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Patient and Clinician-Reported Outcomes and Adherence to Calcipotriene/Betamethasone Dipropionate PAD-Cream in Treatment of Scalp Psoriasis in Adults: An Interim Analysis of the PRO-SCALP Study

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ABSTRACT

Background: Effective management of scalp psoriasis needs treatment with high patient preference and treatment satisfaction. Clinical trials show promising results for calcipotriene and betamethasone dipropionate cream based on polyaphron dispersion (PAD) technology (CAL/BDP PAD-cream). However, real-world data are scarce.

Objectives: To evaluate patient- and clinician-reported outcomes and impact of adherence on treatment outcomes of CAL/BDP PAD-cream in adults with mild-to-moderate scalp psoriasis in real-world settings in Europe.

Methods: PRO-SCALP is an ongoing observational, multicentre cohort study, collecting data primarily at baseline and Week 8 (end of the study, EOS). Patient self-assessments included Treatment Satisfaction Questionnaire for Medication Version 9 (TSQM-9), Scalpdex questionnaire, Worst Itch-Numerical Rating Scale (WI-NRS), sleep patterns, personal preferences and adherence to CAL/BDP PAD-cream using a visual analogue scale (VAS). Clinicians' assessments included physician global assessment of scalp (scalp-PGA) and S-mPASI.

Results: Of 152 patients included in this interim analysis, 134 patients (mean age: 48.4 years; 69.4% females) had evaluable outcome data. At EOS, mean (SD) patient satisfaction scores (TSQM-9) were—effectiveness: 76.0 (23.9), convenience of use: 70.2 (21.3), global satisfaction: 76.1 (22.5). At Week 8, 79.0% of patients attained a scalp-PGA score of 0 (clear) or 1 (almost clear), and 71.0% attained scalp-PGA success, defined as a scalp PGA score of 0/1 and $\geq$ 2-points improvement in scalp-PGA score change from baseline (CFB). CFB of S-mPASI scores, patient-reported symptoms, emotions, functioning and overall Scalpdex scores as well as WI-NRS scores improved significantly ($p < 0.0001$) at EOS, within both low-adherence (VAS < 80) and high-adherence (VAS: 80–100) groups. Across key outcome measures, CFB of treatment outcomes was found to be better in patients with higher adherence.

Conclusions: Findings of the study indicate high treatment satisfaction, significant improvement in clinical outcomes and patients' quality of life associated with CAL/BDP PAD-cream, especially in patients with higher adherence.

1 | Introduction

Psoriasis is a complex, chronic inflammatory skin disease, marked by erythematous and scaly plaques [1]. Approximately 80% of patients experience scalp involvement [2]. It impacts physical and psychosocial well-being, often affecting quality of life (QoL) as patients feel embarrassed, and self-conscious about visible lesions [3–5].

Managing scalp psoriasis remains challenging, despite the availability of various topical treatments. There is high dissatisfaction with topical treatments due to ineffectiveness, time-consuming application, side effects, limited accessibility, and unacceptable cosmetic appeal [2, 5–7]. It is important to consider the specific features of topical treatments/formulations, such as odour, texture and effect on the skin to improve patient's adoption, compliance and overall satisfaction with treatments [2, 8–11].

The combination of calcipotriene and betamethasone dipropionate (CAL/BDP) is recommended as the first-line treatment for mild-to-moderate plaque psoriasis by European, Canadian and American dermatology guidelines and associations [12–15]. Additionally, fixed-dose formulations of CAL/BDP once-daily application support improved treatment adherence [16]. CAL/BDP PAD-cream (Wynzora cream) is a novel topical formulation based on polyaphron dispersion (PAD) technology [9], which enhances the solubility and stability of CAL/BDP in aqueous solution and offers unique advantages of high spreadability, easy penetration into the skin, without leaving stickiness, which in turn may improve patient preference in contrast to conventional oil based formulations [9, 17]. In Phase 3 trials, CAL/BDP PAD-cream demonstrated significantly greater efficacy, with a safety and tolerability profile similar to CAL/BDP gel in mild-to-moderate plaque psoriasis [9].

However, in real-world settings, treatment choices depend on various factors such as treatment effectiveness, disease severity, affected area and patient preferences [18, 19]. Understanding patient-reported outcomes (PROs), treatment preferences and clinicians-reported outcomes (ClinROs) is crucial for improving treatment adherence and clinical outcomes. In real-world settings, both ClinROs and PROs help healthcare professionals assess disease burden and inform reimbursement decisions [11, 20]. However, there is currently no data available on treatment adherence and outcomes associated with CAL/BDP PAD-cream for scalp psoriasis in real-world settings.

This article presents the interim analysis of the PRO-SCALP study, which aims to evaluate PROs and ClinROs, and impact of adherence on treatment outcomes of CAL/BDP PAD-cream in adults with mild-to-moderate scalp psoriasis in real-world settings, in Europe.

2 | Methods

PRO-SCALP study is an ongoing, prospective, observational, multicentre cohort study conducted across sites in Germany, Spain and the UK, assessing treatment satisfaction and PROs of CAL/BDP PAD-cream in approximately 300 adult patients with mild-to-moderate scalp psoriasis in real-world clinical settings. Data collection commenced in June 2023 and is ongoing.

Adult ($\geq$ 18 years) patients with mild-to-moderate scalp psoriasis (defined as scalp-physician global assessment [PGA] score of 2 or 3 at baseline of a 5-point scalp-PGA scale), those who have been prescribed CAL/BDP PAD-cream (Wynzora), willing to participate and comply with all procedures were included in the study. This study excluded patients with severe plaque psoriasis or other scalp conditions affecting evaluations, those receiving any concomitant treatment, pregnant or lactating women and those hypersensitive to CAL/BDP PAD-cream (Wynzora). The inclusion and exclusion criteria are detailed in Supporting Information S1: Table S1.

The recommended duration of treatment was up to 8 weeks. Data were collected at baseline and Week 8 $\pm$ 4 weeks (end of the study; EOS). One study centre each from Germany, Spain and the UK collected clinical outcomes and photographs of scalp psoriasis at baseline, Week-4 and EOS, for a subset of their patients. The study was performed in accordance with the Declaration of Helsinki and the ICH Harmonized Tripartite Guidelines for Good Clinical Practice.

The study was primarily approved by the Ethikkommission der Goethe-Universität Frankfurt (Germany), Health Research Authority and Health and Care Research Wales (United Kingdom-England and Scotland) and CEIC Aragon, IACS and CIBA (Spain) with approval numbers #2023–1145, #23/LO/0474, #EPA23–018, respectively (details given in Supporting Information S1: Table S2). Additional regional ethics approvals were subsequently obtained as required. Written informed consent was provided by all patients before participation.

2.1 | Study Outcome Measures

The primary outcome measure was patients' treatment satisfaction with CAL/BDP PAD-cream at Week 8, assessed using the validated Treatment Satisfaction Questionnaire for Medication Version 9 (TSQM-9), which includes nine items across three domains: effectiveness, convenience and global satisfaction, with scores ranging from 0 to 100, where higher scores indicate greater satisfaction [21].

Additional study measures (Supporting Information S1: Table S3) included responses to the validated 23-item Scalpdex questionnaire (assessing symptoms, emotional impact and functioning) at baseline and Week 8 [22], with each item scored on a 5-point Likert scale transposed to a score of 0 to 100 ('never' = 0, 'rarely' = 25, 'sometimes' = 50, 'often' = 75 and 'all the time' = 100), with higher scores indicating more severe QoL impairment; scalp Worst Itch-Numerical Rating Scale (WI-NRS) responses [23], using scale of 0 (no-itching) to 10 (worst-itching imaginable), at baseline and Week 8; the proportion of patients achieving scalp-PGA success, defined as a scalp PGA score [24] of 0 or 1 on a 5-point scale (0-clear, 1-almost clear, 2-mild, 3-moderate, 4-severe) and a minimum 2-points improvement from baseline at Week 8; Scalp modified

Psoriasis Area and Severity Index (S-mPASI) scores [25, 26]; and physician-reported treatment satisfaction with medication (adapted from TSQM-9).

At EOS, patients reported the number of days scalp psoriasis affected sleep, and how well they slept the previous week on a Likert-scale (1 = very well to 5 = very badly). Proportion of patients experiencing sleep disturbances for ≥ 3 days per week, and those rating sleep quality as 'very well' or 'rather well' were analysed. Treatment preference over past topical treatments was assessed at EOS using a 5-item patient preference questionnaire (PPQ), with Likert scale scores (0 = strongly disagree to 3 = strongly agree) [27]. At EOS, patients reported satisfaction with overall usability of CAL/BDP PAD-cream and likelihood of using it again on a scale from 0 (not at all) to 10 (very much), as part of Cream Usability Scalp Psoriasis Questionnaire (CUSP-Q). Patient adherence to treatment was assessed using patients' self-reported visual analogue scale (VAS) on a scale of 0 (least) to 100 (best) [28]. Psychosocial effects of scalp psoriasis were assessed using Psychosocial Effects of Scalp Psoriasis Questionnaire (PSY-SCALP), consisting of 11 items (three questions at baseline and eight questions at EOS); scored on a 4-point Likert scale (1 = no, 2 = a little, 3 = quite a lot and 4 = very much), with higher scores indicating better outcomes.

2.2 | Statistical Methods

Descriptive statistics were used to summarise categorical data by counts, percentages and continuous data using statistical measures. An interim database lock was achieved when 50% of the enroled subjects had completed the EOS assessment at week 8 ± 4. The interim analysis included patients who received at least one dose of CAL/BDP PAD-cream, completed 8 to 12-week study observation period, and had primary endpoint data at EOS visit. Change from baseline (CFB) in outcomes at EOS was evaluated for Scalpdex, WI-NRS, S-mPASI and sleep measures. Sub-group analysis of selected outcome measures was performed to assess the effect of medication adherence on treatment outcomes by comparing treatment outcomes of patients with low-adherence (VAS < 80) to those with high-adherence (VAS 80−100). Statistical differences in continuous measures were assessed using a paired sample *t*-test, Student's *t*-test or Wilcoxon signed rank test. McNemar's test was used for paired categorical data. For all analyses, $p < 0.05$ was considered statistically significant.

3 | Results

3.1 | Baseline Demographic, Clinical Characteristics and Participating Physicians

This interim analysis evaluated 152 patients with mild-to-moderate scalp psoriasis from 24 hospitals or outpatient clinics across Germany, Spain and the UK. After excluding six patients with missing data, and 12 who discontinued treatment, 134 patients with complete data at EOS were analysed (Figure 1). The patients had a mean (SD) age of 48.4 (16.7) years, with 69.4% being females and 88.8% white/Caucasian. Mostly, patients were occasional drinkers (73.1%) and nonsmokers (75.4%). Nearly half of the patients (47.0%) had Fitzpatrick skin

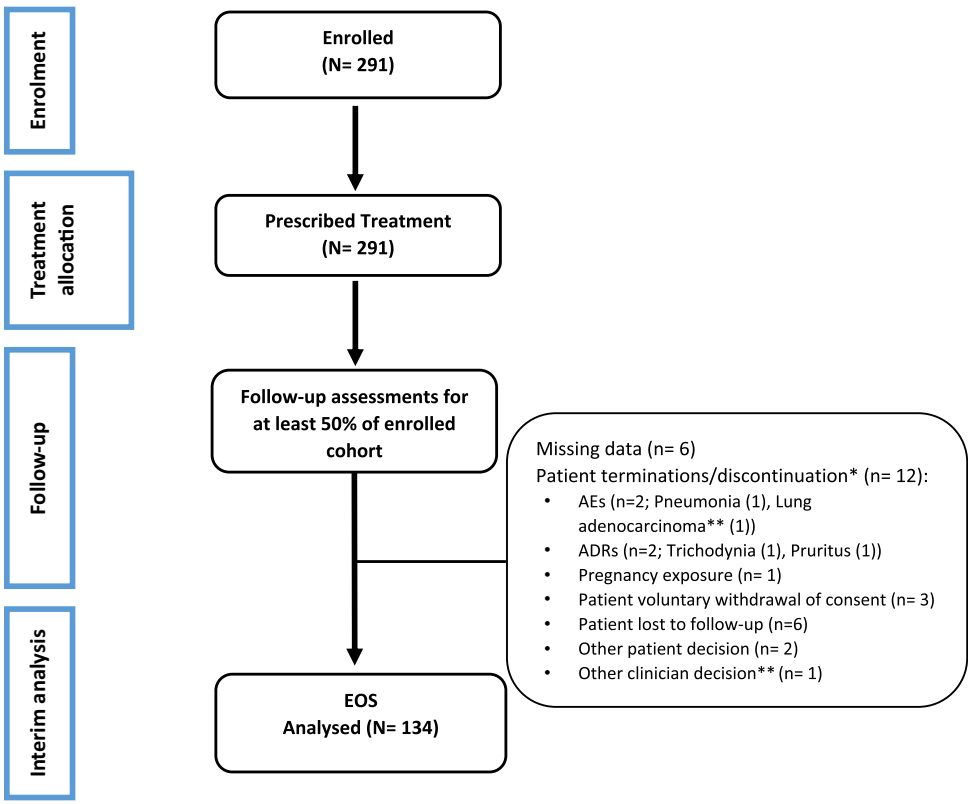


FIGURE 1 | Disposition of patients included in the PRO-SCALP study interim analysis. ADR, adverse drug reaction (related to study treatment); AE, adverse event (not related to study treatment); EOS, end of study. *Not mutually exclusive. **Lung adenocarcinoma that resulted in patient death.

TABLE 1 | Baseline demographic and clinical characteristics.

	Study population ($N = 134$)
Age, mean (SD), years	48.4 (16.7)
Gender, *n* (%)	
Male	41 (30.6%)
Female	93 (69.4%)
Race[a], *n* (%)	
White/Caucasian	119 (88.8%)
Black/African/Caribbean	1 (0.7%)
Asian	4 (3.0%)
Mixed race	4 (3.0%)
Other	4 (3.0%)
I would prefer not to answer	3 (3.2%)
Living status, *n* (%)	
Alone	19 (14.2%)
Not alone	115 (85.8%)
Smoking status, *n* (%)	
Daily	20 (14.9%)
Occasionally	13 (9.7%)
Not anymore	36 (26.9%)
Never smoked	65 (48.5%)
Drinking status, *n* (%)	
Daily	6 (4.5%)
Occasionally	98 (73.1%)
Not anymore	19 (14.2%)
Never drank	11 (8.2%)
Length of patient's hair, *n* (%)	
1. No hair	0 (0.0%)
2. Short	53 (39.6%)
3. Medium	41 (30.6%)
4. Long	40 (29.9%)
Percentage of hair covering the patient's scalp, % (SD)	82.2% (28.7)
Time since diagnosed with plaque PSO (in years)[b], mean (SD)	12.3 (12.6)
Localised areas of the body were initially diagnosed with plaque psoriasis, *n* (%)	
1. Hands	14 (10.5%)
2. Legs	42 (31.3%)
3. Trunk	33 (24.6%)
4. Arms	43 (32.1%)
Time since first date of involvement of the scalp (in years)[c], mean (SD)	9.9 (11.6)
Fitzpatrick skin-type classification, *n* (%)	
1. Type I	28 (20.9%)
2. Type II	63 (47.0%)
3. Type III	31 (23.1%)
4. Type IV	11 (8.2%)
5. Type V	1 (0.8%)
6. Type VI	0 (0.0%)

Abbreviations: *n*, number; PSO, psoriasis; SD, standard deviation.
[a]Not mutually exclusive.
[b]Seven patients had missing data.
[c]Thirteen patients had missing data.

type II. The demographic and baseline clinical characteristics of patients are given in Table 1. The majority of physicians (94%) were dermatologists, with 37.5% from private practices, and 62.5% from hospital settings. Demographic and clinical characteristics were assessed by these physicians at baseline and EOS.

3.2 | Real-World Use of CAL/BDP PAD-Cream

During the study, patients used an average of 1.66 tubes of CAL/BDP PAD-cream. While all applied it to their scalp as prescribed, 24.6% also applied it to other areas. The majority (99.3%) used the cream once daily.

3.3 | Treatment Satisfaction With CAL/BDP PAD-Cream

Patients and clinicians both reported high treatment satisfaction with CAL/BDP PAD-cream. Patients reported the CAL/BDP PAD-cream as effective, convenient and expressed high global satisfaction with mean scores (SD) of 76.0 (23.9), 70.2 (21.3) and 76.1 (22.5), respectively. Clinicians also reported high satisfaction, with mean scores exceeding those of patients (Figure 2).

Patient satisfaction and preference for CAL/BDP PAD-cream were high, with 83.6% of patients agreeing/strongly agreeing on its effectiveness, 71.7% on ease of use, 70.2% on fewer side effects, 79.1% on better tolerability and 82.9% on overall preference over previous topicals (Figure 3). 70.9% and 82.8% of patients with CUSP-Q score of 8/9/10 reported high satisfaction with overall usability of CAL/BDP PAD-cream and said they would use it again.

3.4 | PROs and ClinROs Associated With CAL/BDP PAD-Cream

Post-treatment with CAL/BDP PAD-cream, most of the patients reported improved QoL. The mean (SD) Scalpdex CFB in symptoms, emotions and functioning domain scores and the

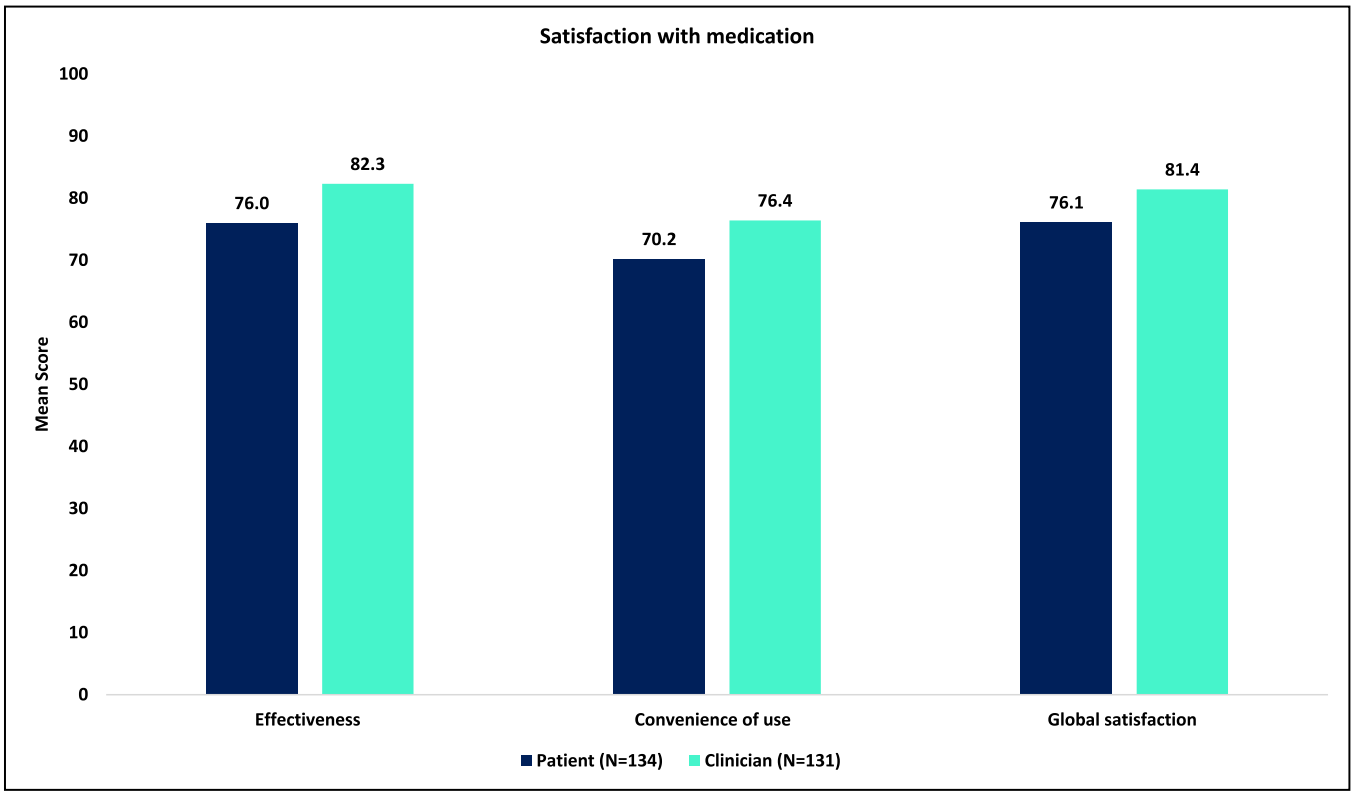


FIGURE 2 | Patient* and clinician-reported** satisfaction with CAL/BDP PAD cream for scalp psoriasis treatment after 8 weeks of treatment. *Based on patient-reported treatment satisfaction questionnaire for medication (TSQM-9). **Clinician measure based on a questionnaire adapted from the patient questionnaire TSQM-9.

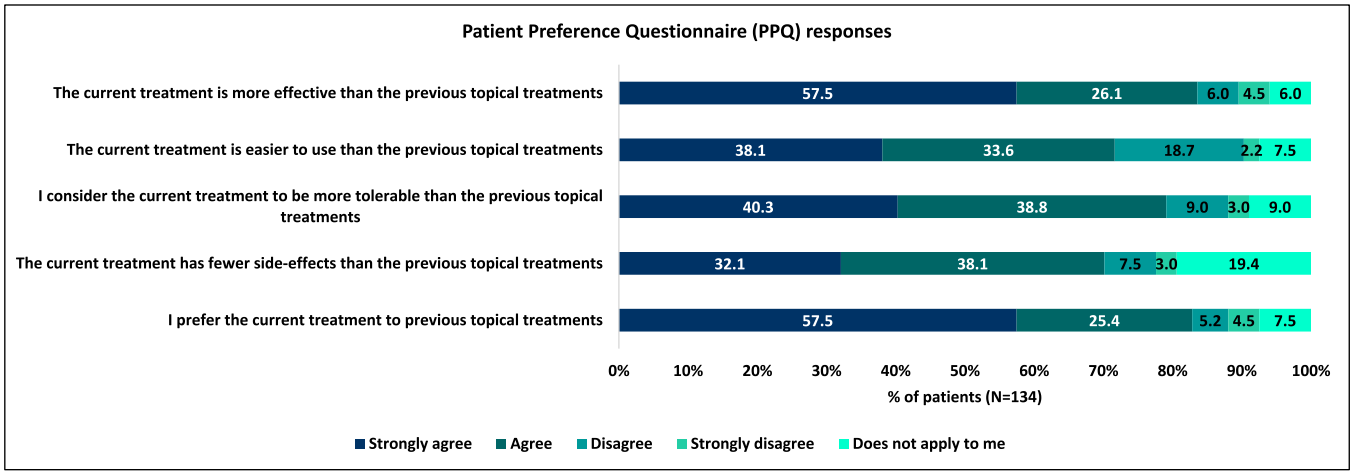


FIGURE 3 | Patient preferences regarding CAL/BDP PAD cream after 8 weeks of treatment. PPQ, patient preference questionnaire.

overall Scalpdex score were −29.2 (24.8), −25.4 (22.6), −21.6 (25.4) and −25.4 (21.8) respectively, with significant decrease in CFB scores ($p < 0.0001$) for all scores (Figure 4). Additionally, the WI-NRS score decreased significantly ($p < 0.0001$) by −3.9 (3.3) from baseline (Figure 5). Overall, 77.9% of patients had scalp-PGA score of 0/1 (clear or almost clear skin), with a statistically significant CFB ($p < 0.0001$); and 71.0% achieved scalp-PGA success. A majority (81.5%) of patients achieved an S-mPASI score < 0.5 at EOS. The mean (SD) S-mPASI score reduced significantly at EOS: 0.31 (0.5) versus baseline: 1.65 (1.1) (−1.3 [1.2]; $p < 0.0001$) (Figure 6). Representative images illustrating the progression of clinical outcomes from baseline through week 4−8 are presented in Figure 7. Patient 1, a female (age: 27), and Patient 2, a male (age: 38), both had moderate scalp psoriasis (scalp-PGA: 3) and were treated with CAL-BDP PAD-cream. Their scalp-PGA scores improved during the study observation period. Both patients achieved 'almost clear' skin status (scalp-PGA: 1) at Week 4, while Patient 1 and Patient 2 had 'almost clear' (scalp-PGA: 1) and 'clear' (scalp-PGA: 0) skin status at Week 8, respectively.

Patients treated with CAL/BDP PAD-cream reported improved psychosocial outcomes on PSY-SCALP questionnaire, with higher item scores at EOS for all assessed measures (Figure 8).

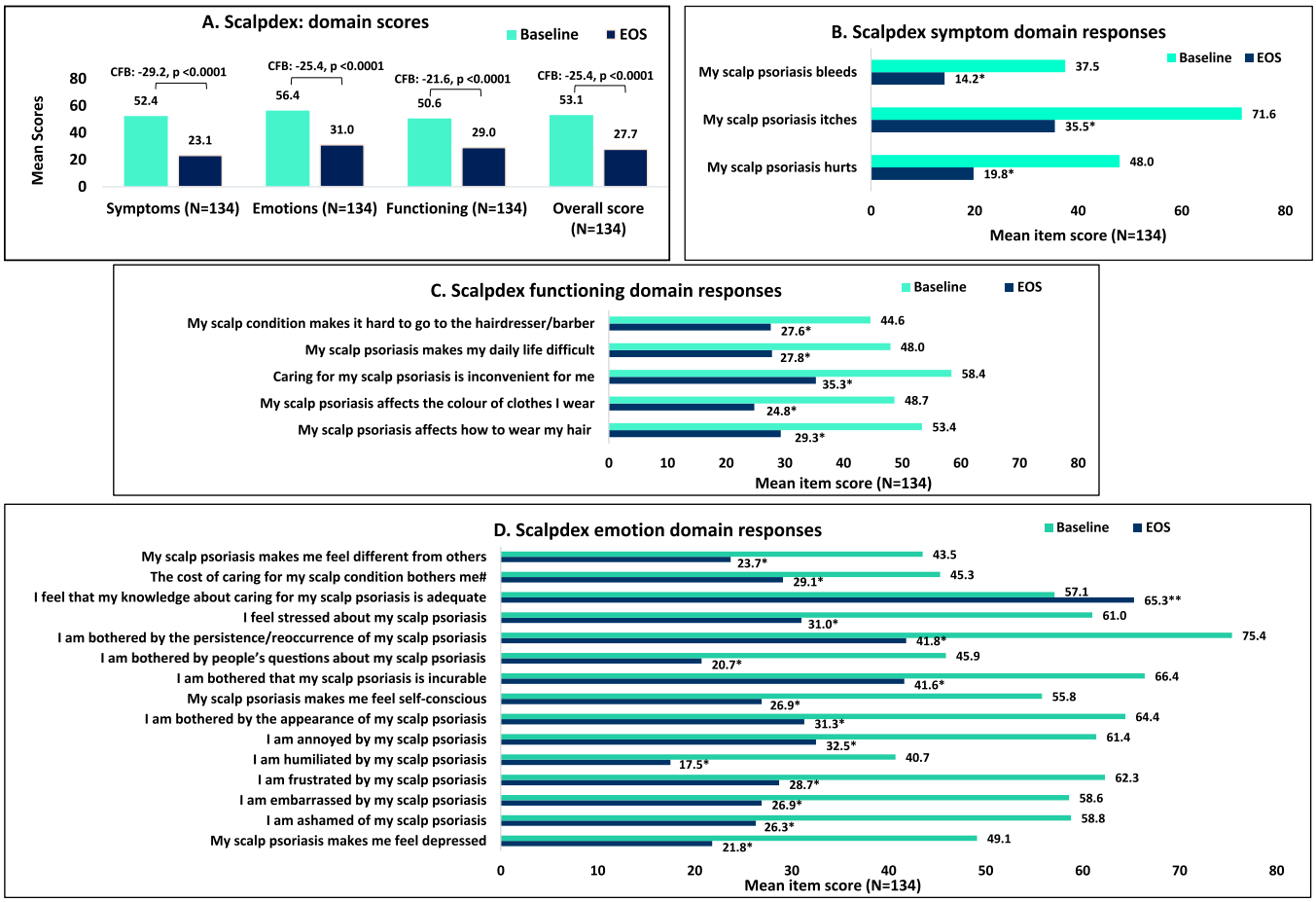


FIGURE 4 | Evaluation of patient-reported symptoms, impact on emotions and functioning. Scalpdex-QoL. CFB, change from baseline; EOS, end of study; Scalpdex-QoL, scalpdex quality of life index (*$p < 0.0001$, in comparison to baseline; **$p = 0.0033$, in comparison to baseline; #1 patient had missing data at EOS). *p* value, calculated by paired *t*-test for emotions domain, functioning domain and overall score and Wilcoxon signed rank test for symptoms domain corresponds to CFB.

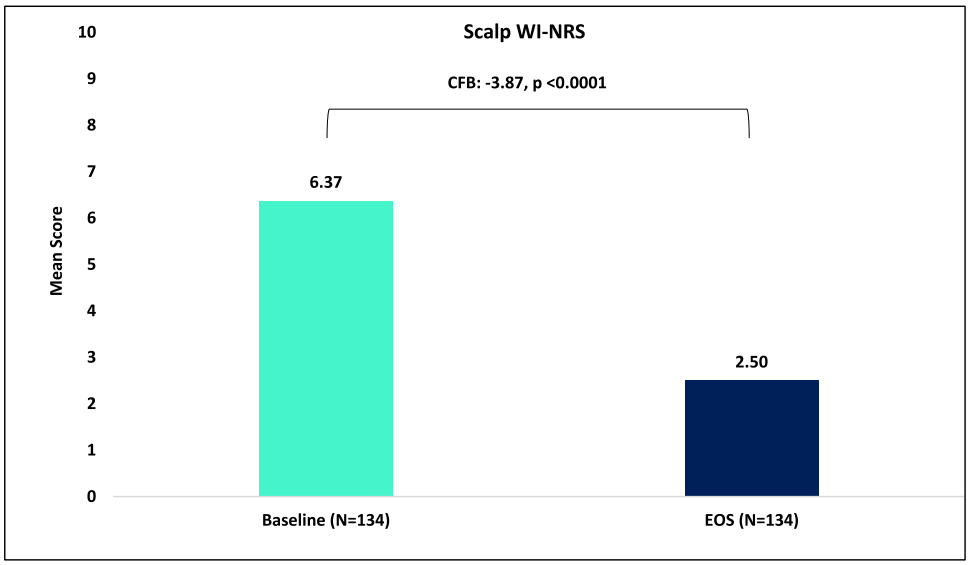


FIGURE 5 | Patient-reported impact on itching. Scalp WI-NRS score. CFB, change from baseline; EOS, end of study; Scalp WI-NRS, scalp worst itch-numerical rating scale. *p* value for CFB in score, calculated by paired *t*-test, corresponds to differences in mean score between time points.

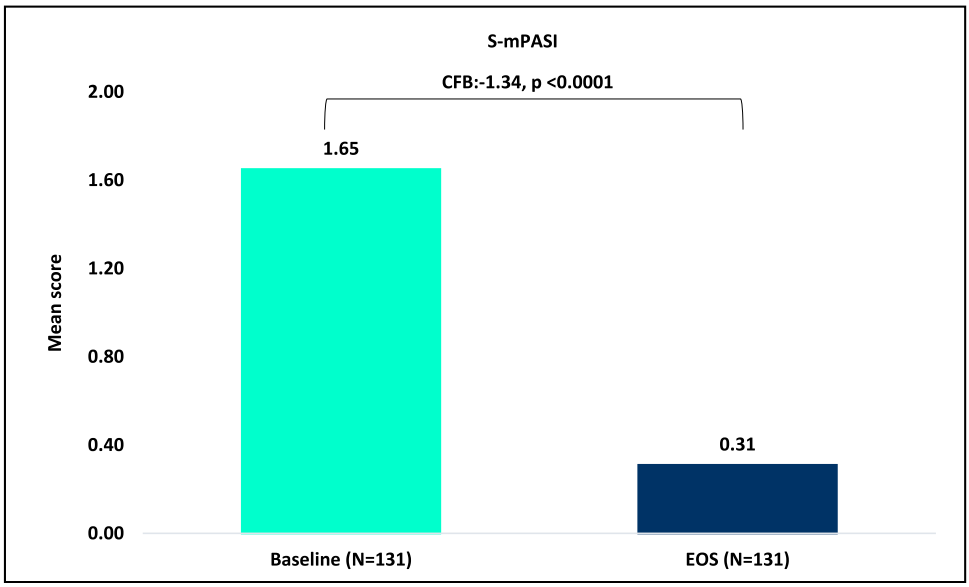


FIGURE 6 | Psoriasis severity assessment. S-mPASI score. CFB, change from baseline; EOS, end of study; S-mPASI score, scalp modified psoriasis area and severity index. *p* value, calculated by paired *t*-test, corresponds to differences in scores between time points.

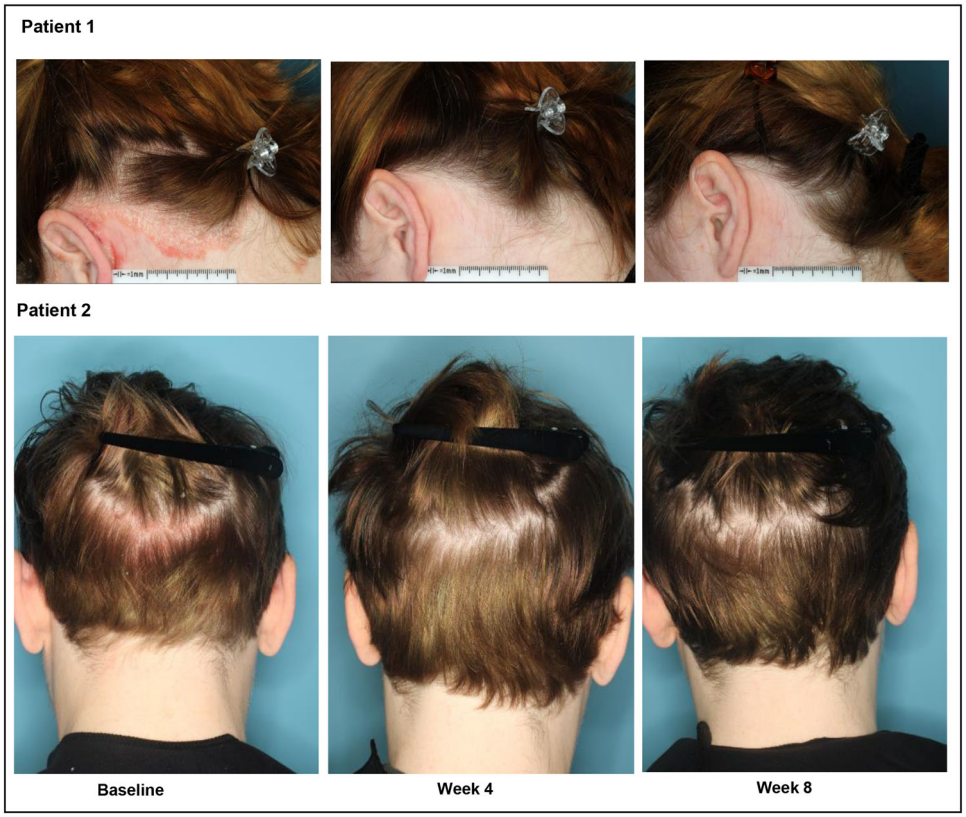
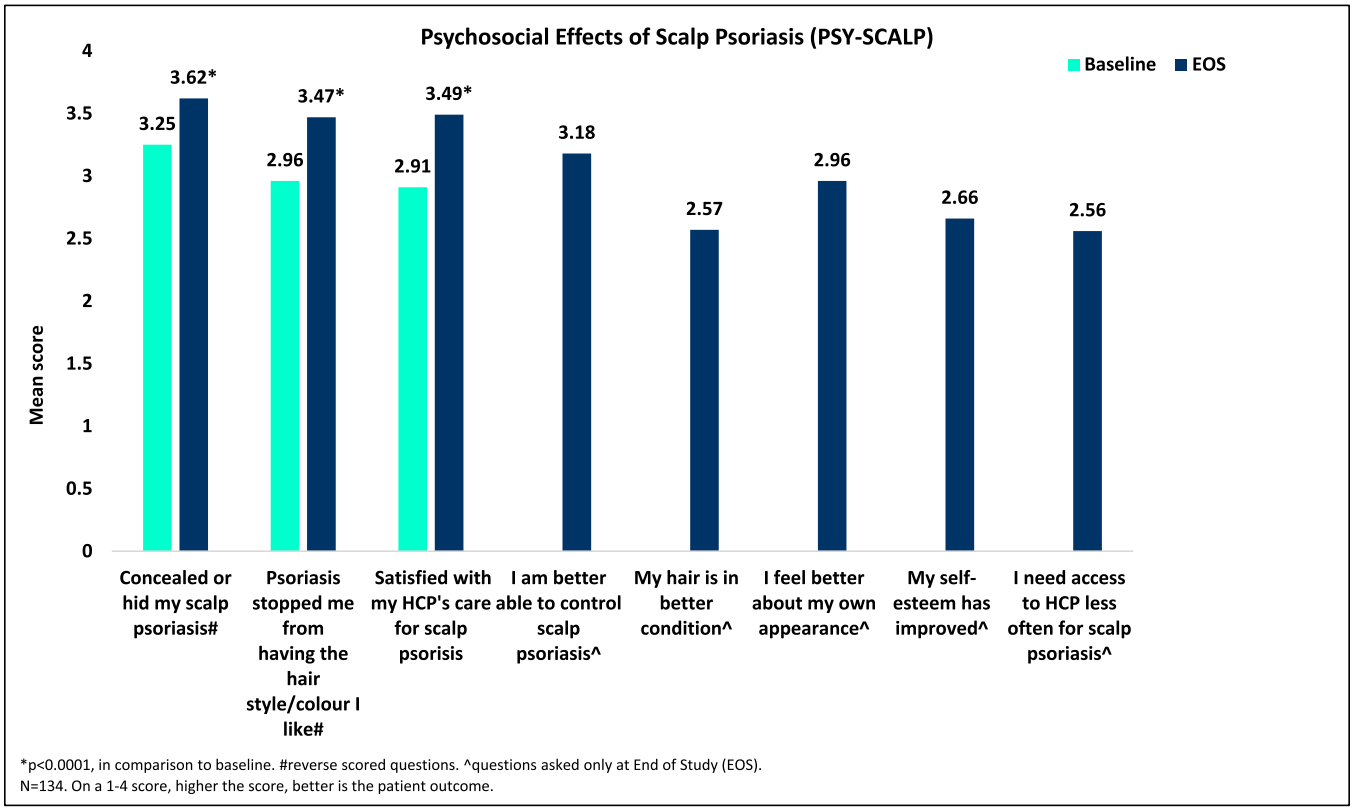


FIGURE 7 | Evolution of clinical outcomes from baseline to Weeks 4 and 8 following the use of CAL/BDP PAD cream in scalp psoriasis.

The need to conceal scalp psoriasis or avoid preferred hair style/colour was significantly reduced ($p < 0.0001$) at EOS. Patients also reported greater satisfaction with their physicians' care ($p < 0.0001$). At EOS, 70.9% of patients felt their psoriasis didn't stop them from having their desired hair style/colour, 72.4% felt better about their appearance and 61.2% reported improved self-esteem.

Treatment with CAL/BDP PAD-cream also improved the sleep pattern in patients. Significantly smaller number of patients reported that their sleep was affected ≥ 3 days per week (EOS: 8.2% vs. baseline: 30.6% [−22.4%; $p < 0.0001$]), and significantly higher number of patients reported better sleep quality in the past week (EOS: 64.9% vs. baseline: 36.6% [+28.4%; $p < 0.0001$]).



*p<0.0001, in comparison to baseline. #reverse scored questions. ^questions asked only at End of Study (EOS).
N=134. On a 1-4 score, higher the score, better is the patient outcome.

FIGURE 8 | Psychosocial effects of scalp psoriasis (PSY-SCALP). EOS, end of study; HCP, healthcare professional.

3.5 | Effect of Medication Adherence on Outcome With CAL/BDP PAD-Cream Treatment

The interim analysis shows CAL/BDP PAD-cream effectively managed mild-to-moderate scalp psoriasis in both low-adherence and high-adherence groups. About 62.4% of patients reported high-adherence (VAS 80−100), with a mean VAS (SD) score of 77.0 (23.6). Sub-group analysis details are in Table 2.

Sub-group analysis revealed significant improvement ($p < 0.0001$) in Scalpdex scores from baseline to EOS, for both low (VAS < 80) and high-adherence (VAS 80–100) sub-groups. Patients with higher adherence (vs. low adherence group) had greater improvement in overall Scalpdex score (CFB: −28.0, $p < 0.0001$ vs. −21.5, $p < 0.0001$), symptoms score (CFB: −32.5, $p < 0.0001$ vs. −23.8, $p < 0.0001$), emotions score (CFB: −27.6, $p < 0.0001$ vs. −22.1, $p < 0.0001$) and functioning score (CFB: −23.8, $p < 0.0001$ vs. −18.5, $p < 0.0001$).

Other treatment outcomes, such as S-mPASI and WI-NRS, also improved significantly ($p < 0.0001$) in both low and high-adherence groups at EOS. Patients with higher adherence showed better improvement in S-mPASI score (CFB: −1.5, $p < 0.0001$ vs. −1.1, $p < 0.0001$) and WI-NRS score (CFB: −4.5, $p < 0.0001$ vs. −2.8, $p < 0.0001$) scores than patients with lower adherence.

4 | Discussion

Topical agents are the mainstay of treatment for mild-to-moderate psoriasis, but patient non-adherence can reduce their effectiveness, as chronic conditions like psoriasis often see lower adherence rates compared to acute illness [12, 29]. A review by Bewley and Page on medication adherence in psoriasis cited several studies reporting that 39%−73% of psoriasis patients do not follow their prescribed treatment regimen [30]. Another study highlighted that treatment non-adherence is often linked to patients, physicians and treatment-related factors [31]. Therefore, PROs, often excluded from clinical trials, offer valuable insights for clinicians [11]. The present study is the first to assess treatment satisfaction, effectiveness, QoL and adherence with CAL/BDP PAD-cream in real-world setting for scalp psoriasis.

In this interim analysis of the PRO-SCALP study, both clinicians and patients agreed on the effectiveness and convenience of CAL/BDP PAD-cream, with high TSQM-9 scores (clinicians: 81.4, patients: 76.1), indicating positive impact and acceptability of CAL/BDP PAD-cream for scalp psoriasis. Similar treatment satisfaction was observed in a pooled analysis of two Phase 3 trials of CAL/BDP PAD-cream in plaque psoriasis as reflected in improvements in Psoriasis Treatment Convenience Scale (PTCS) scores [9]. A recent survey also reported a positive perception among patients with body and scalp psoriasis treated with CAL/BDP PAD-cream [32].

Psoriasis, especially with scalp involvement, can cause profound clinical, psychosocial and QoL impairment, with visible lesions negatively affecting body image and leading to reduced self-esteem [33]. In this study, CAL/BDP PAD-cream led to greater reduction in itching and depression, with clinically meaningful improvement in psychosocial outcomes, from baseline to EOS. Patients found the treatment effective for their

TABLE 2 | Effect of medication adherence on treatment outcomes and quality of life.

Adherence VAS score subgroups	Baseline *n*, mean (SD), 95% CI	EOS *n*, mean (SD), 95% CI	CFB *n*, mean (SD), 95% CI	*p* value
S-mPASI score[a]				
< 80	49, 1.5 (0.9), (1.2, 1.8)	49, 0.4 (0.6), (0.2, 0.5)	49, −1.1 (1.0), (0.9−1.4)	< 0.0001
80−100	81, 1.8 (1.2), (1.5, 2.0)	81, 0.3 (0.4), (0.2, 0.4)	81, −1.5 (1.2), (1.2−1.7)	< 0.0001
Scalp WI-NRS[a]				
< 80	50, 6.0 (2.4)	50, 3.1 (2.6)	50, −2.8 (3.5), (−3.8, −1.8)	< 0.0001
80−100	83, 6.6 (2.4)	83, 2.1 (2.3)	83, −4.5 (3.0), (−5.1, −3.8)	< 0.0001
SCALPDEX domain scores[b]				
Symptoms				
< 80	50, 51.5 (20.3)	50, 27.7 (20)	50, −23.8 (26.1), (−31.3, −16.4)	< 0.0001
80−100	83, 53.2 (20.8)	83, 20.7 (19.5)	83, −32.5 (23.7), (−37.7, −27.4)	< 0.0001
Emotions				
< 80	50, 56.6 (20.9)	50, 34.5 (20.2)	50, −22.1 (24.1), (−28.9, −15.3)	< 0.0001
80−100	83, 56.78 (21)	83, 29.2 (21.2)	83, −27.6 (21.4), (−32.3, −22.9)	< 0.0001
Functioning				
< 80	50, 51.9 (25.1)	50, 33.4 (20.4)	50, −18.5 (26.2), (−25.9, −11.1)	< 0.0001
80−100	83, 50.4 (26.7)	83, 26.6 (24.5)	83, −23.8 (24.8), (−29.2, −18.4)	< 0.0001
Overall score				
< 80	50, 53.3 (18.5)	50, 31.9 (18.3)	50, −21.5 (22.7), (−27.9, −15.0)	< 0.0001
80−100	83, 53.5 (19.8)	83, 25.5 (19.7)	83, −28.0 (21.0), (−32.6, −23.4)	< 0.0001

Abbreviations: Adherence VAS < 80, low adherence; adherence VAS 80−100, high adherence; CFB, change from baseline; EOS, end of study; *n*, number; SD, standard deviation; VAS, visual analogue scale.
[a]*p* values calculated by paired *t*-test or Wilcoxon signed rank test, corresponds to differences in mean score between time points within each of the strata.
[b]*p* values calculated by Student's *t*-test or Wilcoxon signed rank test, correspond to differences in scores between time points within each of the strata.

scalp psoriasis, enhancing their appearance and self-esteem and hair condition. They also expressed satisfaction with their physicians and required less frequent access to medical care. Similar significant ($p < 0.0001$) disease control in scalp psoriasis with CAL/BDP combination was reported by Jemec et al. [34].

CAL/BDP PAD-cream exhibited high effectiveness, with 77.9% of patients achieving a scalp-PGA score of clear/almost clear EOS (Week 8) in this interim analysis. This is similar to the findings of a European clinical study (NCT03802344), where 68.2% of patients in the CAL/BDP PAD-cream group achieved the same score at Week 8, and the scalp-PGA success rate for CAL/BDP PAD-cream was statistically superior compared to the vehicle at Weeks 4 ($p = 0.0051$) and 8 ($p = 0.0002$) [17].

Prescribing topical therapy in patients' preferred vehicle is essential for maximising patient adherence. In a recent publication, sensory analysis has shown that CAL/BDP PAD-cream's vehicle meets the desirable properties for a psoriasis treatment [35]. The interim analyses of the PRO-SCALP study indicate high treatment satisfaction, with most patients preferring this regimen over previous topicals and expressing willingness to use it again. These findings align with another recent study, where 93% of patients were satisfied, 66% reported high-adherence (VAS 80–100) and 91% preferred CAL/BDP PAD-cream to prior topical(s) [32].

CAL/BDP PAD-cream significantly improved treatment outcomes in the overall cohort, as well as in both low and high-adherence groups, indicating benefits for patients at all levels of adherence. Sub-group analysis revealed that higher treatment adherence led to greater improvement in S-mPASI, WI-NRS scores and all Scalpdex metrics.

While this interim analysis indicates the real-world effectiveness and preference for CAL/BDP PAD-cream in treating scalp psoriasis in the studied European population, it has limitations. The lack of a control group makes it difficult to attribute outcomes solely to the intervention, and reliance on self-reported data may affect accuracy. Cultural differences across international sites and the focus on European populations limit generalizability, and the short duration of the interim analysis calls for further long-term studies to assess the long-term effect of the treatment.

5 | Conclusion

The interim analyses of the PRO-SCALP indicate high treatment satisfaction with CAL/BDP PAD-cream, with a majority of patients expressing a preference for it over previous topicals and showing willingness to use it again. Both ClinROs and PROs indicate better clinical outcomes, high treatment satisfaction and significant impact of treatment adherence on treatment outcomes. In conclusion, CAL/BDP PAD-cream improved the QoL and shows promise for treating mild-to-moderate scalp psoriasis in adults.

Author Contributions

Andreas Pinter, Jose Luis López Estebaranz, Anthony Bewley, Jordi Galván, Volker Koscielny, Ismail Kasujee and Siva Narayanan conceived and planned the research study. Andreas Pinter, Jose Luis López Estebaranz, Anthony Bewley and Siva Narayanan carried out research data collection. Siva Narayanan carried out data analyses. Andreas Pinter, Jose Luis López Estebaranz, Anthony Bewley, Jordi Galván, Volker Koscielny, Ismail Kasujee and Siva Narayanan contributed to the interpretation of the results. Siva Narayanan took the lead in writing the manuscript. All authors provided critical feedback and helped shape the research, analysis and manuscript, and all authors reviewed the manuscript to provide final approval.

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Ethics Statement

For Germany: First ethics vote was obtained from Ethikkommission der Goethe-Universität Frankfurt, Theodor-Stern-Kai 7, 60590 Frankfurt am Main, Germany, Phone Number: +49 69 6301 3758, Email Address: ethikkommission@kgu.de, Approval #2023–1145. **For UK**: HRA and HCRW approval was obtained for study implementation in England and Scotland. IRAS project ID: 326834, REC (ethics) reference #23/LO/0474. **For Spain**: First ethics vote/approval was obtained from... CEIC Aragón, Instituto Aragonés de Ciencias de la Salud (IACS), Centro de Investigación Biomédica de Aragón (CIBA), Avda. San Juan Bosco, 13, planta 1, 50009 Zaragoza, Spain, Ethics reference #EPA23–018. Subsequently, additional regional ethics approvals were obtained in Germany and Spain, as needed. All patients in this manuscript have given written informed consent for participation in the study and the use of their deidentified, anonymized, aggregated data and their case details (including photographs) for publication. All patients in this manuscript have given written informed consent for participation in the study and the use of their de-identified, anonymized, aggregated data and their case details (including photographs) for publication.

Conflicts of Interest

Andreas Pinter has received honoraria as investigator and/or has received speakers' honoraria and/or has received grants and/or has been an advisor for AbbVie, Almirall, Amgen, Biogen Idec, Boehringer-Ingelheim, Celgene, Celltrion, Eli-Lilly, GSK, Galderma, Hexal, Janssen, LEO-Pharma, MC2, Medac, Merck Serono, Mitsubishi, MSD, Novartis, Pascoe, Pfizer, Tigercat Pharma, Regeneron, Roche, Sandoz Biopharmaceuticals, Sanofi-Genzyme, Schering-Plough, UCB Pharma and Zuellig Pharma. Jose Luis Lopez Estebaranz has received honoraria as a speaker/member of the Advisory Board from Abbvie, Almirall, Bioderma, Celgene, Galderma, Isdin, Janssen Cilag, Leo Pharma, Lilly, Novartis and Viatris and speaker honoraria from InfectoPharma, Mylan and StreamedUp. Anthony Bewley has consulted for Abbvie, Almirall, Celgene, Galderma, Janssen, Leo Pharma, Lilly, Novartis, Sanofi, UCB, served on advisory boards for Psoriasis Association, Changing Faces, ISG, NES, received grants from EADV and travel grants from Almirall, Janssen, Leo, participated in BAD guidelines committees, is editor for Practical Psychodermatology, president of ESDaP, and chair of APP-GOS. Siva Narayanan has received consulting honoraria or research funding from Almirall, Biogen, Johnson and Johnson, Progentech Diagnostics, Sarepta Therapeutics, SeaGen and Takeda. Jordi Galván, Volker Koscielny and Ismail Kasujee are Almirall employees.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.