has been extensively investigated but is still not fully understood. microRNAs (miRNAs) are single-stranded, small non–protein-coding RNAs, which can regulate various cellular processes by influencing epigenetic modifications. Over 250 miRNAs have been described to have an impact in the pathogenesis of psoriasis, however the connections between psoriasis and comorbidities are still not well recognized. The aim of this study was to investigate the differences in miRNAs involved in CVD risk among psoriatic patients with particular emphasis on overweight and obese individuals.

Materials & Methods:

The study comprised 28 male psoriatic patients who were divided into the overweight/obese (Group 1) and normal weight (Group 2) groups and 16 male healthy controls. miRNA isolated from peripheral blood mononuclear cells was reverse-transcribed and RT-qPCR was performed. The data were normalized relative to RNU48. All the PCR reactions were run in triplicates. The relative expression was calculated by the formula RQ = 2–ΔΔCt The miRNA results were corelated with clinical data and the disease severity assessed with PASI (Psoriasis Area and Severity Index) and BSA (Body Surface Area) scales.

Results:

The decreased levels of miR-22, miR-133a, miR-146a, and miR-369 among the psoriatic patients were recognized. There was a statistically significant difference in miR-22 and miR-146a levels between psoriatic patient groups. There were positive correlations between miR-22 and miR-146a levels and psoriatic arthritis (PsA) in Group 2 and between miR-133a level and PsA Group 1 detected. The statistically significant correlations between miR-22 and BSA, BMI; miR-146a and BMI, Let-7b and PASI, BSA were noticed.

Conclusion:

The decreased levels of selected miRNA are consistent with their levels observed in CVD indicating their impact in the CVD risk in psoriatic patients. miR-22 and miR-146 can be recognized as one of the contributing factors in the obesity-CVD-psoriasis network. Overweight or obesity can also influence epigenetic modulation in PsA, therefore we observed positive correlations between miR-22 and miR-146a levels and PsA in Group 2 and between miR-133a level and PsA in Group 1.

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Abstract N°: 7722

Efficacy and safety of HS-10374 in patients with moderate-to-severe plaque psoriasis: Results from a randomized, double-blind, placebo-controlled phase 2 trial

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Introduction & Objectives:

Tyrosine kinase 2 (TYK2) is essential for signaling of interleukin (IL)-12 and IL-23, which are key cytokines involved in psoriasis pathogenesis. HS-10374 is an oral, selective, allosteric TYK2 inhibitor. This phase 2 trial was to assess the efficacy and safety of HS-10374 in patients with moderate-to-severe plaque psoriasis.

Materials & Methods:

In this phase 2, randomized, double-blind, placebo-controlled trial (NCT06077331), patients with moderate-to-severe plaque psoriasis were randomized 1:1:1 to receive HS-10374 6 mg, 12 mg or placebo (PBO) orally once daily (QD), stratified by previous biologics use (yes/no). The treatment period was 12 weeks, followed by a 4-week follow-up period for safety monitoring. The primary efficacy endpoint was PASI 75 response rate at Week 12. Additional efficacy outcomes and safety were evaluated.

Results:

Of 125 Chinese patients enrolled, 42 were assigned to receive HS-10374 6 mg, 43 to receive HS-10374 12 mg, and 40 to receive PBO. One hundred and fifteen patients (92%) completed 12 weeks of treatment.

Efficacy: At Week 12, the primary endpoint was met, with significantly greater proportion of patients in HS-10374 6 mg and 12 mg groups achieving PASI 75 responses compared with PBO (PBO: 7.5%; HS-10374 6 mg: 28.6%, P=0.013; HS-10374 12 mg: 72.1%, P<0.001). At Week 12, additional efficacy endpoints were met as well, including significantly higher sPGA 0/1, PASI 50 and PASI 90 response rates compared with PBO in HS-10374 12 mg group, and significantly higher sPGA 0/1 and PASI 50 response rates in HS-10374 6mg group. (Figure 1).

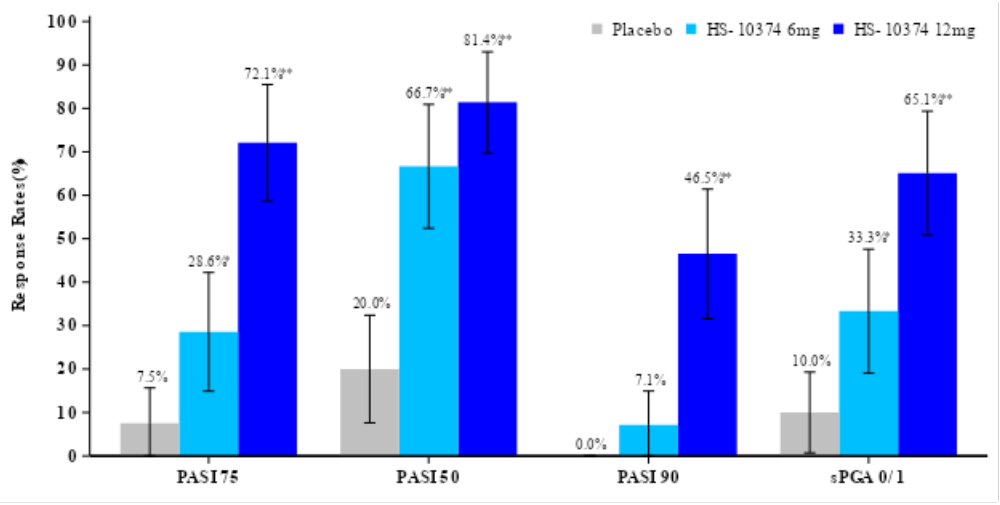

Figure 1. Proportions of patients achieving PASI 50/75/90 response and sPGA 0/1 response.
* $P<0.05$, ** $P<0.001$

Safety: AE rates of HS-10374 groups were slightly higher than PBO group, while rates of treatment-related AEs (TRAEs), serious AEs (SAEs), and AEs leading to discontinuation of trial regimen were comparable across the three treatment groups. One patient in the 6 mg group experienced SAE of limb traumatic amputation that was considered unrelated to treatment, and the only patient with treatment-related SAE (gastrointestinal haemorrhage) was from PBO group. No death occurred. AEs under the SOC "infections and infestations" were most commonly reported, with the majority being graded as CTCAE 1-2 except for one patient receiving intravenous antibiotics. In contrast to the relative higher incidence of skin-related adverse events for some other TYK2 inhibitors, AEs under "skin and subcutaneous disorders" in this study were more commonly reported in PBO group (detailed in Table 1). Treatment with HS-10374 did not result in significant changes from baseline in mean values of blood counts, hepatic and renal parameters, or lipids.

Table 1. Summary of Adverse Events through Week 16

	PBO (N=40) n(%)	HS-10374 6 mg (N=42) n(%)	HS-10374 12 mg (N=43) n(%)
AEs	28(70.0)	32(76.2)	38(88.4)
TRAEs	22(55.0)	19(45.2)	25(58.1)
SAEs	1(2.5)	1(2.4)	0
Treatment-related SAE	1(2.5)	0	0
AEs leading to discontinuation of trial regimen	1(2.5)	0	1(2.3)
Infections and infestations *	9(22.5)	9(21.4)	17(39.5)
Skin and subcutaneous disorders	5(12.5)	3(7.1)	4(9.3)

* Most frequently reported. Events elicited by laboratory testing not included.

Exploratory exposure-response analysis: A relationship between exposure and primary efficacy endpoint (PASI 75 response rate at Week 12) was adequately described by a logistic regression model. PASI 75 response rate increased with increasing steady state average concentration and reached a plateau at the exposure level of 12 mg QD dosage.

Conclusion:

HS-10374 showed significant clinical efficacy versus PBO in PASI 75 response rate and sPGA 0/1 response rate at oral doses ≥ 6 mg in patients with moderate-to-severe plaque psoriasis. The overall safety profile was similar to other TYK2 inhibitors with less risk of skin toxicity. Trials of longer treatment duration with a larger population are required to further confirm the efficacy and safety of HS-10374 in such patients.

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Abstract N°: 7894

Efficacy and safety of apremilast for the treatment of Japanese patients with palmoplantar pustulosis: 52-week results from a phase 3, randomized, placebo-controlled study

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Introduction & Objectives: Palmoplantar pustulosis (PPP) is a difficult to treat, chronic dermatitis with limited treatment options. A phase 3 trial of apremilast 30 mg twice daily (APR) in Japanese patients with moderate to severe PPP showed superior efficacy compared with placebo (PBO) at Week (W)16. The objective of this analysis was to report APR efficacy and safety over 52 weeks.

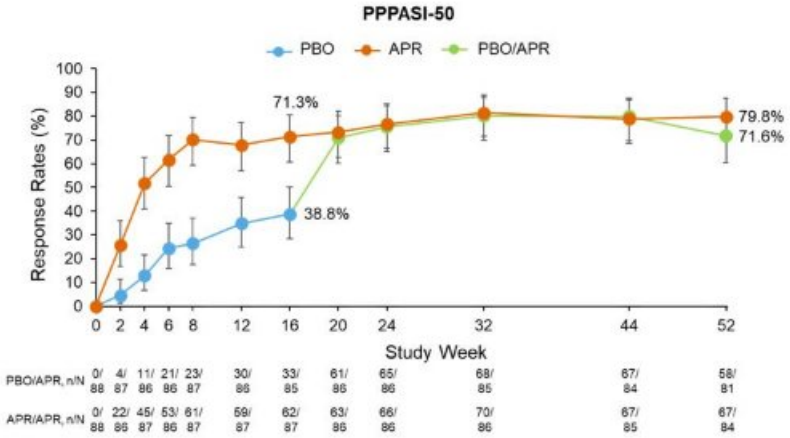
Materials & Methods: This was a randomized, PBO-controlled, double-blind, confirmatory phase 3 study. Adults with PPP Area and Severity Index (PPPASI) total score (TS) ≥12, PPPASI pustules/vesicles severity score ≥2, and inadequate response to topicals were randomized (1:1) to APR or PBO for 16 weeks. After W16, patients continued on APR (APR/APR) or switched from PBO to APR (PBO/APR) through W52. W52 endpoints included ≥50% improvement in PPPASI TS (PPPASI-50); changes from baseline in PPPASI TS, Palmoplantar Pustulosis Severity Index (PPSI) TS, Patient's Visual Analog Scale (VAS) assessment for pruritus and pain/discomfort, Dermatology Life Quality Index (DLQI); and treatment-emergent adverse events (TEAEs). Data are reported as observed.

Results: Among 176 patients randomized (APR, n=88; PBO, n=88), 164 (93.2%) completed W52 (APR/APR, n=84 [95.5%]; PBO/APR, n=80 [90.9%]). Baseline characteristics were balanced across groups: mean age, 57.0 vs 56.0; PPP duration, 6.7 vs 6.0 years; PPPASI TS, 22.1 vs 22.0; PPSI TS, 8.1 vs 8.0; pruritus VAS, 48.7 vs 51.2; pain/discomfort VAS, 43.3 vs 45.8; and DLQI, 5.7 vs 6.7.

Improvements at W16 were maintained or further improved through W52 in the APR/APR group for PPPASI-50 response (W16: 71.3%, W52: 79.8%; **Figure 1**) and for mean change from baseline in PPPASI TS (W16: −13.1, W52: −14.7; **Figure 2**), PPSI TS (W16: −3.7, W52: −4.6; **Figure 3**); pruritus VAS (W16: −18.1, W52: −19.1; **Figure 4**), pain/discomfort VAS (W16: −19.2, W52: −18.8; **Figure 4**), and DLQI (W16: −2.3, W52: −2.4; **Figure 4**). Patients who switched from PBO to APR at W16 experienced rapid improvements in clinical efficacy, with similar levels of response as the APR/APR group by W24. These improvements were maintained through W52. TEAEs were consistent with the known apremilast safety profile.

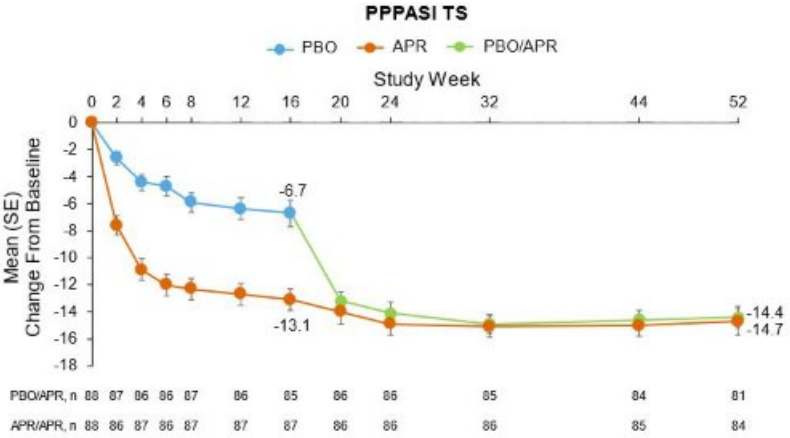
Conclusion: Improvements in PPP seen with APR at W16 were maintained or further improved through W52, including improvements in PPP severity, symptoms (pruritus and pain/discomfort), and patient-reported quality of life. Improvements were also observed when patients transitioned from PBO to APR at W16 through W52. No new safety signals were observed.

Figure 1. PPPASI-50 response rates over 52 weeks in patients with moderate to severe PPP



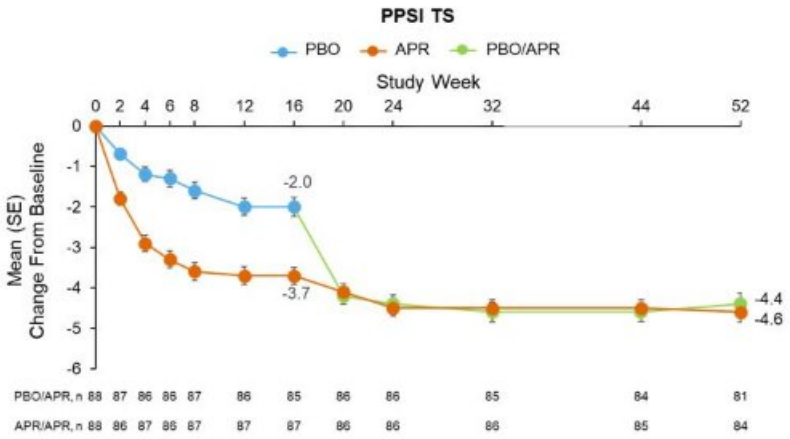
ITT population. Data as observed. Error bars represent 95% CI.
APR, apremilast; CI, confidence interval; ITT, intent-to-treat; PBO, placebo; PPPASI, Palmoplantar Pustulosis Area and Severity Index.

Figure 2. Change from baseline in PPPASI TS over 52 weeks in patients with moderate to severe PPP



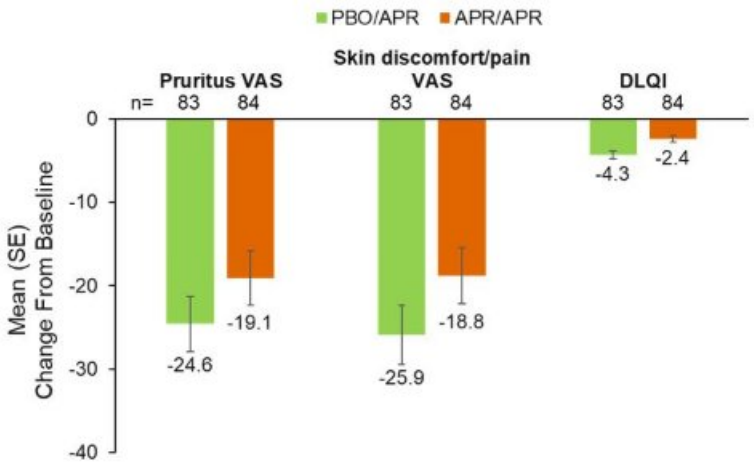
ITT population. Data as observed.
APR, apremilast; ITT, intent-to-treat; PBO, placebo; PPPASI, Palmoplantar Pustulosis Area and Severity Index; SE, standard error; TS, total score.

Figure 3. Change from baseline in PPSI TS over 52 weeks in patients with moderate to severe PPP



ITT population. Data as observed.
APR, apremilast; ITT, intent-to-treat; PBO, placebo; PPSI, Palmoplantar Pustulosis Severity Index; SE, standard error; TS, total score.

Figure 4. Change from baseline in patient-reported outcomes at W52 in patients with moderate to severe PPP



ITT population. Data as observed.

APR, apremilast; DLQI, Dermatology Life Quality Index; ITT, intent-to-treat; PBO, placebo; SE, standard error; VAS, Visual Analog Scale.