Patient and Clinician Reported Outcomes for Calcipotriene/Betamethasone Dipropionate PAD cream effectiveness and safety in the treatment of mild-to-moderate plaque psoriasis of the scalp in adults (PRO-SCALP)

Statistical Analysis Plan

Version 2.4

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AVANT HEALTH

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LIST OF ABBREVIATIONS

Abbreviations	*Definitions*
ADR	Adverse Drug Reaction
AE	Adverse Event
BDP	Betamethasone dipropionate
CAL	Calcipotriene
CFB	Change from baseline
CI	Confidence Interval
CRO	Contract Research Organization
CUSP-Q	Cream Usability in Scalp Psoriasis Questionnaire
DCF	Data Collection Form
DM	Data Management
DMP	Data Management Plan
DVP	Data Validation Plan
eCRF	electronic Case Report Form
EDC	Electronic Data Capture
EOS	End of Study
ETV	Early Termination Visit
EU PAS	European Union Post-Authorization Studies
FAS	Full Analysis Set
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IEC	Independent Ethics Committee
MedDRA	Medical Dictionary for Regulatory Activities
MMAS-4	Morisky Medication Adherence Scale - 4 items
NIS	Non-Interventional Study
PGA	Physician’s Global Assessment
PPQ	Patient Preference Questionnaire
PRO	Patient Reported Outcomes
PSY-SCALP	Psychosocial Effects of Scalp Psoriasis Questionnaire

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Q1	First quartile
Q3	Third quartile
QoL	Quality of life
SAE	Serious Adverse Event
SADR	Serious Adverse Drug Reaction
SAP	Statistical Analysis Plan
SD	Standard Deviation
S-mPASI	Scalp modified Psoriasis Area and Severity Index
SmPC	Summary of Product Characteristic
SOP	Standard Operating Procedures
TSQM	Treatment Satisfaction Questionnaire Medication
UK	United Kingdom
VAS	Visual Analog Scale
WHO	World Health Organization
WI-NRS	Worst Itch Numerical Rating Scale

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PROTOCOL SUMMARY

Title:	Patient and clinician Reported Outcomes for Calcipotriene/Betamethasone Dipropionate PAD cream effectiveness and safety in the treatment of mild-to-moderate plaque psoriasis of the scalp in adults (PRO-SCALP)
Précis:	An international, prospective, observational cohort study to assess patient treatment satisfaction, patient-reported outcomes, effectiveness, and safety of a fixed-dose combination of Calcipotriene/Betamethasone Dipropionate PAD cream in the treatment of mild-to-moderate plaque psoriasis of the scalp in adults (PRO-SCALP).
Objectives:	To assess treatment satisfaction, quality of life, treatment preference, adherence and convenience, psychosocial effects of scalp psoriasis, sleep quality, and effectiveness, and safety of Calcipotriene/Betamethasone Dipropionate PAD cream in a real-world setting. Primary: To assess patient satisfaction with CAL/BDP PAD cream. Secondary: Evaluate CAL/BDP PAD cream treatment effectiveness, and patient quality of life (QoL). Additional: Evaluate patient and clinician satisfaction CAL/BDP PAD cream, future treatment preference, treatment adherence, and CAL/BDP PAD cream safety/tolerability.
Population:	Approximately three hundred (300) patients of age ≥18 years at the time of initiation of treatment with Calcipotriene/Betamethasone Dipropionate PAD cream from clinical practices across Germany, Spain, and the United Kingdom
Number of Sites:	Approximately thirty sites will be recruited.
Duration of Treatment	Once daily up to 8 weeks.
Study Drug & Mode of Administration	Calcipotriene and betamethasone dipropionate (50 microgram/g CAL and 0.64 mg/g BDP, equivalent to 0.5 mg/g of betamethasone) cream (CAL/BDP cream – Wynzora® cream).
Study Duration:	Duration of the study will be approximately 24 months, across three countries. Individual patient study observation period will be up to 8-12 weeks.

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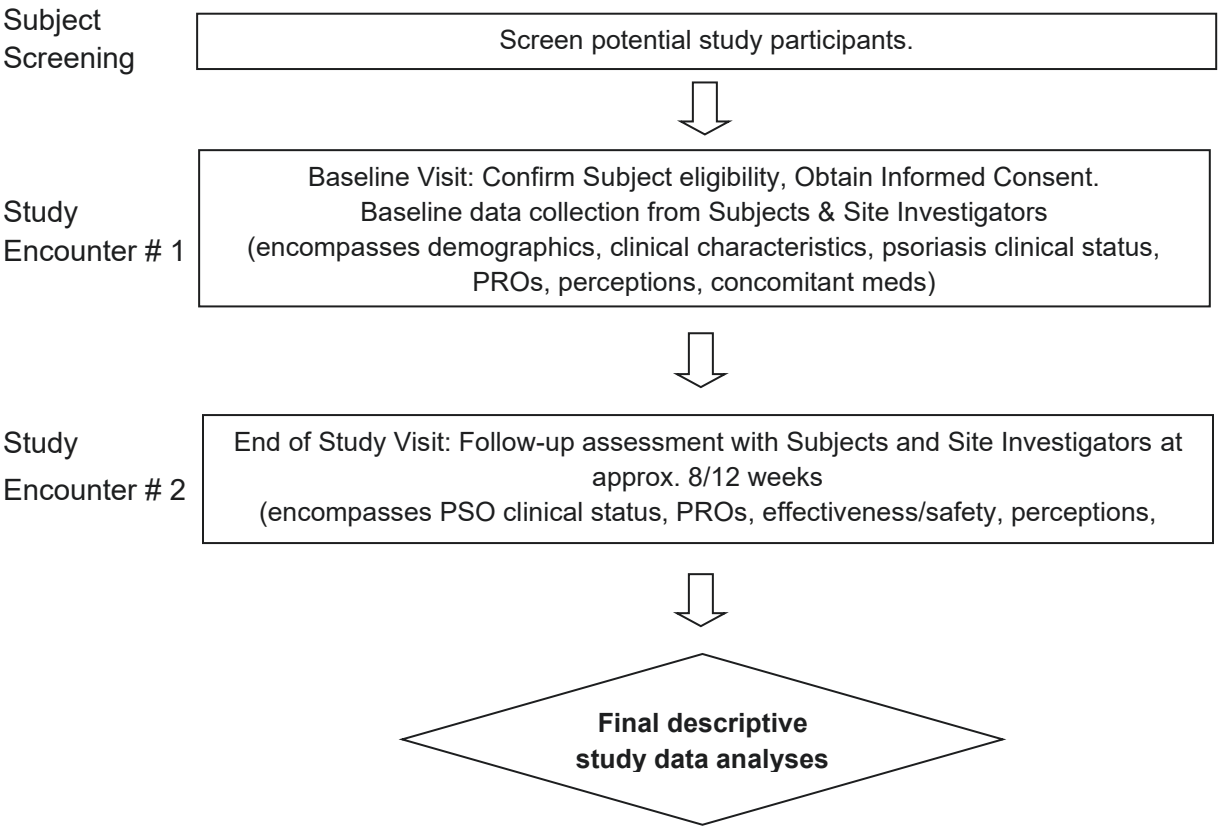
Schematic of Study Design



Note: Clinicians shall prescribe Calcipotriene/Betamethasone Dipropionate PAD cream (Wynzora®) to eligible Subjects per own clinical judgement and manage them as they normally would, in clinical practice.

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1 PRO-SCALP STUDY BACKGROUND RATIONALE

Psoriasis is a chronic inflammatory, immune-mediated skin disease, which affects 2-4% of the population in Europe [7-8] and has a substantial impact on patients' quality of life (QoL) in different degree of severity, including physical, psychologic, social, sexual, and occupational elements [9-10]. Psoriasis is triggered probably by environmental factors in genetically predisposed individuals and sustained by a dysfunctional immune system [11]. Psoriasis vulgaris, also known as plaque psoriasis, is the most common form of the disease, affecting around 80-90% of patients diagnosed and it is characterised by well-defined, sharply demarcated, erythematous plaques [12].

The scalp is one commonly affected region of the body in psoriasis, with a prevalence of about 40- 50% and presents a significant burden to patients due to the difficult-to treat nature of this area and the difficulties in administering treatment [1-4]. Scalp psoriasis is characterized by thickened red plaques with silver-white scale, contained within the hairline or extending to the forehead, ears, and back neck [13]. Importantly, scalp psoriasis presents a significant moderate-to-high burden to patients due to the scalp difficult-to treat nature and treatment administration difficulties [1,14]. In addition, psoriasis, especially with scalp involvement, can lead to significant psychosocial impairment and lower QoL related to the highly visible site of the lesions despite limited skin involvement [15,16]. Due to the presence of hair, poor accessibility, and unacceptable cosmetic appeal of topical therapy, patients with scalp psoriasis tend to have poor treatment satisfaction and adherence [17,18]. Therefore, effective therapeutic regimens for scalp psoriasis are essential in order to improve QoL and treatment satisfaction of patients.

Different scales and scores are used to assess psoriasis severity. The Physician's Global Assessment (PGA), sometimes referred to as the Investigator's Global Assessment (IGA), has been the measure used most frequently after the Psoriasis Area and Severity Index (PASI) [19]. The PGA/IGA is a simple instrument of 5-point ordinal scale used to assess the severity of disease over the body: global, scalp, palmoplantar and nails, ranging from 0 (clear; no symptoms) to 4 (severe) for global, scalp and palmoplantar assessment, being psoriasis of mild severity when PGA = 2 and of moderate severity when PGA = 3 [20].

Psoriasis treatment is still based on controlling the symptoms [10]. Topical therapy is the first-line treatment for patients with mild-to-moderate psoriasis [12,21]. Several classes of topical therapy exist in a variety of formulations and modalities (i.e., creams, ointments, gels and foams) including retinoids, vitamin D derivatives, topical corticosteroids, calcineurin inhibitors, dithranol, tar-based preparations, and combination therapies [22]. However, in patients who do not achieve a good disease control, topical therapies can be combined with phototherapy or systemic conventional or biologic therapies when topical treatment alone is not treating adequately psoriasis [23].

Calcipotriene and betamethasone dipropionate (50 microgram/g CAL and 0.64 mg/g BDP, equivalent to 0.5 mg/g of betamethasone) cream (CAL/BDP PAD cream – Wynzora® cream) is based on PAD Technology enabling development of an easy to apply, aqueous cream of CAL and BDP, despite their known pH-related instability when combined in the presence of water [5,6]. The CAL/BDP combination is recommended as first-line treatment of mild-to-moderate plaque psoriasis by many European, Canadian, and American guidelines and associations of dermatology [24-27]. In a phase 3 clinical trial CAL/BDP PAD cream demonstrated high PGA treatment success and satisfaction, fast onset of action and a favourable safety profile in

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patients with scalp psoriasis [6]. CAL/BDP combination has been shown to be superior to their single constituents alone and it also permits a once-daily application, leading to an increased treatment adherence [28].

RATIONALE:

As stated above, the scalp is one of the most commonly affected regions of the body in psoriasis presenting a significant burden to patients due to the difficult-to treat nature of this area and the difficulties in administering treatment and leading to significant psychosocial impairment. Due to the presence of hair, poor accessibility, and unacceptable cosmetic appeal of topical therapy, patients also tend to have poor adherence and satisfaction with treatment. Effective therapeutic regimens for scalp psoriasis are essential to improve QoL of patients [1].

In order to properly evaluate the effect of CAL/BDP PAD cream (Wynzora®) in the clinical practice in this short-term study (8 weeks), the patient will be asked not to have received systemic treatment for psoriasis before starting CAL/BDP PAD cream for a period of time that will depend on the pharmacokinetic and pharmacodynamic properties of the previous systemic treatments for psoriasis.

Previous data on other topical therapies or CAL/BDP combinations have shown improvements on treatment satisfaction and convenience. Clobetasol 0.05% lotion treatment demonstrated high user convenience and treatment satisfaction rate in patients with scalp psoriasis [29]. CAL/BDP foam has shown a high level of satisfaction with effectiveness and convenience in plaque psoriasis patients, including scalp psoriasis, and in those who had received previous treatments, it has been reported higher preference for CAL/BDP foam compared to previous topical treatments [30].

In phase 3 trials, the CAL/BDP PAD cream has shown high PGA treatment success and satisfaction, a good efficacy, and a favourable safety profile in patients with scalp psoriasis [2] and allows once-daily application, leading to an increased treatment adherence [23] but no data of this new formulation is available in a real-world setting.

Thus, the present observational, non-interventional study (NIS) proposes to evaluate treatment satisfaction of CAL/BDP PAD cream in the treatment of adult patients with mild-to-moderate scalp psoriasis in a real-world setting. In addition, the present study is planned to investigate QoL, preference, adherence, treatment convenience, sleep quality and psychosocial effects on this profile of patients treated with CAL/BDP PAD cream. At last, this study will also assess the CAL/BDP PAD cream effectiveness, safety, and tolerability in a real-world setting.

2 PRO-SCALP STUDY OBJECTIVES

2.1 Study Objectives

Overall objectives are to assess treatment satisfaction, QoL, preference, adherence, convenience, sleep quality, psychosocial effects of scalp psoriasis, effectiveness, and safety of CAL/BDP PAD cream in a real-world setting.

Primary objective:

- To assess patient satisfaction with CAL/BDP PAD cream, using the Treatment Satisfaction Questionnaire TSQM-9.

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Secondary objectives:

- To assess QoL among patients treated with CAL/BDP PAD cream using the Scalpdex questionnaire.
- To assess effectiveness of CAL/BDP PAD cream, measured by Physician Global Assessment of the psoriasis on the Scalp (Scalp PGA).
- To assess effectiveness of CAL/BDP PAD cream, measured in terms of patient-reported worst level of scalp itching due to psoriasis experienced in the last week, using Worst Itch Numerical Rating Scale (WI-NRS).

Additional objectives:

- To assess effectiveness of CAL/BDP PAD cream in terms of disease severity, using Scalp modified Psoriasis Area and Severity Index (S-mPASI).
- To describe treatment convenience of CAL/BDP PAD cream in routine clinical practice using the Cream Usability in Scalp Psoriasis Questionnaire (CUSP-Q).
- To describe patient treatment preference between CAL/BDP PAD cream versus previous topical treatment used for treatment of scalp psoriasis through the Patient Preference Questionnaire (PPQ).
- To assess patient adherence to CAL/BDP PAD cream treatment according to medication adherence (Morisky Medication Adherence Scale 4 items (MMAS-4)), and patient's self-reported adherence (self-reported VAS).
- To describe the sleep quality associated with CAL/BDP PAD cream treatment in routine clinical practice through a two-item questionnaire about sleep quality according to own patient's perception.
- To describe the psychosocial effects of scalp psoriasis, using Psychosocial Effects of Scalp Psoriasis Questionnaire (PSY-SCALP).
- To assess physician satisfaction with CAL/BDP PAD cream.
- To assess safety and tolerability of CAL/BDP PAD cream in routine clinical practice up to 8 weeks of treatment

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2.2 Key Study End Points

All safety outcomes will be assessed on the Safety population. The primary, secondary and additional endpoints (except safety assessments) will be assessed on the FAS population. An intermediate analysis of the primary objective, secondary and selected additional objectives will be performed once the first 150 patients have completed the study.

Primary Endpoint:

- Absolute TSQM-9 effectiveness, convenience, and global satisfaction domain scores at end of study observation period.

Secondary Endpoints:

- Absolute symptoms, emotions, and functioning scores of the Scalpdex questionnaire at end of study observation period.
- Proportion of patients achieving scalp-PGA treatment success* at week 4 (if applicable) and at end of study observation period.
- Absolute scalp WI-NRS score at Baseline and at end of study observation period.

*Scalp-PGA treatment success is defined as a scalp-PGA score of 0 (clear) or 1 (almost clear) and with a minimum 2 points improvement from baseline, on the scalp.

Additional Endpoints:

- Change from baseline in the absolute symptoms, emotions, and functioning scores of the Scalpdex questionnaire at end of study observation period.
- Absolute PPQ score at end of study observation period.
- Proportion of patients achieving scores of 2 (agree) or 3 (strongly agree) for each item of the PPQ at end of study observation period.
- Absolute scalp PGA score at all visits and change from baseline in the absolute scalp PGA score at week 4 (if applicable) and at end of study observation period.
- Proportion of patients achieving scalp PGA treatment score of 0 [clear] or 1 [almost clear] at week 4 (if applicable) and at end of study observation period.
- Time to scalp-PGA treatment success*.
- Absolute S-mPASI score at all visits and change from baseline in the absolute S-mPASI score at week 4 (if applicable) and at end of study observation period.
- Proportion of patients with a reduction of at least 75% in S-mPASI score from baseline to week 4 (if applicable) and at end of study observation period (S-mPASI 75).
- Change from baseline in the absolute scalp WI-NRS score at end of study observation period.
- Proportion of patients achieving a scalp WI-NRS score of <3 at end of study observation period, in those patients with a minimum scalp WI-NRS score of 3 at baseline.
- Proportion of patients obtaining a minimum 4-point improvement in scalp WI-NRS at end of study observation period, in those patients with a minimum scalp WI-NRS score of 4 at baseline.
- Absolute CUSP-Q scores (overall and for each item) at end of study observation period.
- Absolute MMAS-4 score at end of study observation period.

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- Proportions of patients scoring 0 (high adherence), 1-2 (intermediate adherence), and 3-4 (low adherence) in the MMAS-4 at end of study observation period.
- Absolute self-reported VAS for treatment adherence score at end of study observation period.
- Proportion of patients with sleep affected due to scalp psoriasis ≥3 days per week at baseline and at end of study observation period.
- Proportion of patients sleeping well (defined as: “very well” and “rather well”) at baseline and at end of study observation period.
- Absolute PSY-SCALP scores (overall and for each item) at baseline and at end of study observation period.
- Frequency of responses to individual items of the PSY-SCALP Questionnaire, at baseline and at end of study observation period.
- Change from baseline in PSY-SCALP score, according to questions 2 and 3 of the PSY-SCALP questionnaire (collected at baseline) and corresponding questions 5 and 6 (collected at end of study observation period), at end of study observation period.
- Absolute physician satisfaction scores for effectiveness, convenience, and global satisfaction domains at end of study observation period.
- Incidence of SAEs, SADRs, maternal/paternal pregnancy exposure and other special situations during study observation period.

*Scalp-PGA treatment success is defined as a scalp-PGA score of 0 (clear) or 1 (almost clear) and with a minimum 2 points improvement from baseline, on the scalp.

3 STUDY DESIGN

This is an international, prospective, observational, multicentre study to assess the satisfaction of adult patients with mild-to-moderate plaque psoriasis of the scalp with a fixed-dose combination of CAL/BDP PAD cream (Wynzora®) under real-life conditions.

It is planned to include 300 patients. In this study, CAL/BDP PAD cream will be prescribed according to Summary of Product Characteristic (SmPC). Special care must be taken that the decision to prescribe the treatment will be made independently and prior to the decision to include the patient in the study, meaning that CAL/BDP PAD cream prescription to a patient will not be decided in advance by the study protocol but will be done within current clinical practice, thus the prescription of CAL/BDP PAD cream will be clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures will be applied to the patients. Assessments aligned with those usually performed in the routine clinical practice are planned. A follow-up of up to 8 $\pm$ 4 weeks for each recruited patient will be performed.

3.1 Subject Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

- Adult (≥18 years) male or female patients with mild-to-moderate plaque psoriasis of the scalp (defined as scalp-PGA score of 2 or 3 at baseline) with or without involvement of the trunk and limbs, and who may or may not have been previously treated (treatment-naive patients) with other anti-psoriatic therapies.

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- Patients who have been prescribed CAL/BDP PAD cream (Wynzora®) treatment to manage plaque psoriasis of the scalp according to SmPC in routine clinical practice.
- Willingness and ability to participate in the study; patients must give their written consent to participate.

3.2 Subject Exclusion Criteria

An individual who meets any of the following criteria were excluded from participation in this study:

1. Patients with severe plaque psoriasis, per physician global assessment.
2. Patients with erythrodermic, exfoliative or pustular psoriasis.
3. Patients previously treated with systemic drugs for psoriasis (conventional or biologic) within the last 12 weeks prior to inclusion.
4. Concomitant systemic treatment with anti-psoriatic drugs.
5. Concomitant treatment of any type for plaque psoriasis of the scalp.
6. Hypersensitivity to the active substances or to any of the excipients of CAL/BDP PAD cream (Wynzora®).
7. Patients with known disorders of calcium metabolism.
8. Patients with viral (e.g., herpes or varicella) lesions of the skin, fungal or bacterial skin infections, parasitic infections, skin manifestations in relation to tuberculosis, perioral dermatitis, atrophic skin, striae atrophicae, fragility of skin veins, ichthyosis, acne vulgaris, acne rosacea, rosacea, ulcers, and wounds.
9. Pregnant or breastfeeding women, except when the potential benefit justifies the potential risk.
10. Patients unable to comply with the requirements of the study or who in the opinion of the study physician should not participate in the study.
11. Patients for whom medical chart is inaccessible to physicians to complete baseline data collection.

4 STUDY SCHEDULE & PROCEDURES

In this study, the visit schedule is not defined by the study protocol but is driven by routine clinical practice according to SmPC.

Data will be collected at study inclusion (baseline visit) and approximately at 8 + 4 weeks after treatment initiation (as per clinical practice) or at the time of CAL/BPD pad cream treatment discontinuation, whichever occurs earlier. Information regarding any unscheduled visit within the observation period due to early disease control, worsening of psoriasis or tolerability problems

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will be collected at the time of follow-up visit close to week 8 + 4 weeks (end of study (EOS) visit).

Sub-study (only in 3 selected study sites taking photographs per standard of psoriasis treatment).

All patients from sites taking photographs (approx. 30 patients from three selected sites [1 site each from Germany, Spain, and UK; approx. 10 patients per site]) will be asked to participate in the sub-study. In this subgroup, in addition to the rest of the study assessments, photographs of the scalp psoriasis-treated areas will be taken at baseline and approximately after 4 and 8 weeks of treatment start. The sub-study week-4 timepoint will be considered within an interval of approximately ± 1 weeks and the week-8 timepoint interval will correspond to the main study follow-up visit of 8 ± 4 weeks (EOS visit).

The schedule of events is summarized in Appendix A.

5 STUDY ASSESSMENTS

PROs, encompassing TSQM-9, Scalpdex, WI-NRS, PPQ, treatment adherence, CUSP-Q, sleep-quality, and PSY-SCALP, will be assessed with study Subjects. CAL/BDP PAD cream (Wynzora®) treatment effectiveness and treatment satisfaction will be assessed with Site Investigators. Safety will be evaluated in terms of AEs and ADRs during the treatment period. For pertinent measures, the study respondents will be given an option to indicate “don’t know / not applicable”, especially related to absence of information tied to a missing visit or Subject discontinuation from the study.

5.1 Treatment Satisfaction Assessments

5.1.1 Subject Treatment Satisfaction Questionnaire for Medication (TSQM-9)

Treatment Satisfaction Questionnaire for Medication (TSQM-9) will be used to assess the treatment satisfaction of Subjects at Baseline & EOS for all patients, in relation to the CAL/BDP PAD cream (Wynzora®) treatment they received at the beginning of the study. TSQM-9 will measure patient satisfaction with treatment on three key domains, namely, effectiveness, convenience, and global satisfaction [36]. The following questions (items) correspond to each subscale:

Scale	**Items**
Effectiveness	1-3
Convenience	4-6
Global satisfaction	7-9

Most items are scored on a 7-point Likert scale of: 1: very dissatisfied; 2: moderately dissatisfied; 3: slightly dissatisfied; 4: neutral; 5: slightly satisfied; 6: moderately satisfied; 7: very satisfied. Items 7 and 8 of TSQM-9 are scored on a 5-point scale of: 1: not at all confident/certain; 2: a little confident/certain; 3: somewhat confident/certain; 4: very

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confident/certain; 5: extremely confident/certain. TSQM subscale scores will be computed per tool owner specifications and transformed to scores ranging from 0 to 100, with higher scores representing higher satisfaction on respective domains.

The TSQM-9 questionnaire will be administered at EOS among subjects who are retreated with CAL/BDP PAD cream (Wynzora®) in the past 8-12 weeks (since Baseline visit), to solicit their satisfaction with the most recent course of CAL/BDP PAD cream (Wynzora®) treatment.

5.1.2 Site Investigator Treatment Satisfaction Assessments

An ad hoc satisfaction questionnaire very similar to TSQM-9 will be used to assess Site Investigators' satisfaction with CAL/BDP PAD cream (Wynzora®) treatment at EOS, in relation to the CAL/BDP PAD cream (Wynzora®) treatment they administered to Subjects at the beginning of the study. The individual item and subscale scorings will be done similar to the original TSQM-9 questionnaire.

5.2 Subject Quality of Life Assessments

5.2.1 Scalpdex

This questionnaire is intended to be completed by the patients at baseline, and at the EOS visit or ETV in case of premature withdrawal.

Scalpdex is a scalp dermatitis-specific QoL instrument that can be used to determine which aspect of the disease most bothers the patient and to evaluate QoL as one variable of responsiveness to the therapeutic intervention [37]. It has 23 items, with possible answers scoring on a 5-point Likert-type scale ("never" = 0, "rarely" = 25, "sometimes" = 50, "often" = 75, and "all the time" = 100). The final scale scores (symptoms, emotions, and functioning) are calculated by the mean of the item scores pertaining to each scale. A lower score on symptoms, emotions, and functioning represents a better related-QoL for each scale.

5.3 Treatment Effectiveness Assessments

The effectiveness of CAL/BDP PAD cream (Wynzora®) treatment will be assessed from the perspective of Site Investigators as well as the Subjects. It is expected that the Site Investigator assessments will be conducted via in-person visits/encounters at baseline and end of study, and when in-person assessments are not feasible, the assessments may be done via virtual/remote visits. The same evaluator at study site shall perform all evaluations for a subject during the study, as feasible.

5.3.1 Scalp Physician's Global Assessment (Scalp-PGA)

The scalp PGA describes the severity of scalp psoriasis using 5 categories [33]. Scalp PGA for patients is assessed by site investigators at all visits.

The PGA of scalp psoriasis will be made on a 5-point scale, ranging from 0 to 4 as follows:

0 = none (clear)

1 = almost clear

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2 = mild

3 = moderate

4 = severe

5.3.2 Scalp Modified Psoriasis Area and Severity Index (S-mPASI)

The S-mPASI scale is a modification of the original PASI used for assessing and grading the severity of scalp psoriatic lesions and their response to therapy [31,32]. S-mPASI for patients is documented by the site investigators at all visits.

The severity of the scalp psoriasis is calculated by scoring the signs of the disease (erythema, induration, and scaling) on the scalp, each ranging from 0 = none to 4 = very severe, multiplied by an area score for the extent of the disease (percentage of scalp involved with psoriasis), multiplied by a constant factor, 0.1, resulting in a range of 0 to 7.2.

The scale for estimating the area of involvement for scalp involved with psoriasis is:

0 = No scalp involvement

1 = <10% scalp involvement

2 = 10-29% scalp involvement

3 = 30-49% scalp involvement

4 = 50-69% scalp involvement

5 = 70-89% scalp involvement

6 = 90-100% scalp involvement

5.3.3 WI-NRS

It is a self-administered scale to assess patients' worst level of itching on the scalp (in the last week). The scale has a single-item that describes the worst level of itching on the scalp due to psoriasis in the last week on an 11-point scale anchored at 0 (no itching) and 10 (worst itching imaginable) [34]. An WI-NRS <3 points represent mild pruritus [35].

WI-NRS is completed by the patient at baseline and at EOS visit.

5.3.4 Study Subject Photographic Assessments

Site Investigators from a subset of study sites (up to 3) will take photographs of scalp psoriasis in Subject's treatment area on the face or scalp at baseline encounter and at Baseline, Week 4, and EOS during the in-person visits. This photographic data will be used to document and depict the changes in scalp psoriasis that may be associated with CAL/BDP PAD cream (Wynzora®) treatment in the study.

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5.4 Additional Subject Assessments

5.4.1 Patient Treatment Preference – PPQ

This questionnaire is intended to be completed by the patients at the EOS visit or ETV in case of premature withdrawal.

The PPQ is a 10-item instrument to assess patients' treatment preference [38,39]. It includes 5 items comparing with previous topical treatments and 5 items comparing with previous systemics. Each item is scored on a 4-point Likert-type scale (0 = strongly disagree, 1 = disagree, 2 = agree and 3 = strongly agree) and a supplementary option 'Does not apply to me'. Overall score ranges from 0 to 30. In this study, the 5 questions comparing with systemics will be excluded. Thus, overall score of 5-item PPQ will range from 0 to 15. The higher the score, the more preferred the current treatment is (compared to previous topical treatment).

5.4.2 Treatment Convenience - Cream Usability in Scalp Psoriasis Questionnaire (CUSP-Q)

The CUSP-Q is intended to be completed by the patients at EOS visit or ETV in case of premature withdrawal.

The CUSP-Q is a self-reported instrument to assess patients' treatment convenience. It consists of ten items on an 11-point scale anchored at 0 (not at all) and 10 (very much). The items 3, 4, 5, 7, 8 are reverse scored questions.

5.4.3 Treatment Adherence - MMAS-4; VAS

The MMAS-4 is a patient self-reported, medication-taking behaviour scale in which the specific health issue (scalp psoriasis) is inserted for the "health concern". It consists of four items with a scoring scheme of "Yes" = 1 and "No" = 0. The items are summed to give a range of scores from 0 to 4. A score of 0 indicates high adherence; a score of 1 or 2 indicates intermediate adherence; and a score of 3 or 4 indicates low adherence.

Self-reported VAS for treatment adherence

Treatment adherence to CAL/BDP PAD cream will be assessed by the patients on visual analogue scale (VAS, 100 mm) where 0% represents the lowest possible adherence and 100% the highest possible adherence.

MMAS-4 and VAS for treatment adherence are completed by the patients at EOS visit.

5.4.4 Sleep Quality Questionnaire

The sleep quality of patients is assessed at baseline and EOS visit.

It consists of two questions to assess the sleep quality of the patients according to their own perception: # of days of sleep affected due to scalp psoriasis, and how well the patient slept at night.

5.4.5 Psychosocial Effects of Scalp Psoriasis questionnaire - PSY-SCALP

The PSY-SCALP is completed by the patients at baseline and EOS visit.

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The questionnaire is a self-reported instrument to assess patients' feelings, self-esteem, hair style changes, and relationship and satisfaction with physician's care. It consists of 11 items (three questions at baseline and eight questions at EOS visit) with possible answers "No", "A little", "Quite a lot", and "Very much". The baseline items 1 and 2, and EOS visit items 5 and 6 are reverse scored questions.

5.5 Safety Tolerability - Safety Assessments

5.5.1 Definition of Adverse Events & Adverse Drug Reactions

An AE is any untoward medical occurrence in a patient administered with a pharmaceutical product which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product.

The Site Investigator will use the following terms to assess the severity of each AE:

- Mild: Awareness of symptoms or signs, but easily tolerated (acceptable)
- Moderate: Enough discomfort to interfere with usual activity (disturbing)
- Severe: Interferes significantly with ability to do work or usual activity (unacceptable)

A Serious Adverse Event (SAE) is any experience that suggests a significant hazard, contraindication, side effect or precaution. With respect to human clinical experience, this includes any event which:

- results in death,
- is life-threatening,
- requires inpatient hospitalization* or prolongation of hospitalization, unless hospitalization is for:
    - routine treatment or monitoring of the studied indication, not associated with any deterioration in condition.
    - elective or pre-planned treatment for a pre-existing condition that is unrelated to the indication under study and has not worsened since the start of study drug.
    - treatment on an emergency outpatient basis for an event not fulfilling any of the definitions of a SAE given above and not resulting in hospital admission.
    - social reasons and respite care in the absence of any deterioration in the subject's general condition.
- results in persistent of significant disability / incapacity, or
- is a congenital anomaly / birth defect,
- is a significant or important medical event that, based on appropriate medical judgment, may jeopardize the subject or may require intervention to prevent one of the other outcomes listed above.

* Hospitalization is defined as an overnight (in-patient) stay at the hospital or emergency room.

For all AEs (either related or not related to study medication), information about the outcome (i.e., recovered, recovering, not recovered, recovered with sequelae, fatal, unknown) and the

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action taken with the study treatment (i.e., drug withdrawn, dose reduced, dose increased, dose not changed, not applicable) will be documented and tabulated.

Each AE, either serious or non-serious for which a causal relationship to CAL/BDP PAD cream (Wynzora®) cannot be excluded, will be considered as an ADR. An ADR is an injury caused by taking medication. The World Health Organization defines an ADR as a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function. ADRs may occur following a single dose or prolonged administration of a medicinal product (CAL/BDP PAD cream (Wynzora®)) or result from the combination of two or more medicinal products, that includes CAL/BDP PAD cream (Wynzora®).

The determination of whether an AE is related to study treatment (CAL/BDP PAD cream (Wynzora®)) will be based on information regarding the degree to which the study treatment had caused or contributed to the event and will be categorized per the following criteria:

- Related: There were good reasons and sufficient information (e.g., plausible time sequence, dose-response relationship, pharmacology, positive de-challenge and/or re-challenge) to assume a causal relationship with the study medication in the sense that it is plausible, conceivable or likely.

- Not Related: There were good reasons and sufficient information (e.g., implausible time sequence and/or attributable to concurrent disease or other drugs) to rule out a causal relationship with the study medication.

6 STATISTICAL CONSIDERATIONS

6.1 Sample Size Considerations

No formal sample size and power calculations were undertaken. A sample size of 300 adult patients will suffice to estimate with a 95% confidence and a precision +/-2.5 units, a population mean of TSQM-9 score, which has been considered to present a standard deviation of 20 units. Assuming 20% of patients with missing data for the primary analysis due to data unavailability, or dropout, we estimate the achievable precision of the primary endpoint on 240 patients. These subjects will be recruited from across a maximum of 50 clinical sites for the entire study.

6.2 Analysis Populations and Datasets

Statistical analysis and data tabulation will be performed using the following analysis populations unless specified otherwise:

- Safety population: all patients for whom it is known that they had at least one CAL/BDP PAD cream application during the study observation period.
- Full Analysis Set (FAS): all those patients in the safety population that had at least one post-baseline assessment* for primary endpoint.

*Note: This will only include patients who were not prematurely terminated from the study prior to the 8-12 week study observation period.

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All safety evaluations (part of additional objectives) will be conducted among the safety population, while FAS will be used to conduct analyses addressing the rest of the study objectives, including the primary objective.

6.3 General Statistical Procedures

6.3.1 Overview

Data from Site Investigators and study Subjects will be combined into one dataset. Evaluation of key study outcome measures stratified by country will be conducted. No site-specific analyses will be conducted. Validated instruments will be scored according to developer guidelines, reporting domain scores and overall summary scores, as appropriate. Ad hoc questions will be analyzed and reported individually, based on the respective response scales. For all outcome measures, the analyses will focus on baseline and EOS visits, as applicable. For select clinical outcome measures, data will be reported for Week-4, if available.

All statistical analyses will be based on all available data assuming that all missing data are uninformative and will be conducted using appropriate statistical software, such as SAS (version 9.4). An interim analysis will be conducted after approximately half of the study subjects (150 subjects) have completed 8 weeks of data collection. The final study analyses will be conducted after the completion of EOS visit (approximately 8-12 weeks of data collection) for all enrolled study Subjects.

Statistical differences between continuous endpoints will be assessed using parametric tests (Student's t-test, ANOVA) for normal distribution samples, or non-parametric tests (Mann-Whiteny U test, Kruskal-Wallis test) will be performed for non-normal distribution samples. Comparison of measures for discrete variables will be performed with the Chi-square test or Fisher’s exact test, according to the assumption validations of the statistical test. Paired continuous data will be analyzed with paired t- test and McNemar’s test will be used to compare paired proportions, while appropriate non-parametric tests (Wilcoxon Signed rank test, Friedman test) will be considered for non-normal data. For adherence subgroup comparison (for relevant endpoints), two-way repeated measures analysis of variance (ANOVA) will be carried out to evaluate the statistical differences for normally distributed data, In case of non normal data appropriate non parametric alternative (Wilcoxon Signed rank test, Mann-Whiteny U test or Kruskal-Wallis test) may be used to test the statistical significance.

Statistical significance will be defined as a two-sided p-value < 0.05. Initially, the footnote of the results tables in Section 7.0 will be updated accordingly based on the type of tests performed, during the creation of statistical report(s) and clinical study report.

6.3.2 Summary Statistics

The descriptive statistics for all the continuous variables will include the mean, median, standard deviation (SD), Q1, Q3, 95% CI, and number of Subjects with available data (n). Number of subjects with missing data may also be reflected in relevant tables. Descriptive summaries will be provided for raw, CFB, and %CFB values for relevant endpoints, where applicable. Frequency distributions for all the categorical variables will be presented as counts and

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percentages. Summaries will be provided by encounters, as appropriate. Results from the descriptive analyses will be presented as summary tables and figures.

6.3.3 Subgroup Analysis

Primary, secondary, and additional (non-safety) endpoints may be summarized and repeated for the following subgroups, if sample size permits, using FAS:

- Country: DE, ES, and UK
- Gender: male and female
- Age groups: 18-49 years, 50-64 years, and ≥ 65 years.
- Fitzpatrick skin type: I/II, and III/IV/V/VI.
- Baseline Scalp-PGA: mild and moderate
- Prior treatment experience, as applicable:
    - Use of other topical treatments for scalp psoriasis in the past 12 months
    - Treatment naïve for scalp psoriasis at baseline
- Country; UK, Germany, and Spain
- Medication Adherence; VAS rating 0 -79 (low adherence), 80-100 (high adherence)

Subgroup analyses will either assess the difference in outcomes within a specific strata at a given time period (for measures collected only at EOS visit), or assess CFB within a specific strata (for measures collected at baseline and at EOS visit). In case of medication adherence and Scalp-PGA subgroups, comparison of CFB values (at EOS) between subgroups will also be undertaken.

6.4 Primary Endpoint Analysis

The primary endpoint of Subject's satisfaction with CAL/BDP PAD cream (Wynzora®) treatment at EOS visit measured using TSQM-9 will be analyzed for all subjects and relevant subgroups, using descriptive statistics, using FAS. The TSQM-9 domain scores (effectiveness, convenience, and global satisfaction) will be calculated as recommended by the instrument authors [40]. No missing data imputation is planned for the primary endpoint.

6.5 Secondary Endpoint Analysis

The secondary endpoint of PROs measured using Scalpdex questionnaire at Baseline and EOS visit will be assessed descriptively (per Section 6.3.2) using the FAS dataset. The individual item and domain/subscale scores of Scalpdex will be created per instrument developer instructions, analyzed descriptively to generate summary statistics, for the baseline and EOS encounters, treating the responses as categorical variables and/or continuous variable, as appropriate. CFB in Scalpdex score will be explored and reported using descriptive statistics.

The secondary endpoint of proportion of Subjects with a Scalp-PGA success at Week-4 (in photography sites) and at EOS visit (for all sites) will be analyzed using the FAS dataset. Scalp-PGA treatment success is defined as a scalp-PGA score of 0 (clear) or 1 (almost clear) and with a minimum 2 points improvement from baseline, on the scalp. The additional secondary endpoint of absolute scalp WI-NRS score at Baseline and at EOS visit will be assessed

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descriptively (per Section 6.3.2) using the FAS dataset. No missing data imputation is planned for the secondary endpoints.

6.6 Additional Analyses

The additional endpoints to be presented in this analysis are summarised in Section 2.2. The analysis of the non-safety additional endpoints will be based on the FAS population; these endpoints will be summarised using descriptive statistics (per Section 6.3.2).

S-mPASI, S-mPASI 75, and Scalp-PGA measures will be described as categorical and/or continuous variables for point of time, where applicable. To evaluate them, the answers will be described by each point of time they were completed according to study design; relevant sub-categories of responses (such as % achieving Scalp-PGA of 0/1; ≥75% reduction in S-mPASI score from baseline) will be assessed for relevant endpoint evaluations. Changes will be calculated as the difference between baseline and follow-up visits (4 weeks [if applicable] and EOS visit).

Physician satisfaction measures will be analysed using methods identical to the analyses of study primary endpoint (see Section 6.4). Furthermore, all answers will be described by number of patients who answer in each category or domain, as appropriate.

Questionnaires scores and individual answers (where applicable; PPQ, scalp WI-NRS, MMAS-4, self-reported VAS, CUSP-Q, sleep quality, and PSY-SCALP) provided by patients will be described by each point of time they were completed according to study design; relevant sub-categories of responses (such as % with PPQ response = 2/3 for each question; WI-NRS <3 or a 4-point improvement from baseline, % patients with sleep affected for ≥3 days/week) will be assessed for relevant endpoint evaluations. Changes in questionnaires completed at baseline and end of study observation period will be calculated as the difference between baseline visit and end of study observation period. Furthermore, all answers will be described by the number of patients who answer in each category or domain (if applicable).

Time to achieve Scalp-PGA success will be defined as the time from prescription date of CAL/BDP PAD cream to the Scalp-PGA assessment date corresponding to Scalp-PGA-success; patients with no Scalp-PGA success will be censored at the end of study visit date. The data will be summarized using Kaplan-Meier (i.e. product-limit) method and Kaplan-Meier plot with number of subjects at risk will be generated. The estimate of median time to achieve Scalp-PGA success with 95% confidence interval will be reported.

Concomitant scalp psoriasis and non- scalp psoriasis medications are captured at Baseline and at Week-8 to characterize the use of concomitant medications among the study cohort. Medication usage will be coded using the latest WHO Drug Dictionary. Medications are presented by WHO Drug Anatomical/Therapeutic/Chemical (ATC) category and WHO Drug preferred name. Summaries are presented for prior (prior to the first dose of study treatment, gathered as aggregate indicators as well as at individual item level) medication use and concomitant (after first dose of study treatment had been given, gathered at individual item level) medication use. Medications with an end date occurring before the first study treatment (CAL/BDP PAD cream) date in the treatment period are identified as prior medications. Medications with a start date occurring on or after the first study treatment (CAL/BDP PAD cream) date in the treatment period or medications with a start date prior to the first

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(CAL/BDP PAD cream) dose that were ongoing or with end dates that were on or after EOS visit post index date are identified as concomitant medications. All summaries will be presented as number and % of subjects for each medication. The denominators for calculating the percentages are based on the number of subjects in the relevant analytic population.

6.6.1 Safety Assessments

The safety data will be analyzed descriptively using Safety Population dataset (if it is different from FAS), to report the frequency of occurrences of AEs, SAEs, and ADRs. These will be reported at individual item level as well in aggregate at relevant category level for EOS post-index date. The number of patients discontinuing treatment within the EOS visit post-index date because of AEs, ADRs and for any other reasons will be reported, as documented in patient medical charts.

6.7 Missing Data Handling

The missing data pertinent to the validated instruments Scalpdex, and TSQM-9 will be handled per instrument owner instructions / scoring manual. For all study variables and endpoints, no missing data imputation is planned.

6.8 Significant Protocol Deviations

A protocol deviation is defined as any intentional or unintentional failure to follow the requirements and procedures described in the study protocol. Deviations may have occurred at the subject level or at the site level, and could have been recorded by the site, or uncovered data review. Considering the real-world study design of PRO-SCALP, reflecting the routine clinical practices in the studied countries and associated patient encounters and routine/standard of care data documentation, patients are expected to miss clinic visits or reschedule planned visits as life situations change. These will not be considered as protocol deviations.

Significant protocol deviations will be flagged, and these are defined as study-related issues that were likely to result in: significant impairment of the rights, welfare or safety of subjects; misconduct and/or fraud; and significant impairment of the integrity/validity of study results. Significant protocol deviations also include issues that were likely to impair monitoring and oversight of the study.

6.9 Sensitivity Analyses

Sensitivity analyses will explore the impact of missing data on the robustness of the results, if unusual number of missing data is observed in the study. If some Subject visits are conducted via remote visits instead of in-person visits, the nature of visit (remote vs. in-person) may be used to stratify the analysis of secondary endpoint involving PGA, if sample size permits.

7 DATA TABLES

All patients who received at least one dose of CAL/BDP PAD cream during the study observation period, not prematurely terminated from the study prior to the 8-12 week study observation period, and had at least some data pertaining to study primary endpoint at EOS visit

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will be included in **Full Analysis Set (FAS)** to facilitate the planned descriptive analysis. Correspondingly, patients who completed the study survey at EOS will be included in FAS, since patients answering EOS survey will have completed questions for the primary endpoint.

Safety data analyses will be conducted among the **Safety Population**, that correspond to the entire study cohort that took at least one dose of CAL/BDP PAD cream. Correspondingly, all patients completing the baseline survey and took at least one dose of CAL/BDP PAD cream will be included in this analysis.

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7.1 Patient Demographics, Perceptions & PROs (FAS Population)

7.2 Tables from Clinician's eCRF (FAS Population)

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7.3 Tables from Clinician DCF: Safety Population

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7.4 Sensitivity Analyses

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7.1 Patient Demographics, Perceptions & PROs (FAS Population)

Patient data analysis including demographics, perceptions, and PRO data is analyzed using the FAS dataset. All results depicted in this section pertain to FAS Population.

Table 1.1 Population

S1: Population	
Total # of patients in FAS dataset	N (100%)

Note: Data from patient data collection form. FAS: Full Analysis Set; N: available data.

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Table 1.2 Patient Demographic Characteristics

This table depicts the baseline demographics for the FAS population.

Adult Demographic Data	Statistics	Total (N=x)
S1: Age	Mean (SD) Median Q1, Q3, 95% CI	
S2: Gender Male Female Other	 n (%) n (%) n (%)	
S3: Living Status Alone Not alone	 n (%) n (%)	
S4: Smoking Status Yes, daily Yes, occasionally No, not anymore I have never smoked Average number of cigarettes per day^	 n (%) n (%) n (%) n (%) Missing n n, Mean (SD) Median Q1, Q3, 95% CI	
S5: Drinking status Yes, daily Yes, occasionally No, not anymore I never drank alcohol Average number of alcoholic drinks per week^	 n (%) n (%) n (%) n (%) n, Mean (SD) Median Q1, Q3, 95% CI	
S6: Race* White/Caucasian Black/African/Caribbean Asian Mixed race Other I would prefer not to answer	 n (%) n (%) n (%) n (%) n (%) n (%)	

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Note: Data from Patient data collection form. FAS: Full Analysis Set; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data. *Response options were not mutually exclusive. ^Data analyzed from individuals selecting “Yes, daily,” “Yes, occasionally,” and “No, not anymore”.

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Table 1.3 Scalp Worst Itch – Numerical Rating Scale (Scalp WI-NRS) Patient Scores

Scalp Worst Itch	Statistics	Baseline (N=x)	EOS (N=x)	CFB Scores at EOS (N=x)	p-value
NRS1. Please consider the worst level of itching on the scalp (in the past week) you experienced in the area identified for treatment with CAL/BDP PAD cream (Wynzora®).	Mean, SE* (SD) Median Q1, Q3, 95% CI				*p*
No itching (0)	n (%)				
(1)	n (%)				
(2)	n (%)				
(3)	n (%)				
(4)	n (%)				
(5)	n (%)				
(6)	n (%)				
(7)	n (%)				
(8)	n (%)				
(9)	n (%)				
Worst itching imaginable (10)	n (%)				
Patients with WI-NRS score <3, among patients with ≥3 at baseline	n (%)				
Patients with ≥4 point improvement in WI-NRS score, among patients with ≥4 at baseline	n (%)				

Note: Data from Patient data collection form; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data for the subset; CFB: Change from baseline; EOS: End of Study; SE: Standard Error. *SE calculated for CFB scores at EOS only. X patients had missing data; The denominator for the percentage is the number of patients with available data (N=XX). P-value for CFB in score, calculated by paired t-test, corresponds to differences in mean score between time points.

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Table 1.4 Subgroup Analysis of Scalp Worst Itch – Numerical Rating Scale (Scalp WI-NRS)

Subgroups	Baseline (N=x)	EOS (N=x)	*p*-value
Gender			
Male	n, mean	n, mean	*p*
Female	n, mean	n, mean	*p*
Age Group			
18 – 49 years	n, mean	n, mean	*p*
50 – 64 Years	n, mean	n, mean	*p*
≥ 65 years	n, mean	n, mean	*p*
Fitzpatrick Skin Type			
I / II	n, mean	n, mean	*p*
III / IV / V / VI	n, mean	n, mean	*p*
Baseline Scalp PGA			
Mild	n, mean	n, mean	*p*
Moderate	n, mean	n, mean	*p*
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months			
Yes	n, mean	n, mean	*p*
No	n, mean	n, mean	*p*
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline			
Yes	n, mean	n, mean	*p*
No	n, mean	n, mean	*p*
By Country			
Germany	n, mean	n, mean	*p*
Spain	n, mean	n, mean	*p*
United Kingdom	n, mean	n, mean	*p*
Medication Adherence Score (VAS)			
< 80	n, mean	n, mean	*p*
80 - 100	n, mean	n, mean	*p*

Note: Data from Patient data collection form; n: available data. 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.

Subgroups	Scalp WI-NRS CFB at EOS n, mean
Baseline Scalp PGA	
Mild	n, mean
Moderate	n, mean
	p
Medication Adherence Score (VAS)	
< 80	n, mean
80 - 100	n, mean
	p

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Note: CFB, change from baseline; EOS: End of study. For subgroup evaluation of difference in CFB values, two-way repeated measures analysis of variance (ANOVA) or Wilcoxon Signed rank test, Mann-Whiteny U test or Kruskal-Wallis test will be performed to calculate p-values.

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Table 1.5 SCALPDEX: Patient Response Summary

Domain Question	Statistics	Baseline (N=X)	EOS (N=X)	P value
Symptoms SD1: My scalp psoriasis hurts: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD2: My scalp psoriasis makes me feel depressed: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Symptoms SD3: My scalp psoriasis itches: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD4: I am ashamed of my scalp psoriasis: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD5: I am embarrassed by my scalp psoriasis: Never (1)	Mean (SD) Median Q1, Q3, (95% CI) n (%)			

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Rarely (2) Sometimes (3) Often (4) All the time (5)	n (%) n (%) n (%) n (%)			
Emotions SD6: I am frustrated by my scalp psoriasis: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD7: I am humiliated by my scalp psoriasis: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Symptoms SD8: My scalp psoriasis bleeds: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD9: I am annoyed by my scalp psoriasis: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions	Mean (SD) Median			

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SD10: I am bothered by the appearance of my scalp psoriasis: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD11: My scalp psoriasis makes me feel self-conscious: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD12: I am bothered that my scalp psoriasis is incurable: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Functioning SD13: My scalp psoriasis affects how to wear my hair (hairstyle, hats): Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD14: I am bothered by people's questions about my scalp psoriasis: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			

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Functioning SD15: My scalp psoriasis affects the colour of clothes I wear Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD16: I am bothered by the persistence/reoccurrence of my scalp psoriasis: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD17: I feel stressed about my scalp psoriasis: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Functioning SD18: Caring for my scalp psoriasis is inconvenient for me: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD) Median Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD19: I feel that my knowledge about caring for my scalp psoriasis is adequate: Never (1) Rarely (2) Sometimes (3) Often (4)	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%)			

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All the time (5)	n (%)			
Emotions SD20: The cost of caring for my scalp condition bothers me: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Functioning SD21: My scalp psoriasis makes my daily life difficult: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Emotions SD22: My scalp psoriasis makes me feel different from others: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			
Functioning SD23: My scalp condition makes it hard to go to the hairdresser/barber: Never (1) Rarely (2) Sometimes (3) Often (4) All the time (5)	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%) n (%)			

Note: Data from Patient data collection form; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data; EOS: End of study. The denominator for the percentage is the number of patients with available data (N=XX) at Baseline and N=XX at EOS except SD20 at EOS. P-values correspond to change from baseline (CFB) in mean scores.

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Table 1.6 SCALPDEX: CFB at EOS for Individual Items

Domain	Baseline (N=X) n (%)	EOS (N=X) n (%)	CFB in Proportion at EOS %	*p*-value
Symptoms				
SD1: My scalp psoriasis hurts:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD2: My scalp psoriasis makes me feel depressed:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Symptoms				
SD3: My scalp psoriasis itches:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD4: I am ashamed of my scalp psoriasis:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD5: I am embarrassed by my scalp psoriasis:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD6: I am frustrated by my scalp psoriasis:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD7: I am humiliated by my scalp psoriasis:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Symptoms				
SD8: My scalp psoriasis bleeds:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*

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Emotions				
SD9: I am annoyed by my scalp psoriasis:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD10: I am bothered by the appearance of my scalp psoriasis:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD11: My scalp psoriasis makes me feel self-conscious:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD12: I am bothered that my scalp psoriasis is incurable:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Functioning				
SD13: My scalp psoriasis affects how to wear my hair (hairstyle, hats):				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD14: I am bothered by people's questions about my scalp psoriasis:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Functioning				
SD15: My scalp psoriasis affects the colour of clothes I wear				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD16: I am bothered by the persistence/ reoccurrence of my scalp psoriasis:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD17: I feel stressed about my scalp psoriasis:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	

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Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Functioning				
SD18: Caring for my scalp psoriasis is inconvenient for me**:**				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD19: I feel that my knowledge about caring for my scalp psoriasis is adequate:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD20: The cost of caring for my scalp condition bothers me:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Functioning				
SD21: My scalp psoriasis makes my daily life difficult:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Emotions				
SD22: My scalp psoriasis makes me feel different from others:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*
Functioning				
SD23: My scalp condition makes it hard to go to the hairdresser/barber:				
Never (1) / Rarely (2)	n (%)	n (%)	%	*p-value*
Sometime (3)	n (%)	n (%)	%	
Often (4) / All the time (5)	n (%)	n (%)	%	*p-value*

Note: Data from Patient data collection form; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; CFB, Change from baseline; EOS: End of study; n: available data. X patients had missing data; The denominator for the percentage is the number of patients with available data (N=XX). For all Scalpdex items, the response options ranged from 1 (never) to 5 (always). *P*-value, calculated by McNemar's test, corresponds to CFB (in proportion of patients) in groups 1/2 vs. all others and groups 4/5 vs. all others. Additional information about missing data…

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Table 1.7 SCALPDEX: Domain Scores

Domain	Statistics	Scores at Baseline N=x	Scores at EOS N=x	CFB in Scores at EOS N=x	*p*-value
Symptoms					
	Mean, SE* (SD) Median Q1, Q3, (95% CI^)	Mean (SD) Median Q1, Q3, 95% CI	Mean (SD) Median Q1, Q3, (95% CI)	Mean, SE (SD) Median, Q1, Q3	*p*
Emotions					
	Mean, SE* (SD) Median Q1, Q3, (95% CI^)	Mean (SD) Median Q1, Q3, (95% CI)	Mean (SD) Median Q1, Q3, (95% CI)	Mean, SE (SD) Median, Q1, Q3	*p*
Functioning					
	Mean, SE* (SD) Median Q1, Q3, (95% CI^)	Mean, SE (SD) Median Q1, Q3, (95% CI)	Mean, SE (SD) Median Q1, Q3, (95% CI)	Mean, SE (SD) Median, Q1, Q3	*P*
Overall Score					
	Mean, SE* (SD) Median Q1, Q3, (95% CI^)	Mean, SE (SD) Median Q1, Q3, (95% CI)	Mean, SE (SD) Median Q1, Q3, (95% CI)	Mean, SE (SD) Median, Q1, Q3	*P*

Note: Data from Patient data collection form. SD: Standard deviation; SE: Standard error; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data; SE: Standard Error; CFB: Change from Baseline; EOS: End of study; QoL: Quality of life. *SE only added for CFB scores at EOS. ^95% CI data only added for scores at baseline and scored 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 baseline response group domain scores in comparison to EOS domain scores (CFB; change from baseline). The CFB is calculated using available matching data for each domain.

SCORING NOTES: Scalpdex has 23 items, with possible answers scoring on a 5-point Likert-type scale (“never” = 0, “rarely” = 25, “sometimes” = 50, “often” = 75, and “all the time” = 100). The final scale scores (symptoms, emotions, and functioning) are calculated by the mean of the item scores pertaining to each scale. Overall score is the mean of the three domain scores. A lower score on symptoms, emotions, and functioning represents a better related-QoL for each scale.

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Table 1.8 Subgroup Analysis of *SCALPDEX Domain Scores*

Subgroups	Symptoms			Emotions			Functioning			Overall Score		
	Baseline n, Mean (SD) Median, Q1, Q2	EOS n, Mean (SD) Median, Q1, Q2	*p*	Baseline n, Mean (SD) Median, Q1, Q2	EOS n, Mean (SD) Median, Q1, Q2	*p*	Baseline n, Mean (SD) Median, Q1, Q2	EOS n, Mean (SD) Median Q1, Q2	*p*	Baseline n, Mean (SD) Median, Q1, Q2	EOS n, Mean (SD) Median, Q1, Q2	p
Gender												
Male												
Female												
Age Group												
18-49 years												
50-64 Years												
≥ 65 years												
Fitzpatrick Skin Type												
I / II												
III / IV / V / VI												
Baseline Scalp PGA												
Mild												
Moderate												
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months												
Yes												
No												
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline												
Yes												
No												
By Country												
Germany Spain United Kingdom												
Medication Adherence Score (VAS)												
<80												
80 - 100												

Note: CFB, Change from baseline; EOS, End of Study. P-values correspond to CFB at week-8, within respective strata. The mean score is calculated using the available matching data for each domain. P-values calculated by

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student's t-test or Wilcoxon signed rank test, corresponds to differences in scores between time points within each of the strata.

Subgroups	**Symptoms Score** **CFB at EOS** n, mean	**Emotions Score** **CFB at EOS** n, mean	**Functioning Score** **CFB at EOS** n, mean	**Overall Score** **CFB at EOS** n, mean
Medication Adherence Score (VAS)				
< 80	n, mean	n, mean	n, mean	n, mean
80 - 100	n, mean	n, mean	n, mean	n, mean
	p	*p*	*p*	*p*
Baseline Scalp PGA				
Mild	n, mean	n, mean	n, mean	n, mean
Moderate	n, mean	n, mean	n, mean	n, mean
	p	*p*	*p*	*p*

Note: CFB, Change from baseline; EOS, End of Study. For subgroup evaluation of difference in CFB values within each Scalpdex domain, two-way repeated measures analysis of variance (ANOVA) or Wilcoxon Signed rank test, Mann-Whiteny U test or Kruskal-Wallis test will be performed to calculate p values.

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Table 1.9 Patient Evaluation of Sleep Quality Questionnaire

Questions	Statistics	Baseline (N=X)	EOS (N=X)	CFB in Scores at EOS (N=X)	*p*-value
SQQ1: In the last week, how many days has your scalp psoriasis affected your sleep at night?	Mean (SD), Median, Q1, Q3, (95% CI)^				p
1. None	n (%)				
2. 1 day per week	n (%)				
3. 2 day per week	n (%)				
4. 3 day per week	n (%)				
5. 4 day per week	n (%)				
6. 5 day per week	n (%)				
7. 6 day per week	n (%)				
8. All days of the week	n (%)				
Patients with sleep affected for ≥3 days per week	n (%)				*p*
SQQ2: In the last week, have you slept well at night?	Mean (SD), Median, Q1, Q3, (95% CI)^				*p*
1. Very well	n (%)				
2. Rather well	n (%)				
3. Not well but not badly	n (%)				
4. Rather badly	n (%)				
5. Very badly	n (%)				
(1 / 2)	n (%)				p
(3)	n (%)				
(4 / 5)	n (%)				p

Note: Data from patient data collection form. SD: Standard deviation; SE: Standard error; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data; SE: Standard Error; CFB: Change from baseline; EOS: End of Study; SQ: Sleep Questionnaire. *SE only added for CFB scores at EOS. ^95% CI data only added for scores at baseline and scored at EOS. P-value for SQ1 and SQ2, calculated by Wilcoxon signed rank test, corresponds to baseline scores in comparison to EOS scores (CFB; change from baseline). P Value for Patients with sleep affected for ≥3 days per week, calculated by McNemar's test. For SQ2, additional p-values, calculated by McNemar's test, corresponds to CFB (in proportion of patients) in groups 1/2 vs. all others and groups 4/5 vs. all others.

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Table 1.10 Select Subgroup Analysis of Patient Evaluation of Sleep Quality Questionnaire

Questions	Baseline (N=X)	EOS (N=X)	CFB in Scores at EOS (N=X)	*p*-value
SQQ1: In the last week, how many days has your scalp psoriasis affected your sleep at night?				
Baseline Scalp PGA				
Mild	n, mean	n, mean	n, mean	p*
Moderate	n, mean	n, mean	n, mean	p*
Statistical difference in CFBs between groups at EOS				p**
Medication Adherence Score (VAS)				
< 80	n, mean	n, mean	n, mean	p*
80 - 100	n, mean	n, mean	n, mean	p*
Statistical difference in CFBs between groups at EOS				p**
SQQ2: In the last week, have you slept well at night?				
Baseline Scalp PGA				
Mild	n, mean	n, mean	n, mean	p*
Moderate	n, mean	n, mean	n, mean	p*
Statistical difference in mean CFBs between subgroups at EOS				p**
Medication Adherence Score (VAS)				
< 80	n, mean	n, mean	n, mean	p*
80 - 100	n, mean	n, mean	n, mean	p*
Statistical difference in mean CFBs between subgroups at EOS				p**

Note: CFB, change from baseline; EOS, End of Study.

*P-values correspond to CFB at EOS, within respective strata. P-values calculated by student's t-test or Wilcoxon signed rank test, corresponds to differences in scores between time points within each of the strata.

**For subgroup evaluation of difference in CFB values, two-way repeated measures analysis of variance (ANOVA) or Wilcoxon Signed rank test, Mann-Whiteny U test or Kruskal-Wallis test will be performed to calculate p-values.

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Table 1.11 Patient Psychosocial Effects (PSY-SCALP) Evaluation

Questions	Statistics	Baseline (N=x)	EOS (N=x)	*p*-value
PSY1: Have you ever concealed or hidden your scalp psoriasis? (i.e., needed to wear a hat, cap, or headscarf)? 4. No 3. A little 2. Quite a lot 1. Very much	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%)	PSY1	PSY8	*p*
PSY2: Has your psoriasis stopped you from having the hair style/colour that you would like? 4. No 3. A little 2. Quite a lot 1. Very much	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%)	PSY2	PSY9	*p*
PSY3: Are you satisfied with your HCP's care of your scalp psoriasis? 1. No 2. A little 3. Quite a lot 4. Very much	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%)	PSY3	PSY10	*p*
PSY4: Are you better able to control your scalp psoriasis? 1. No 2. A little 3. Quite a lot 4. Very much	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%)			
PSY5: Is your hair in better condition? 1. No 2. A little 3. Quite a lot 4. Very much	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%)			
PSY6: Do you feel better about your own appearance?	Mean (SD), Median, Q1, Q3,			

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1. No 2. A little 3. Quite a lot 4. Very much	(95% CI) n (%) n (%) n (%) n (%)	[redacted]			
PSY7: Has your self-esteem improved? 1. No 2. A little 3. Quite a lot 4. Very much	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%)	[redacted]			
PSY11: Will you need to access your HCP **less** often about your scalp psoriasis? 1. No 2. A little 3. Quite a lot 4. Very much	Mean (SD), Median, Q1, Q3, (95% CI) n (%) n (%) n (%) n (%)	[redacted]			
PSY-SCALP Composite Score	Mean (SD), Median, Q1, Q3, (95% CI)	[redacted]			

Note: Data from patient data collection form. SD: Standard deviation; SE: Standard error; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data; PSY: Psychosocial effects; EOS: End of study. The questions PSY1, PSY2, and PSY3 are asked both at baseline and EOS. P-value calculated by Wilcoxon signed rank test corresponds to change from baseline (CFB) in mean scores at EOS.

SCORING: Eight items (PSY1-7, PSY11) are individually scored on a 4-point Likert-type scale (No=1 to very much=4; with PSY1 & PSY2 reverse scored). Overall composite score of 8-item PSY-SCALP will range from 8 to 32. The higher the score, the better is patient outcome.

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Table 1.12 Subgroup Analysis of Patient Psychosocial Effects (PSY-SCALP)

	EOS (N=X)	
Subgroups	**Subgroup Total (N)**	**PSY-SCALP Mean Score**
Gender		
Male		
Female		
p-value		
Age Group		
18-49 years		
50-64 Years		
≥ 65 years		
p-value		
Fitzpatrick Skin Type		
I / II		
III / IV / V / VI		
p-value		
Baseline Scalp PGA		
Mild		
Moderate		
p-value		
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months		
Yes		
No		
p-value		
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline		
Yes		
No		
p-value		
By Country		
Germany		
Spain		
United Kingdom		
Medication Adherence Score (VAS)		
< 80		
80 - 100		
p-value		

Note: P-values, calculated by student's t-test/ Mann Whitney U test for dichotomous variables or ANOVA/Kruskal Wallis test for >2 groups, correspond to difference between strata at EOS. EOS: End of Study; n: available data; PSY: Psychosocial effects.

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Table 1.13 Abbreviated Patient Treatment Satisfaction Questionnaire for Medication (TSQM-9)

Domain	Statistics	EOS (N=x)
Effectiveness		
	Mean (SD) Median Q1, Q3, (95% CI)	
Convenience		
	Mean (SD) Median Q1, Q3, (95% CI)	
Global Satisfaction		
	Mean (SD) Median Q1, Q3, (95% CI)	

Note: Data from Patient data collection form. SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; EOS, End of Study; n: available data. Scores range from 0 to 100 with a higher domain score indicates higher domain satisfaction with the study medication. A score can be computed for a subscale/domain only if no more than one item is missing from that subscale/domain.

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Table 1.14 Subgroup Analysis of Patient Treatment Satisfaction Questionnaire for Medication (TSQM-9)

Subgroups	EOS (N=X)			
	Subgroup Total (N)	Effectiveness Mean	Convenience Mean	Global Satisfaction Mean
Gender				
Male				
Female				
p-value				
Age Group				
≤ 49 years				
50 – 64 Years				
≥ 65 years				
p-value				
Fitzpatrick Skin Type				
I / II				
III / IV / V / VI				
p-value				
Baseline Scalp PGA				
Mild				
Moderate				
p-value				
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months				
Yes				
No				
p-value				
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline				
Yes				
No				
p-value				
By Country				
Germany				
Spain				
United Kingdom				
Medication Adherence Score (VAS)				
< 80				
80 - 100				
p-value				

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Note: EOS, End of Study. Data from Patient data collection form. P-values, calculated by student's t-test / Mann Whitney U test for dichotomous variables or ANOVA/Kruskal Wallis test for >2 groups, correspond to difference between strata within respective domains at EOS.

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Table 1.15 Patient Preference Questionnaire (PPQ)

Questions	Statistics	EOS (N=x)
PPQ1: The current treatment is more effective than the previous topical treatments:	Mean (SD), Median, Q1, Q3, (95% CI)	
0. Strongly disagree	n (%)	
1. Disagree	n (%)	
2. Agree	n (%)	
3. Strongly agree	n (%)	
Does not apply to me	n (%)	
2/3 (agree/strongly agree)	n (%)	
PPQ2: The current treatment is easier to use than the previous topical treatments:	Mean (SD), Median, Q1, Q3, (95% CI)	
0. Strongly disagree	n (%)	
1. Disagree	n (%)	
2. Agree	n (%)	
3. Strongly agree	n (%)	
Does not apply to me	n (%)	
2/3 (agree/strongly agree)	n (%)	
PPQ3: The current treatment has fewer side-effects than the previous topical treatments:	Mean (SD), Median, Q1, Q3, (95% CI)	
0. Strongly disagree	n (%)	
1. Disagree	n (%)	
2. Agree	n (%)	
3. Strongly agree	n (%)	
Does not apply to me	n (%)	
2/3 (agree/strongly agree)	n (%)	
PPQ4: I consider the current treatment to be more tolerable than the previous topical treatments:	Mean (SD), Median, Q1, Q3, (95% CI)	
0. Strongly disagree	n (%)	
1. Disagree	n (%)	
2. Agree	n (%)	
3. Strongly agree	n (%)	
Does not apply to me	n (%)	
2/3 (agree/strongly agree)	n (%)	
PPQ5 I prefer the current treatment to previous topical treatments:	Mean (SD),	

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	Median, Q1, Q3, (95% CI)	
0. Strongly disagree	n (%)	
1. Disagree	n (%)	
2. Agree	n (%)	
3. Strongly agree	n (%)	
Does not apply to me	n (%)	
2/3 (agree/strongly agree)	n (%)	

Note: Data from Patient data collection form. SD : Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; EOS : End of Study; n: available data at EOS.

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Table 1.16 Patient Preference Questionnaire (PPQ) – Composite Score

Character	Statistics	EOS (N=x)
PPQ Composite Score	Mean (SD), Median, Q1, Q3, (95% CI)	

Note: Data from Patient data collection form. SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; EOS: End of Study; n: available data; PPQ: Patient Preference Questionnaire. 7 patients selected "'Does not apply to me' for all PPQ1- PPQ5 questions.

SCORING: Each item is scored on a 4-point Likert-type scale (0 = strongly disagree, 1 = disagree, 2 = agree and 3 = strongly agree) and a supplementary option 'Does not apply to me'. Overall score of 5-item PPQ will range from 0 to 15. The higher the score, the more preferred the current treatment is (compared to previous topical treatment).

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Table 1.17 Subgroup Analysis of *Patient Preference Questionnaire (PPQ) – Composite Score*

	EOS (N=X)	
Subgroups	**Subgroup Total (N)**	**PPQ Mean Score**
Gender		
Male		
Female		
p-value		
Age Group		
18-49 years		
50-64 Years		
≥ 65 years		
p-value		
Fitzpatrick Skin Type		
I / II		
III / IV / V / VI		
p-value		
Baseline Scalp PGA		
Mild		
Moderate		
p-value		
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months		
Yes		
No		
p-value		
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline		
Yes		
No		
p-value		
By Country		
Germany		
Spain		
United Kingdom		
Medication Adherence Score (VAS)		
< 80		
80 - 100		
p-value		

Note: EOS, End of Study. P-values, calculated by student's t-test/ Mann Whitney U test for dichotomous variables or ANOVA/Kruskal Wallis test for >2 groups, correspond to difference between strata at EOS.

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Table 1.18 Patient Treatment Behaviours

Question	Statistics	EOS (N=X)
USE1: How many tubes of CAL/BDP PAD cream (Wynzora®) you have used since the beginning of the study?	Mean (SD), Median, Q1, Q3, (95% CI)	
¼ Tube	n (%)	
½ Tube	n (%)	
¾ Tube	n (%)	
1 Tube	n (%)	
1 ¼ Tubes	n (%)	
1 ½ Tubes	n (%)	
1 ¾ Tubes	n (%)	
2 Tubes	n (%)	
2 ¼ Tubes	n (%)	
2 ½ Tubes	n (%)	
2 ¾ Tubes	n (%)	
3 Tubes	n (%)	
3 ¼ Tubes	n (%)	
3 ½ Tubes	n (%)	
3 ¾ Tubes	n (%)	
4 Tubes	n (%)	
4 ¼ Tubes	n (%)	
4 ½ Tubes	n (%)	
4 ¾ Tubes	n (%)	
5 Tubes	n (%)	
> 5 tubes [USE1r21oe]	n (%)	
Did not use CAL/BDP PAD cream	n (%)	0 (0.00%)
USE2: If you used CAL/BDP PAD cream (Wynzora®), in which areas of your body did you apply the cream?		
1. Scalp*	n (%)	n (100%)
2. Other parts of the body*	n (%)	

Note: Data from Patient data collection form. *Not mutually exclusive. SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; EOS: End of Study; n: available data. 33 Patients selected Scalp and Other parts of the body as cream applying area.

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Subgroups	EOS
	n, mean
USE1: How many tubes of CAL/BDP PAD cream (Wynzora®) you have used since the beginning of the study?	
Baseline Scalp PGA	
Mild	n, mean
Moderate	n, mean
	p
Medication Adherence Score (VAS)	
< 80	n, mean
80 - 100	n, mean
	p

Note: EOS, End of Study. P-values, calculated by student's t-test/ Mann Whitney U test for dichotomous variables or ANOVA/Kruskal Wallis test for >2 groups, correspond to difference between strata at EOS.

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Table 1.19 Morisky Medication Adherence Scale (MMAS-4)

Questions	Statistics	EOS (N=x)
[PTA1] Do you ever forget to use your scalp psoriasis medicine? 0. No 1. Yes	 n (%) n (%)	
[PTA2] Do you ever have problems remembering to use your scalp psoriasis medication? 0. No 1. Yes	 n (%) n (%)	
[PTA3] When you feel better, do you sometimes stop using your scalp psoriasis medicine? 0. No 1. Yes	 n (%) n (%)	
[PTA4] Sometimes if you feel worse when you use your scalp psoriasis medicine, do you stop using it? 0. No 1. Yes	 n (%) n (%)	

Note: Data from Patient data collection form

Table 1.20 Morisky Medication Adherence Scale (MMAS-4) – Composite Score

Questions	Statistics	EOS (N=x)
MMAS-4 Score	Mean (SD), Median, Q1, Q3, (95% CI)	
Patients with MMAS-4 Score: 0 (high adherence) 1-2 (intermediate adherence) 3-4 low adherence)	 n (%) n (%) n (%)	

Note: Data from Patient data collection form. SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; EOS: End of Study; n: available data; MMAS-4: Morisky Medication Adherence Scale – 4 items.

MMAS-4 Scoring: Items are summed up to obtain scores ranging from 0 (high adherence) to 4 (poor adherence).

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Table 1.21 Subgroup Analysis of Morisky Medication Adherence Scale (MMAS-4) – Composite Score

	EOS (N=X)	
Subgroups	**Subgroup Total (N)**	**MMAS Mean Score**
Gender		
Male		
Female		
p-value		
Age Group		
18-49 years		
50-64 Years		
≥ 65 years		
p-value		
Fitzpatrick Skin Type		
I / II		
III / IV / V / VI		
p-value		
Baseline Scalp PGA		
Mild		
Moderate		
p-value		
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months		
Yes		
No		
p-value		
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline		
Yes		
No		
p-value		
By Country		
Germany		
Spain		
United Kingdom		
Medication Adherence Score (VAS)		
< 80		
80 - 100		
p-value		

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Note: EOS, End of Study. P-values, calculated by student's t-test or Mann Whitney U test for dichotomous variables or ANOVA/Kruskal Wallis test for >2 groups, correspond to difference between strata at EOS.

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Table 1.22 Self-reported Visual Analogic Scale (VAS) for treatment adherence

Question	Statistics	EOS (N=x)
[VAS1] Please estimate your level of treatment adherence to CAL/BDP PAD cream (Wynzora®) by using the following sliding scale.	Mean (SD), Median, Q1, Q3, (95% CI)	
Medication Adherence Score (VAS)		
< 80	n, %	
80 - 100	n, %	

Note: Data from Patient data collection form. SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; EOS: End of Study; n: available data. 1 patient has missing data.

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Table 1.23 Subgroup Analysis of *Self-reported Visual Analogic Scale (VAS) for treatment adherence*

	EOS (N=X)	
Subgroups	**Subgroup Total (N)**	**VAS Mean**
Gender Male Female *p*-value		
Age Group 18-49 years 50-64 Years ≥ 65 years *p*-value		
Fitzpatrick Skin Type I / II III / IV / V / VI *p*-value		
Baseline Scalp PGA Mild Moderate *p*-value		
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months Yes No *p*-value		
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline Yes No *p*-value		
By Country Germany Spain United Kingdom		

Note: EOS, End of Study. P-values, calculated by student's t-test or Mann Whitney U test for dichotomous variables or ANOVA/Kruskal Wallis test for >2 groups, correspond to difference between strata at EOS.

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Table 1.24 Cream Usability Scalp Psoriasis Questionnaire (CUSP-Q)

Questions	Statistics	EOS (N=x)
CUS1. Was it easy to apply the cream and spread it on the scalp?	Mean (SD), Median, Q1, Q3, (95% CI)	
No at all (0)	n (%)	
(1)	n (%)	
(2)	n (%)	
(3)	n (%)	
(4)	n (%)	
(5)	n (%)	
(6)	n (%)	
(7)	n (%)	
(8)	n (%)	
(9)	n (%)	
Very Much (10)	n (%)	
CUS2. Was the cream absorbed quickly into the scalp?	Mean (SD), Median, Q1, Q3, (95% CI)	
No at all (0)	n (%)	
(1)	n (%)	
(2)	n (%)	
(3)	n (%)	
(4)	n (%)	
(5)	n (%)	
(6)	n (%)	
(7)	n (%)	
(8)	n (%)	
(9)	n (%)	
Very Much (10)	n (%)	
CUS3. Once the cream was absorbed, did your scalp or hair feel sticky?	Mean (SD), Median, Q1, Q3, (95% CI)	
Very Much (0)	n (%)	
(1)	n (%)	
(2)	n (%)	
(3)	n (%)	
(4)	n (%)	
(5)	n (%)	
(6)	n (%)	
(7)	n (%)	
(8)	n (%)	
(9)	n (%)	

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Not at all (10)	n (%)	
CUS4. Did you feel any stinging or burning sensation after applying the cream?	Mean (SD), Median, Q1, Q3, (95% CI)	
Very Much (0)	n (%)	
(1)	n (%)	
(2)	n (%)	
(3)	n (%)	
(4)	n (%)	
(5)	n (%)	
(6)	n (%)	
(7)	n (%)	
(8)	n (%)	
(9)	n (%)	
Not at all (10)	n (%)	
CUS5. Did the cream leave residues on your scalp or hair?	Mean (SD), Median, Q1, Q3, (95% CI)	
Very Much (0)	n (%)	
(1)	n (%)	
(2)	n (%)	
(3)	n (%)	
(4)	n (%)	
(5)	n (%)	
(6)	n (%)	
(7)	n (%)	
(8)	n (%)	
(9)	n (%)	
Not at all (10)	n (%)	
CUS6. Was the cream easy to remove when you washed your hair?	Mean (SD), Median, Q1, Q3, (95% CI)	
No at all (0)	n (%)	
(1)	n (%)	
(2)	n (%)	
(3)	n (%)	
(4)	n (%)	
(5)	n (%)	
(6)	n (%)	
(7)	n (%)	
(8)	n (%)	
(9)	n (%)	
Very Much (10)	n (%)	

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CUS7. Was the cream on your scalp or hair noticeable to you?	Mean (SD), Median, Q1, Q3, (95% CI)	
Very Much (0)	n (%)	
(1)	n (%)	
(2)	n (%)	
(3)	n (%)	
(4)	n (%)	
(5)	n (%)	
(6)	n (%)	
(7)	n (%)	
(8)	n (%)	
(9)	n (%)	
Not at all (10)	n (%)	
CUS8. Was the cream on your scalp or hair noticeable to others?	Mean (SD), Median, Q1, Q3, (95% CI)	
Very Much (0)	n (%)	
(1)	n (%)	
(2)	n (%)	
(3)	n (%)	
(4)	n (%)	
(5)	n (%)	
(6)	n (%)	
(7)	n (%)	
(8)	n (%)	
(9)	n (%)	
Not at all (10)	n (%)	
CUS9. Considering all the issues associated with the usability of the cream, how satisfied are you with the cream?	Mean (SD), Median, Q1, Q3, (95% CI)	
No at all (0)	n (%)	
(1)	n (%)	
(2)	n (%)	
(3)	n (%)	
(4)	n (%)	
(5)	n (%)	
(6)	n (%)	
(7)	n (%)	
(8)	n (%)	
(9)	n (%)	
Very Much (10)	n (%)	
CUS10. Would you use the cream again in the future to treat your scalp psoriasis?	Mean (SD), Median,	

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	Q1, Q3, (95% CI)	
No at all (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) Very Much (10)	n (%) n (%) n (%) n (%) n (%) n (%) n (%) n (%) n (%) n (%) n (%)	
CUSP-Q Overall/composite score*	Mean (SD), Median, Q1, Q3, (95% CI)	

Note: Data from Patient data collection form.SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; EOS: End of Study; n: available data; CUSP – Q: Cream Usability in Scalp Psoriasis Questionnaire. *CUSP-Q composite score (range: 0-100) is the sum of individual item scores

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Table 1.25 Subgroup Analysis of Cream Usability Scalp Psoriasis Questionnaire (CUSP-Q)

	EOS (N=X)	
Subgroups	**Subgroup Total (N)**	**CUSP-Q Mean Score**
Gender		
Male		
Female		
p-value		
Age Group		
18-49 years		
50-64 Years		
≥ 65 years		
p-value		
Fitzpatrick Skin Type		
I / II		
III / IV / V / VI		
p-value		
Baseline Scalp PGA		
Mild		
Moderate		
p-value		
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months		
Yes		
No		
p-value		
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline		
Yes		
No		
p-value		
By Country		
Germany		
Spain		
United Kingdom		
Medication Adherence Score (VAS)		
< 80		
80 - 100		
p-value		

Note: EOS, End of Study. P-values, calculated by student's t-test or Mann Whitney U test for dichotomous variables or ANOVA/Kruskal Wallis test for >2 groups, correspond to difference between strata at EOS.

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7.2 Tables from Clinician's eCRF (FAS Population)

Clinician data is analyzed using the FAS dataset. In relevant instances (such as IGA and physician satisfaction evaluations), only FAS dataset with corresponding week clinician data is used. All data tables in this section correspond to FAS population.

Table 2.1 Site Characteristics

Domain	Statistics	(N=x)
SC1: Current workplace Private, office-based practice Hospital-based practice	 n (%) n (%)	
SC2: Total number of board-certified dermatologists in the practice (including yourself, if applicable)	Mean (SD), Median, Q1, Q3, (95% CI)	
SC3: At present, how many patients with Scalp Psoriasis do you personally manage in a given month?	Mean (SD), Median, Q1, Q3, (95% CI)	
SC4: How long (in years) have you been practicing dermatology, post-residency?	Mean (SD), Median, Q1, Q3, (95% CI)	

Note: Data from Clinician data collection form. The denominator for the percentage is 24 which refers to total number of unique sites in PRO-SCALP study. SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data; FAS: Full Analysis Set.

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Table 2.2 Study Subject Selection Criteria

Domain (N=XXX)	Statistics	Yes	No
SS1. Adult (≥18 years) male or female patients with mild-to-moderate plaque psoriasis of the scalp (defined as scalp-PGA score of 2 or 3 at baseline) with or without involvement of the trunk and limbs, and who may or may not have been previously treated (treatment-naive patients) with other anti-psoriatic therapies.	n (%)		0 (0.00%)
SS2. Patients who have been prescribed CAL/BDP PAD cream* (Wynzora®) treatment to manage plaque psoriasis of the scalp according to SmPC in routine clinical practice.	n (%)		0 (0.00%)
SS3. Willingness and ability to participate in the study; patients must give their written consent to participate.	n (%)		0 (0.00%)
SS4. Patients with severe plaque psoriasis, per physician global assessment.	n (%)	0 (0.00%)	
SS5. Patients with erythrodermic, exfoliative or pustular psoriasis.	n (%)	0 (0.00%)	
SS6. Patients previously treated with systemic drugs for psoriasis (conventional or biologic) within the last 12 weeks prior to inclusion.	n (%)	0 (0.00%)	
SS7.Concomitant systemic treatment with anti-psoriatic drugs.	n (%)	0 (0.00%)	
SS8. Concomitant treatment of <u>any type</u> for plaque psoriasis of the scalp.	n (%)	0 (0.00%)	
SS9. Hypersensitivity to the active substances or to any of the excipients of CAL/BDP PAD cream* (Wynzora®).	n (%)	0 (0.00%)	
SS10. Patients with known disorders of calcium metabolism.	n (%)	0 (0.00%)	
SS11. Patients with viral (e.g., herpes or varicella) lesions of the skin, fungal or bacterial skin infections, parasitic infections, skin manifestations in relation to tuberculosis, perioral dermatitis, atrophic skin, striae atrophicae, fragility of skin veins, ichthyosis, acne vulgaris, acne rosacea, rosacea, ulcers, and wounds.	n (%)	0 (0.00%)	
SS12. Pregnant or breastfeeding women, except when the potential benefit justifies the potential risk.	n (%)	0 (0.00%)	
SS13. Patients unable to comply with the requirements of the study or who in the opinion of the study physician should not participate in the study.	n (%)	0 (0.00%)	
SS14. Patients for whom medical chart is inaccessible to physicians to complete baseline data collection.	n (%)	0 (0.00%)	

Note: Data from Clinician data collection form. The denominator for the percentage is the number of patients with available data (N=X). There are no missing data

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Table 2.3 Patient Clinical Characteristics from Medical Chart

Character	Statistics	Baseline
CC2 Height (in centimeters)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
CC3 Weight (in kgs/kilograms)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
CC4 Waist circumference (in centimeters)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
Body Mass Index (BMI - calculated)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
CC5 Blood pressure (in mm HG)		
Systolic	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
Diastolic	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
CC7 Length of patient's hair (in centimeters)		
1. No Hair 2. Short 3. Medium 4. Long	n (%) n (%) n (%) n (%)	

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CC8 Percentage of hair covering the patient's scalp	N, Mean (SD), Median, Q1, Q3, (95% CI)	
PPC1r1: Time since diagnosed with Plaque PSO [Wynzora prescription date – Diagnosis date]	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
PPC2: Localized areas of the body were initially diagnosed with plaque psoriasis. 1. Hands 2. Legs 3. Trunk 4. Arms	 n (%) n (%) n (%) n (%)	
PPC3: Time since first date of involvement of the scalp [Wynzora prescription date – date of involvement]	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
PPC4 Fitzpatrick Skin-type classification 1. Type I 2. Type II 3. Type III 4. Type IV 5. Type V 6. Type VI	 n (%) n (%) n (%) n (%) n (%) n (%)	

Note: Data from Clinician data collection form; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data**.** The denominator for the percentage is the number of patients with available data (N=X).

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Table 2.4 Clinician Evaluation of Current Scalp Severity - Scalp-PGA

Character	Statistics	Baseline (N=x)	Week-4 N=x)	EOS (N=x)
PPC5 Overall, how is your patient's plaque psoriasis of the scalp right now?	Mean (SD), Median, Q1, Q3, (95% CI)			
0. Clear				
1. Almost clear	n (%)			
2. Mild	n (%)			
3. Moderate	n (%)			
4. Severe	n (%)			
Don't know / Not applicable	n (%)			
	n (%)			
(0 / 1) Clear / Almost Clear	n (%)			
(2) Mild	n (%)			
(3 / 4) Moderate / Severe	n (%)			
PPC10 Who did the evaluation of patient's plaque psoriasis severity?				
1. Dermatologist	n (%)			
2. Nurse practitioner	n (%)			
3. Physician's assistant	n (%)			
4. General Practitioner	n (%)			
PPC11 How was the evaluation of plaque psoriasis severity done?				
1. During in-person patient visit (face-to-face)	n (%)			
2. Via tele-health visit (video)	n (%)			

Note: Data from Clinician data collection form; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; EOS: End of study; n: available data**.** No patients had missing data; The denominator for the percentage is the number of patients with available data (N=XXX, N=XX & XXX at Baseline, Week-4 and EOS visit)

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Table 2.5 Change from Baseline in Clinician Evaluation of Current Scalp Severity - Scalp-PGA

Domain	Statistics N=X	CFB in Proportion at Week-4 N=x	*p*-value	CFB in Proportion at EOS N=x	*p*-value
Overall, how is your patient's plaque psoriasis of the scalp right now?					
(0 / 1) Clear / Almost Clear	%		*p*		*p*
(2) Mild	%				
(3 / 4) Moderate / Severe	%		*p*		*p*

Note: Data from Clinician data collection form; CFB: Change from Baseline; EOS: End of study; n= available data. *P-value, calculated by McNemar's test, corresponds to CFB (in proportion of patients) in groups 0/1 vs. all others and groups 3/4 vs. all others.

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Table 2.6 Scalp-PGA Success

Character	Week-4	EOS
Scalp-PGA Success	**N=XX** n (%)	**N=XX** n (%)
No		
Yes		

Note: PGA: Physician Global Assessment; EOS: End of Study, n= available data. *Scalp-PGA treatment success is defined as a scalp-PGA score of 0 (clear) or 1 (almost clear) and with a minimum 2 points improvement from baseline, on the scalp.

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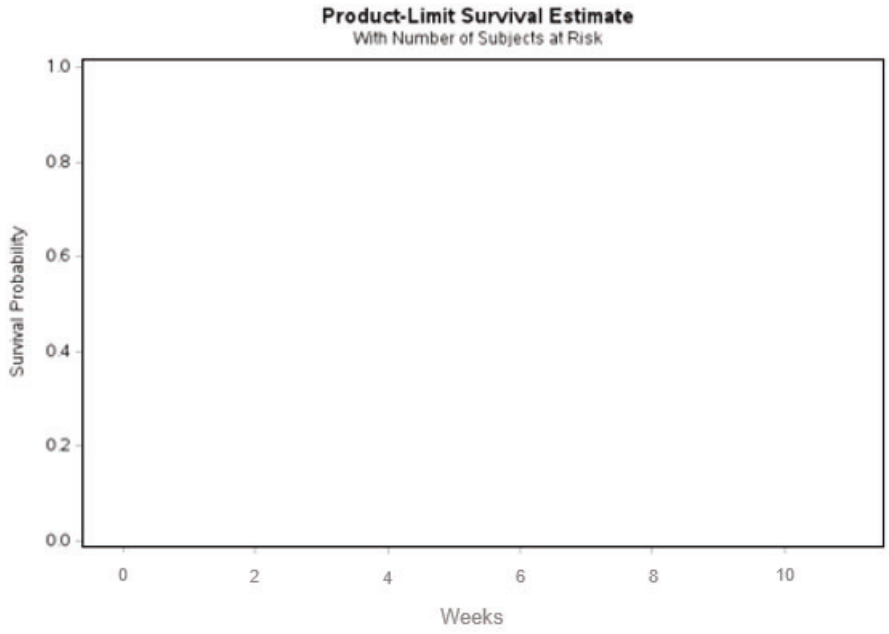
Table 2.6A Time to Scalp-PGA Success

Time to achieve Scalp-PGA success, assessed using survival analysis / Kaplan-Meier graphs will be explored, if feasible. Number of patients at risk will be generated with Kaplan-Meier graph.

A sample graphical template is shown below. Final study analytic output may differ from this example.



Time (weeks)	0	2	4	6	8	10
No. at risk						

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Table 2.7 Subgroup Analysis of Clinician Evaluation of Current Scalp Severity - Scalp-PGA Success

Scalp-PGA Success = Yes	EOS	
Subgroups	**Subgroup total (N)**	**n (%)**
Gender		
Male		
Female		
p-value		
Age Group		
18-49 years		
50-64 Years		
≥ 65 years		
p-value		
Fitzpatrick Skin Type		
I / II		
III / IV / V / VI		
p-value		
Baseline Scalp PGA		
Mild		
Moderate		
p-value		
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months		
Yes		
No		
p-value		
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline		
Yes		
No		
p-value		
By Country		
Germany		
Spain		
United Kingdom		
Medication Adherence Score (VAS)		
< 80		
80 - 100		
p-value		

Note: EOS: End of Study. P-values, calculated by chi-squared test, correspond to difference between strata within EOS.

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Table 2.8 S-mPASI Individual Items

Character	Statistics	Baseline (N=x)	Week-4 (N=x)	EOS (N=x)
PPC6 What is the current severity of erythema of the scalp?	Mean (SD), Median, Q1, Q3, 95% CI			
0. None	n (%)			
1. Slight	n (%)			
2. Moderate	n (%)			
3. Severe	n (%)			
4. Very Severe	n (%)			
PPC7 What is the current severity of induration of the scalp psoriasis plaques?	Mean (SD), Median, Q1, Q3, 95% CI			
0. None	n (%)			
1. Slight	n (%)			
2. Moderate	n (%)			
3. Severe	n (%)			
4. Very Severe	n (%)			
PPC8 What is the current severity of scaling of the scalp psoriasis plaques?	Mean (SD), Median, Q1, Q3, 95% CI			
0. None	n (%)			
1. Slight	n (%)			
2. Moderate	n (%)			
3. Severe	n (%)			
4. Very Severe	n (%)			
PPC9 Estimate the area of involvement of plaque psoriasis on the patient's scalp:	Mean (SD), Median, Q1, Q3, 95% CI			
0. No scalp involvement	n (%)			
1. 1% to 9% scalp involvement	n (%)			
2. 10% to 29% scalp involvement	n (%)			
3. 30% to 49% scalp involvement	n (%)			
4. 50% to 69% scalp involvement	n (%)			
5. 70% to 89% scalp involvement	n (%)			
6. 90% to 100% scalp involvement	n (%)			

Note: Data from Clinician data collection form. EOS: End of Study; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data.

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Table 2.9 S-mPASI Score

Domain	Statistics	Baseline	Week-4	Baseline	EOS
		(N=x)		(N=x)	
S-mPASI Score	Mean, (SD) Median Q1, Q3, (95% CI)				
Patients with ≥75% reduction (from BL) in S-mPASI score	n (%)				
Patients with S-mPASI score <0.5	n (%)				

Domain	Statistics	CFB Scores at Week-4 (N=x)	p-value	CFB Scores at EOS (N=x)	p-value
S-mPASI Score	Mean, SE*, (SD) Median Q1, Q3, (95% CI)		*p*		*p*

Note: Data from Clinician data collection form; BL, Baseline. SD: Standard deviation; SE: Standard error; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data; SE: Standard Error; CFB: Change from baseline; EOS: End of study. *SE calculated for CFB scores only. X patients had missing data at Week-4 and EOS visit; The denominator for the percentage is the number of patients with available data (N=XX & XXX at Week-4 and EOS visit). P-value, calculated by paired t-test, corresponds to differences in scores between time points.

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Table 2.10 Subgroup Analysis of *S-mPASI Score*

	Baseline Score	**EOS Score**	***p*-value**
Subgroups	n, mean (SD) Median, Q, Q3 95% CI	n, mean (SD) Median, Q, Q3 95% CI	*p*
Gender			
Male			
Female			
Age Group			
18-49 years			
50-64 Years			
≥ 65 years			
Fitzpatrick Skin Type			
I / II			
III / IV / V / VI			
Baseline Scalp PGA			
Mild			
Moderate			
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months			
Yes			
No			
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline			
Yes			
No			
By Country			
Germany			
Spain			
United Kingdom			
Medication Adherence Score (VAS)			
< 80			
80 - 100			

Note: Data from Clinician data collection form. The mean score is calculated using the available matching data within the strata for each domain. EOS: End of Study. P-value, calculated by t-test or Wilcoxon signed rank test, corresponds to differences in mean score between time points within each of the strata.

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Subgroups	SmPASI Score CFB at EOS n, mean
Medication Adherence Score (VAS)	
< 80	n, mean
80 - 100	n, mean
	p
Baseline Scalp PGA	
Mild	n, mean
Moderate	n, mean
	p

Note: CFB, change from baseline; EOS, End of Study. For subgroup evaluation of difference in CFB values, two-way repeated measures analysis of variance (ANOVA) or Wilcoxon Signed rank test, Mann-Whiteny U test or Kruskal-Wallis test will be performed to calculate p-values.

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Table 2.11 CAL/BDP PAD cream (Wynzora®) Treatment Characteristics

	Baseline (N=x)
TH1_2: Prescription frequency	
1. Once a day	n (%)
2. Other (specify): [TH1Cr2oe]	n (%)
a. 3 times per week	n (%)

Table 2.11A. Subgroup analyses

	Baseline Scalp PGA = Mild (N=x)	Baseline Scalp PGA = Moderate (N=x)
TH1_2: Prescription frequency		
1. Once a day	n (%)	n (%)
2. Other (specify): [TH1Cr2oe]	n (%)	n (%)
a. 3 times per week	n (%)	n (%)

	Adherence VAS score <80 (N=x)	Adherence VAS score 80-100 (N=x)
TH1_2: Prescription frequency		
1. Once a day	n (%)	n (%)
2. Other (specify): [TH1Cr2oe]	n (%)	n (%)
a. 3 times per week	n (%)	n (%)

Note: Data from Clinician data collection form. VAS, visual analog scale. N: available data.

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Table 2.12 Prior Scalp Psoriasis Topical Treatments (To-Date) Including within the Past 12 Months

(Start date prior to Wynzora®; End date within the past 12 months or No end date)	**Baseline (N=x)**
TH1A Has **not** used any type of treatment (e.g., topical, biologic, non-biologic, phototherapy) to manage scalp psoriasis in the past (Treatment Naïve)	n (%)
TH2_1. Patients who have used a **topical treatment** to manage scalp psoriasis within the past 12 months.	N (%)
<<categories from WHO ATC classifications>> A B C D	**n (%)** n (%) n (%) n (%) n (%)

Note: Data from Clinician data collection form; X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X)

Table 2.12A Prior Scalp Psoriasis Topical Treatments (To-Date) Including within the Past 12 Months – Stratified by Baseline Scalp PGA

(Start date prior to Wynzora®; End date within the past 12 months or No end date)	**Baseline Scalp PGA = Mild (N=x)**	**Baseline Scalp PGA = Moderate (N=x)**
TH1A Has **not** used any type of treatment (e.g., topical, biologic, non-biologic, phototherapy) to manage scalp psoriasis in the past (Treatment Naïve)	n (%)	n (%)
TH2_1. Patients who have used a **topical treatment** to manage scalp psoriasis within the past 12 months.	N (%)	N (%)
<<categories from WHO ATC classifications>> A B C D	**n (%)** n (%) n (%) n (%) n (%)	**n (%)** n (%) n (%) n (%) n (%)

Note: Data from Clinician data collection form; X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X).

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Table 2.12B Prior Scalp Psoriasis Topical Treatments (To-Date) Including within the Past 12 Months – Stratified by Patient-Reported Adherence VAS Score

(Start date prior to Wynzora®; End date within the past 12 months or No end date)	**Adherence VAS score <80 (N=x)**	**Adherence VAS score 80-100 (N=x)**
TH1A Has **not** used any type of treatment (e.g., topical, biologic, non-biologic, phototherapy) to manage scalp psoriasis in the past (Treatment Naïve)	n (%)	n (%)
TH2_1. Patients who have used a **topical treatment** to manage scalp psoriasis within the past 12 months.	N (%)	N (%)
<<categories from WHO ATC classifications>>	**n (%)**	**n (%)**
A	n (%)	n (%)
B	n (%)	n (%)
C	n (%)	n (%)
D	n (%)	n (%)

Note: Data from Clinician data collection form; VAS, visual analog scale. X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X).

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Table 2.13 Last Treatment of Plaque Psoriasis of the Scalp; Last Treatment Used Before Start of the Study

	Baseline (N=x)
TH3_1_1	
Patients who were on any treatment	n (%)
None (no treatment used)	n (%)
Don't know	n (%)
TH3_1_1 **Type of Treatment:**	
1. Topical	n (%)
2. Biologic systemic treatment	n (%)
3. Non-biologic systemic treatment	n (%)
4. Phototherapy	n (%)
5. Other	n (%)
TH3_1_1 **Type of Treatment:**	
<<categories from WHO ATC classifications>>	**n (%)**
A	n (%)
B	n (%)
C	n (%)
D	n (%)
TH3_1_3 **Area Used:**	
TH3_1_3r2 Other parts of the body	n (%)
TH3_1_3r1 Scalp	n (%)
Reason for stopping:	
Patient completed the planned treatment course	n (%)
Discontinued due to treatment side-effects	n (%)
Discontinued due to lack of effectiveness	n (%)
Discontinued due to other reasons:	
X	n (%)
Y	n (%)
Z	n (%)
Don't know / Not applicable	n (%)

Note: Data from Clinician data collection form; X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X)

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Table 2.14 Ongoing Concomitant Treatment for Plaque Psoriasis in Other Parts of the Body (Excluding Scalp)

Character	Baseline (N=x)
TH4: Patients **not** using any ongoing concomitant treatment(s) for plaque psoriasis in other parts of the body (excluding scalp). **TH4_1_1** Patients **using any** ongoing concomitant treatment(s) for plaque psoriasis in other parts of the body (excluding scalp).	n (%) n (%)
TH4_1_1 Type of Treatment 1. Topical 2. Phototherapy 3. Other	 n (%) n (%) n (%)
TH4_1_1 **Type of Treatment:** <<categories from WHO ATC classifications>> A B C D	 n (%) n (%) n (%) n (%) n (%)

Note: Data from Clinician data collection form; X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X)

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Table 2.15 Non-plaque psoriasis Concomitant Medication Use During Observation Period

Character	Baseline (N=X)
TH5: Is currently **not using** any concomitant medication to manage conditions other than plaque psoriasis.	**n (%)**
TH5: Is currently **using any** concomitant medication to manage conditions other than plaque psoriasis. TH5_1_2oe <<categories from WHO ATC classifications>> A B C D E	**n (%)** **n (%)** n (%) n (%) n (%) n (%) n (%)

Note: Data from Clinician data collection form; X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X). This concomitant non- plaque psoriasis medication use correspond to use of medications at any time during the study observation period, overlapping with Wynzora® medication use.

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Table 2.16 Treatment Satisfaction Questionnaire for Medication: Clinician Scores

Domain	Statistics	EOS (N = X)
Effectiveness		
	Mean (SD) Median Q1, Q3, (95% CI)	
Convenience		
	Mean (SD) Median Q1, Q3, (95% CI)	
Global Satisfaction		
	Mean (SD) Median Q1, Q3, (95% CI)	

Note: Data from Clinician data collection form. Questions and scoring were adopted from original patient-version of TSQM-9. SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data; EOS: End of study; TSQM: Treatment Satisfaction Questionnaire Medication. N patients had missing data.

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Table 2.17 Subgroup Analysis of Treatment Satisfaction Questionnaire for Medication: Clinician Scores

Subgroups	EOS (N=X)			
	Subgroup Total (N)	Effectiveness Mean	Convenience Mean	Global Satisfaction Mean
Gender				
Male				
Female				
p-value				
Age Group				
18-49 years				
50-64 Years				
≥ 65 years				
p-value				
Fitzpatrick Skin Type				
I / II				
III / IV / V / VI				
p-value				
Baseline Scalp PGA				
Mild				
Moderate				
p-value				
Prior Treatment Experience: Use of Other Topical Treatments for Scalp psoriasis in the past 12 months				
Yes				
No				
p-value				
Prior Treatment Experience: Treatment Naïve for Scalp psoriasis at Baseline				
Yes				
No				
p-value				
By Country				
Germany				
Spain				
United Kingdom				
Medication Adherence Score (VAS)				
< 80				
80 - 100				
p-value				

Note: Data from Clinician data collection form. P-values, calculated by calculated by student's t-test or Mann Whitney U test for dichotomous variables or ANOVA/Kruskal Wallis test for >2 groups, correspond to difference between strata within respective time periods.

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Table 2.18 Patient Demographic Characteristics - Stratified by Baseline Scalp PGA

This table depicts the patient baseline demographics stratified by Baseline Scalp PGA strata, for the FAS population.

Adult Demographic Data	Statistics	Baseline Scalp PGA = Mild (N=x)	Baseline Scalp PGA = Moderate (N=x)
S1: Age	Mean (SD) Median Q1, Q3, 95% CI		
S2: Gender Male Female Other	 n (%) n (%) n (%)		
S3: Living Status Alone Not alone	 n (%) n (%)		
S4: Smoking Status Yes, daily Yes, occasionally No, not anymore I have never smoked Average number of cigarettes per day^	 n (%) n (%) n (%) n (%) Missing n n, Mean (SD) Median Q1, Q3, 95% CI		
S5: Drinking status Yes, daily Yes, occasionally No, not anymore I never drank alcohol Average number of alcoholic drinks per week^	 n (%) n (%) n (%) n (%) n, Mean (SD) Median Q1, Q3, 95% CI		
S6: Race* White/Caucasian Black/African/Caribbean Asian Mixed race Other I would prefer not to answer	 n (%) n (%) n (%) n (%) n (%) n (%)		

Note: Data from Patient data collection form. FAS: Full Analysis Set; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data. *Response options were not mutually exclusive. ^Data analyzed from individuals selecting “Yes, daily,” “Yes, occasionally,” and “No, not anymore”.

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Table 2.19 Patient Demographic Characteristics - Stratified by Patient-reported Adherence VAS Scores

This table depicts the patient baseline demographics stratified by patient-reported Adherence VAS score at EOS, in the FAS population.

Adult Demographic Data	Statistics	Adherence VAS score <80 (N=x)	Adherence VAS score 80-100 (N=x)
S1: Age	Mean (SD) Median Q1, Q3, 95% CI		
S2: Gender Male Female Other	 n (%) n (%) n (%)		
S3: Living Status Alone Not alone	 n (%) n (%)		
S4: Smoking Status Yes, daily Yes, occasionally No, not anymore I have never smoked Average number of cigarettes per day^	 n (%) n (%) n (%) n (%) Missing n n, Mean (SD) Median Q1, Q3, 95% CI		
S5: Drinking status Yes, daily Yes, occasionally No, not anymore I never drank alcohol Average number of alcoholic drinks per week^	 n (%) n (%) n (%) n (%) n, Mean (SD) Median Q1, Q3, 95% CI		
S6: Race* White/Caucasian Black/African/Caribbean Asian Mixed race Other I would prefer not to answer	 n (%) n (%) n (%) n (%) n (%) n (%)		

Note: Data from Patient data collection form. FAS: Full Analysis Set; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; VAS, visual analog scale; n: available data. *Response options were not mutually exclusive. ^Data analyzed from individuals selecting “Yes, daily,” “Yes, occasionally,” and “No, not anymore”.

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Table 2.20 Patient Clinical Characteristics from Medical Chart - Stratified by Baseline Scalp PGA Score

This table depicts the patient baseline clinical characteristics stratified by Baseline Scalp PGA strata, for the FAS population.

Character	Statistics	Baseline Scalp PGA = Mild (N=x)	Baseline Scalp PGA = Moderate (N=x)
CC2 Height (in centimeters)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
CC3 Weight (in kgs/kilograms)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
CC4 Waist circumference (in centimeters)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
Body Mass Index (BMI - calculated)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
CC5 Blood pressure (in mm HG)			
Systolic	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
Diastolic	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
CC7 Length of patient's hair (in centimeters)			
5. No Hair	n (%) n (%)		

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6. Short 7. Medium 8. Long	n (%) n (%)		
CC8 Percentage of hair covering the patient's scalp	N, Mean (SD), Median, Q1, Q3, (95% CI)		
PPC1r1: Time since diagnosed with Plaque PSO [Wynzora prescription date – Diagnosis date]	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
PPC2: Localized areas of the body were initially diagnosed with plaque psoriasis. 5. Hands 6. Legs 7. Trunk 8. Arms	 n (%) n (%) n (%) n (%)		
PPC3: Time since first date of involvement of the scalp [Wynzora prescription date – date of involvement]	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
PPC4 Fitzpatrick Skin-type classification 7. Type I 8. Type II 9. Type III 10. Type IV 11. Type V 12. Type VI	 n (%) n (%) n (%) n (%) n (%) n (%)		

Note: Data from Clinician data collection form; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; VAS, visual analog scale; n: available data. The denominator for the percentage is the number of patients with available data (N=X).

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Table 2.21 Patient Clinical Characteristics from Medical Chart - Stratified by Patient-reported Adherence VAS Scores

This table depicts the patient baseline clinical characteristics stratified by patient-reported Adherence VAS score at EOS, in the FAS population.

Character	Statistics	Adherence VAS score <80 (N=x)	Adherence VAS score 80-100 (N=x)
CC2 Height (in centimeters)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
CC3 Weight (in kgs/kilograms)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
CC4 Waist circumference (in centimeters)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
Body Mass Index (BMI - calculated)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
CC5 Blood pressure (in mm HG)			
Systolic	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
Diastolic	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
CC7 Length of patient's hair (in centimeters)			
9. No Hair	n (%) n (%)		

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10. Short 11. Medium 12. Long	n (%) n (%)		
CC8 Percentage of hair covering the patient's scalp	N, Mean (SD), Median, Q1, Q3, (95% CI)		
PPC1r1: Time since diagnosed with Plaque PSO [Wynzora prescription date – Diagnosis date]	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
PPC2: Localized areas of the body were initially diagnosed with plaque psoriasis. 9. Hands 10. Legs 11. Trunk 12. Arms	 n (%) n (%) n (%) n (%)		
PPC3: Time since first date of involvement of the scalp [Wynzora prescription date – date of involvement]	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n		
PPC4 Fitzpatrick Skin-type classification 13. Type I 14. Type II 15. Type III 16. Type IV 17. Type V 18. Type VI	 n (%) n (%) n (%) n (%) n (%) n (%)		

Note: Data from Clinician data collection form; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; VAS, visual analog scale; n: available data. The denominator for the percentage is the number of patients with available data (N=X).

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7.3 Tables from Clinician DATA COLLECTION FORM: Safety Data Analysis

These analyses will use Safety Population dataset.

All patients who started the study and received at least one dose of Wynzora® during the study observation period, as part of usual care. This may correspond to the entire cohort of _____ eligible patients who started the study.

Table 3.1 Safety Analysis Population

S1: Population	**N=x**
Total FAS Population	n (%)
Total Safety Population	n (100.00%)

Note: Data from patient data collection form. FAS: Full Analysis Set; N: available data.

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Table 3.2 Study Subject Selection Criteria, Safety Population

Domain (N=X)	Statistics	Yes	No
SS1 Adult (≥18 years) male or female patients with mild-to-moderate plaque psoriasis of the scalp (defined as scalp-PGA score of 2 or 3 at baseline) with or without involvement of the trunk and limbs, and who may or may not have been previously treated (treatment-naive patients) with other anti-psoriatic therapies.	n (%)	n (%)	0 (0.00%)
SS2 Patients who have been prescribed CAL/BDP PAD cream* (Wynzora®) treatment to manage plaque psoriasis of the scalp according to SmPC in routine clinical practice.	n (%)	n (%)	0 (0.00%)
SS3 Willingness and ability to participate in the study; patients must give their written consent to participate.	n (%)	n (%)	0 (0.00%)
SS4. Patients with severe plaque psoriasis, per physician global assessment.	n (%)	0 (0.00%)	n (%)
SS5. Patients with erythrodermic, exfoliative or pustular psoriasis.	n (%)	0 (0.00%)	n (%)
SS6. Patients previously treated with systemic drugs for psoriasis (conventional or biologic) within the last 12 weeks prior to inclusion.	n (%)	0 (0.00%)	n (%)
SS7. Concomitant systemic treatment with anti-psoriatic drugs.	n (%)	0 (0.00%)	n (%)
SS8. Concomitant treatment of any type for plaque psoriasis of the scalp.	n (%)	0 (0.00%)	n (%)
SS9. Hypersensitivity to the active substances or to any of the excipients of CAL/BDP PAD cream* (Wynzora®).	n (%)	0 (0.00%)	n (%)
SS10. Patients with known disorders of calcium metabolism.	n (%)	0 (0.00%)	n (%)
SS11. Patients with viral (e.g., herpes or varicella) lesions of the skin, fungal or bacterial skin infections, parasitic infections, skin manifestations in relation to tuberculosis, perioral dermatitis, atrophic skin, striae atrophicae, fragility of skin veins, ichthyosis, acne vulgaris, acne rosacea, rosacea, ulcers, and wounds.	n (%)	0 (0.00%)	n (%)
SS12. Pregnant or breastfeeding women, except when the potential benefit justifies the potential risk.	n (%)	0 (0.00%)	n (%)
SS13. Patients unable to comply with the requirements of the study or who in the opinion of the study physician should not participate in the study.	n (%)	0 (0.00%)	n (%)
SS14. Patients for whom medical chart is inaccessible to physicians to complete baseline data collection.	n (%)	0 (0.00%)	n (%)

Note: Data from Clinician data collection form. The denominator for the percentage is the number of patients with available data (N=X). There is no missing data.

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Table 3.3 Patient Demographic Characteristics, Safety Population

Adult Demographic Data	Statistics	Total (N=x)
S1: Age	Mean (SD) Median Q1, Q3, (95% CI)	
S2: Gender Male Female Other	 n (%) n (%) n (%)	
S3: Living Status Alone Not alone	 n (%) n (%)	
S4: Smoking Status Yes, daily Yes, occasionally No, not anymore I have never smoked Average number of cigarettes per day^	 n (%) n (%) n (%) n (%) Missing n n, Mean (SD) Median Q1, Q3, (95% CI)	
S5: Drinking status Yes, daily Yes, occasionally No, not anymore I never drank alcohol Average number of alcoholic drinks per week^	 n (%) n (%) n (%) n (%) Missing n n, Mean (SD) Median Q1, Q3, (95% CI)	
S6: Race* White/Caucasian Black/African/Caribbean Asian Mixed race Other I would prefer not to answer	 n (%) n (%) n (%) n (%) n (%) n (%)	

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Note: Data from Patient data collection form. SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data**.** *Not mutually exclusive. ^Data analyzed from individuals selecting “Yes, daily,” “Yes, occasionally,” and “No, not anymore.” XX patient selected ‘White/Caucasian’, and ‘Black/African/Caribbean’ as Race. XX patient selected ‘White/Caucasian’, and ‘Mixed race’ as Race

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Table 3.4 Patient Clinical Characteristics from Medical Chart, Safety Population

Character	Statistics	Baseline
CC2 Height (in centimeters)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
CC3 Weight (in kgs/kilograms)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
CC4 Waist circumference (in centimeters)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
Body Mass Index (BMI - calculated)	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
CC5 Blood pressure (in mm HG)		
Systolic	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
Diastolic	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
CC7 Length of patient's hair (in centimeters)		
13. No Hair 14. Short 15. Medium 16. Long	n (%) n (%) n (%) n (%)	

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CC8 Percentage of hair covering the patient's scalp	N, Mean (SD), Median, Q1, Q3, (95% CI)	
PPC1r1: Time since diagnosed with Plaque PSO [Wynzora prescription date – Diagnosis date]	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
PPC2: Localized areas of the body were initially diagnosed with plaque psoriasis. 1. Hands 2. Legs 3. Trunk 4. Arms	 n (%) n (%) n (%) n (%)	
PPC3: Time since first date of involvement of the scalp [Wynzora prescription date – date of involvement]	N, Mean (SD), Median, Q1, Q3, (95% CI) Missing n	
PPC4 Fitzpatrick Skin-type classification 1. Type I 2. Type II 3. Type III 4. Type IV 5. Type V 6. Type VI	 n (%) n (%) n (%) n (%) n (%) n (%)	

Note: Data from Clinician DATA COLLECTION FORM; SD: Standard deviation; Q1: quartile 1; Q3: quartile 3; 95% CI: 95% confidence interval; n: available data**.** The denominator for the percentage is the number of patients with available data (N=X).

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Table 3.5 Wynzora® Treatment Characteristics for the Original Treated Area, Safety Population

Character	Statistics (N=x)	Baseline (N=x)
TH1:Prescription frequency		
5. Once daily	n (%)	n (%)
6. Other, please specify: [TH1Cr2oe]	n (%)	n (%)
a. 3 times per week	n (%)	n (%)

Note: Data from Clinician data collection form. N: available data.

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Table 3.6 Prior Scalp Psoriasis Topical Treatments (To-Date) Including within the Past 12 Months, Safety Population

Character (Start date prior to Wynzora®; End date within the past 12 months or No end date)	**Baseline (N=x)**
TH1A Has **not** used any type of treatment (e.g., topical, biologic, non-biologic, phototherapy) to manage scalp psoriasis in the past (Treatment Naïve)	n (%)
TH2_1. Patients who have used a **topical treatment** to manage scalp psoriasis within the past 12 months.	N (%)
<<categories from WHO ATC classifications>>	**n (%)**
A	n (%)
B	n (%)
C	n (%)
D	n (%)

Note: Data from Clinician data collection form; X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X)

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Table 3.7 Last Treatment of Plaque Psoriasis of the Scalp; Last Treatment Used Before Start of the Study, Safety Population

Character	Baseline (N=x)
TH3_1_1	
Patients who were on any treatment	n (%)
None (no treatment used)	n (%)
Don't know	n (%)
TH3_1_1 **Type of Treatment:**	
1. Topical	n (%)
2. Biologic systemic treatment	n (%)
3. Non-biologic systemic treatment	n (%)
4. Phototherapy	n (%)
5. Other	n (%)
TH3_1_1 **Type of Treatment:**	
<<categories from WHO ATC classifications>>	**n (%)**
A	n (%)
B	n (%)
C	n (%)
D	n (%)
TH3_1_3 **Area Used:**	
TH3_1_3r2 Other parts of the body	n (%)
TH3_1_3r1 Scalp	n (%)
Reason for stopping:	
Patient completed the planned treatment course	n (%)
Discontinued due to treatment side-effects	n (%)
Discontinued due to lack of effectiveness	n (%)
Discontinued due to other reasons:	n (%)
X	n (%)
Y	
Z	
Don't know / Not applicable	n (%)

Note: Data from Clinician data collection form; X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X)

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Table 3.8 Ongoing Concomitant Treatment for Plaque Psoriasis in Other Parts of the Body (Excluding Scalp), Safety Population

Character	Baseline (N=x)
TH4: Patients **not** using any ongoing concomitant treatment(s) for plaque psoriasis in other parts of the body (excluding scalp).	n (%)
TH4_1_1 Patients **using any** ongoing concomitant treatment(s) for plaque psoriasis in other parts of the body (excluding scalp).	n (%)
TH4_1_1 **Type of Treatment**	
1. Topical	n (%)
2. Phototherapy	n (%)
3. Other	n (%)
TH4_1_1 **Type of Treatment:**	
<<categories from WHO ATC classifications>>	**n (%)**
A	n (%)
B	n (%)
C	n (%)
D	n (%)

Note: Data from Clinician data collection form; X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X)

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Table 3.9 Non-Wynzora® Concomitant Medication Use During the 8-Week Observation Period, Safety Population

Character	Baseline (N=X)
TH5: Is **not** currently on any concomitant medication to manage conditions other than plaque psoriasis.	n (%)
TH5: Is currently **using any** concomitant medication to manage conditions other than plaque psoriasis. TH5_1_2oe	n (%)
<<categories from WHO ATC classifications>> A B C D	**n (%)** n (%) n (%) n (%) n (%)

Note: Data from Clinician data collection form; X patients had missing data; The denominator for the percentages is the number of patients with available data (N=X). This concomitant non- plaque psoriasis medication use corresponds to use of medications at any time during the study observation period, overlapping with Wynzora® medication use.

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Table 3.10 Patient Disposition Throughout the Study

	Baseline n (%)		Week 4 n (%)		EOS n (%)	
(Cumulative numbers)	**Patient Survey**	**Clinician Survey**	**Patient Survey**	**Clinician Survey**	**Patient Survey**	**Clinician Survey**
Patients completing study visit						
Patients achieved early disease control						
Patient completed the planned 8-week treatment course for CAL/BDP PAD cream (Wynzora®), and the treatment was stopped						
The Treatment course was continued beyond 8 weeks						
Patient Terminations/Discontinuation*						
Loss of Effectiveness						
Adverse event ([S]AE, [S]ADR, or special situations, including overdose, off-label use, misuse, abuse, medication error, occupational exposure, lactation exposure, suspected drug interaction, unexpected therapeutic clinical benefit, and suspected transmission of infectious agents)						
Maternal/paternal pregnancy exposure						
Disease relapse						
Disease progression						
Other Clinician Decision: - Long adenocarcinoma disease evolution /death						
Patient voluntarily withdrawal of consent (for reasons other than adverse event or adverse drug reaction)						
Patient Lost to follow-up						
Other Patient Decision: - Personal reason, or the patient stops taking the study treatment						
Missing Data						
Total Patients						

Note: Data from Clinician and Patient data collection forms. SD: Standard deviation; EOS: End of study; n: Available data. SD: *Patient termination/Discontinuation reasons are not mutually exclusive. EOS termination/discontinuation counts are cumulative from week 4. XX patients indicated both patient voluntary withdrawal and patient lost to follow-up as the discontinuation reasons, XX patient indicated adverse event and other patient decision as the discontinuation reasons, and XX patient indicated adverse event, other clinician reason, and patient lost to follow-up as the discontinuation reasons.

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Table 3.11 Reason for Discontinuation

	Statistics	Loss of effectiveness	[S]AE, [S]ADR	Pregnancy exposure	Disease relapse	Disease progression	Other clinician decision	Patient voluntarily withdrawal of consent	Patient lost to follow-up	Other patient decision	TOTAL
Week 4	n (%)										
EOS	n (%)										
TOTAL	n (%)										

Note: Data from Clinician data collection form. ADR: Adverse Drug Reaction; SAE: Serious Adverse Event; EOS: End of Study. Week 4 and EOS data are mutually exclusive. Within respective visits, reasons for discontinuation are not mutually exclusive. The denominator for the percentage is the number of terminated patients (n=XX).

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Table 3.12 Subject Level Summary of Adverse Events, Any Type

Adverse Events, Any Type	N=X n (%)
Subjects with at least 1 adverse event (any type)	
Intensity of adverse event, among Subjects with at least 1 adverse event (any type)	
Mild	
Moderate	
Severe	
Adverse event outcome, among Subjects with at least 1 adverse event (any type)	
Recovered	
Recovering	
Not recovered	
Recovered with sequelae	
Fatal	
Unknown	
Action taken with Wynzora®, among Subjects with at least 1 adverse event (any type)	
Drug withdrawal / study discontinuation	
Other Actions:	
Dose Not Changed	
Subjects with at least 1 SAE or Serious ADR	
Subjects with at least 1 SAE or Serious ADR resulting in death	

Note: Data from clinician data collection form. Subject-level data does not include repeated or recurrent AEs.

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Table 3.13 Subject Level Summary of 'Not-Related to Wynzora®' Adverse Events

'Not-Related to Wynzora®' Adverse Events	N=X n (%)
Subjects with at least 1 'not-related' AE	
Intensity of adverse event, among Subjects with at least 1 'not-related' AE	
Mild	
Moderate	
Severe	
Adverse event outcome, among Subjects with at least 1 'not-related' AE	
Recovered	
Recovering	
Not recovered	
Recovered with sequelae	
Fatal	
Unknown	
Action taken with Wynzora®', among Subjects with at least 1 'not-related' AE	
Drug withdrawal / study discontinuation	
Other Actions:	
Dose Not Changed	
Subjects with at least 1 'not related' SAE	
Subjects with at least 1 'not related' SAE resulting in death	

Note: Data from clinician data collection form. Subject-level data does not include repeated or recurrent AEs.

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Table 3.14 Subject Level Summary of 'Not-Related' AEs by Organ Class & Preferred Term

System Organ Class: Preferred Term	N=X	Intensity	Action Taken
	n (%)	Mild, Moderate, Severe	A: Dose not changed; B: Drug withdrawn; C. Not Applicable
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			

Note: Data from clinician data collection form. Subject-level data does not include repeated or recurrent AEs.

Document Ref: 6LDXK-7CS8F-HSUJL-FHFJH

Table 3.15 Subject Level Summary of Adverse Drug Reactions

Adverse Drug Reactions	N=X n (%)
Subjects with at least 1 ADR	
Intensity of adverse event, among Subjects with at least 1 ADR	
Mild	
Moderate	
Severe	
Adverse event outcome, among Subjects with at least 1 ADR	
Recovered	
Recovering	
Not recovered	
Recovered with sequelae	
Fatal	
Unknown	
Action taken with Wynzora®, among Subjects with at least 1 ADR	
Drug withdrawal / study discontinuation	
Other Actions:	
Dose Not Changed	
Subjects with at least 1 Serious ADR	
Subjects with at least 1 Serious ADR resulting in death	

Note: Data from clinician data collection form. Subject-level data does not include repeated or recurrent AEs.

Document Ref: 6LDXK-7CS8F-HSUJL-FHFJH

Table 3.16 Subject Level Summary of ADRs by Organ Class & Preferred Term

System Organ Class: Preferred Term	N=X	Intensity	Action Taken
	n (%)	Mild, Moderate, Severe	A: Dose not changed; B: Drug withdrawn; C. Not Applicable
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			

Note: Data from clinician data collection form. Subject-level data does not include repeated or recurrent AEs.

Document Ref: 6LDXK-7CS8F-HSUJL-FHFJH

Table 3.17 Subject Level Summary of Serious ADRs by Organ Class & Preferred Term

System Organ Class: Preferred Term	N=X	Intensity	Action Taken
	n (%)	Mild, Moderate, Severe	A: Dose not changed; B: Drug withdrawn; C. Not Applicable
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			

Note: Data from clinician data collection form. Subject-level data does not include repeated or recurrent AEs.

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Table 3.18 Event Level Summary of Adverse Events, Any Type

Adverse Events, Any Type	N=X n (%)
Total number of adverse event (any type)	
Intensity of adverse event, among documented adverse events (any type)	
Mild	
Moderate	
Severe	
Adverse event outcome, among documented adverse events (any type)	
Recovered	
Recovering	
Not recovered	
Recovered with sequelae	
Fatal	
Unknown	
Action taken with Wynzora®, for documented adverse events (any type)	
Drug withdrawal / study discontinuation	
Other Actions:	
Dose Not Changed	
Number of SAEs or Serious ADRs	
Number of SAEs or Serious ADRs resulting in death	

Note: Data from clinician data collection form.

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Table 3.19 Event Level Summary of 'Not-Related to Wynzora®' Adverse Events

'Not-Related to Wynzora®' Adverse Events	N=X n (%)
Total number of 'not-related' AE	
Intensity of adverse event, among documented 'not-related' AEs	
Mild	
Moderate	
Severe	
Adverse event outcome, among documented 'not-related' AEs	
Recovered	
Recovering	
Not recovered	
Recovered with sequelae	
Fatal	
Unknown	
Action taken with CAL/BPD cream, for documented 'not-related' AEs	
Drug withdrawal / study discontinuation	
Other Actions:	
Dose Not Changed	
Number of SAEs	
Number of SAEs resulting in death	

Note: Data from clinician data collection form.

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Table 3.20 Event Level Summary of 'Not-Related' AEs by Organ Class & Preferred Term

System Organ Class: Preferred Term	N=X	Intensity	Action Taken
	n (%)	Mild, Moderate, Severe	A: Dose not changed; B: Drug withdrawn; C. Not Applicable
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			

Note: Data from clinician data collection form.

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Table 3.21 Event Level Summary of 'Not-Related' AEs by Patient ID

Patient ID	Study/ Survey Timepoint	Reported Term for the Adverse Event	AE Preferred Term	Primary System Organ Class	Date of Onset (yyyy/mm/dd)	Date of Resolution (yyyy/mm/dd)	Action Taken with CAL/BPD cream	Intensity of Adverse Event	Is this a SAE?

Note: Data from clinician data collection form. AE: Adverse Event; ADR: Adverse Drug Reaction; SAE: Serious Adverse Event.

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Table 3.22 Event Level Summary of Adverse Drug Reactions

Adverse Drug Reactions	N=X n (%)
Total number of ADRs	
Intensity of adverse event, among documented ADRs	
Mild	
Moderate	
Severe	
Adverse event outcome, for documented ADRs	
Recovered	
Recovering	
Not recovered	
Recovered with sequelae	
Fatal	
Unknown	
Action taken with CAL/BPD cream, for documented ADRs	
Drug withdrawal / study discontinuation	
Other Actions:	
Dose Not Changed	
Number of Serious ADRs	
Number of Serious ADRs resulting in death	

Note: Data from clinician data collection form.

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Table 3.23 Event Level Summary of ADRs by Organ Class & Preferred Term

System Organ Class: Preferred Term	N=X	Intensity	Action Taken
	n (%)	Mild, Moderate, Severe	A: Dose not changed; B: Drug withdrawn; C. Not Applicable
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			

Note: Data from clinician data collection form.

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Table 3.24 Event Level Summary of Serious ADRs by Organ Class & Preferred Term

System Organ Class: Preferred Term	N=X	Intensity	Action Taken
	n (%)	Mild, Moderate, Severe	A: Dose not changed; B: Drug withdrawn; C. Not Applicable
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			
System Organ Class Preferred Term 1 Preferred Term 2			

Note: Data from clinician data collection form.

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Table 3.25 Event Level Summary of ADRs by Patient ID

Patient ID	Study/ Survey Timepoint	Reported Term for the Adverse Event	AE Preferred Term	Primary System Organ Class	Date of Onset (yyyy/mm/dd)	Date of Resolution (yyyy/mm/dd)	Action Taken with CAL/BPD cream	Intensity of Adverse Event	Is this a SAE?

Note: Data from clinician data collection form. AE: Adverse Event; ADR: Adverse Drug Reaction; SAE: Serious Adverse Event.

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Table 3.26 Subject Level Summary of Other Safety Events

Safety events	**N=300**
	n (%)

Note: Data from clinician data collection form. Subject-level data does not include repeated or recurrent Safety Events.

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Table 3.27 Event Level Summary of Other Safety Events

Safety events	**N=300**
	n (%)

Note: Data from clinician data collection form.

Table 3.28 Significant Protocol Deviations

Patient ID	Deviation Type	Description

If no significant protocol deviations were observed in the study, it will be stated so.

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7.4 Sensitivity Analyses

A data-driven approach will be adopted. Sensitivity analyses will explore the impact of missing data on the robustness of the results, if unusual number of missing data is observed in the study. If some Subject visits are conducted via remote visits instead of in-person visits, the nature of visit (remote vs. in-person) will be used to stratify the analysis of secondary endpoint involving PGA, if sample size permits.

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8 LITERATURE REFERENCES

1. Mosca M, Hong J, Hadeler E, Brownstone N, Bhutani T, Liao W. Scalp Psoriasis: A Literature Review of Effective Therapies and Updated Recommendations for Practical Management. Dermatol Ther. 2021;11(3):769-97.
2. Merola JF, Li T, Li WQ, Cho E, Qureshi AA. Prevalence of psoriasis phenotypes among men and women in the USA. Clin Exp Dermatol. 2016;41(5):486-9.
3. Dopytalska K, Sobolewski P, Błaszczak A, Szymańska E, Walecka I. Psoriasis in special localizations. Reumatologia. 2018;56(6):392-8.
4. Egeberg A, See K, Garrelts A, Burge R. Epidemiology of psoriasis in hard-to-treat body locations: data from the Danish skin cohort. BMC Dermatol. 2020;20(1):3.
5. Pinter A et al. Calcipotriene and betamethasone dipropionate cream demonstrates high treatment success in patients with scalp psoriasis. Poster accepted at Winter Clinical Dermatology Conference 2022. February 4-7, 2022. Vermont (USA).
6. Pinter A, Green LJ, Selmer J, Praestegaard M, Gold LS, Augustin M, et al. A pooled analysis of randomized, controlled, phase 3 trials investigating the efficacy and safety of a novel, fixed dose calcipotriene and betamethasone dipropionate cream for the topical treatment of plaque psoriasis. J Eur Acad Dermatol Venereol JEADV. 2022;36(2):228-36.
7. Boehncke WH, Schon MP. Psoriasis. The Lancet. 2015;386(9997):983-94.
8. Parisi R, Symmons DPM, Griffiths CEM, Ashcroft DM. Global Epidemiology of Psoriasis: A Systematic Review of Incidence and Prevalence. J Invest Dermatol. 2013;133(2):377-85.
9. Møller AH, Erntoft S, Vinding GR, Jemec GB. A systematic literature review to compare quality of life in psoriasis with other chronic diseases using EQ-5D-derived utility values. Patient Relat Outcome Meas. 2015;6:167-77.
10. World Health Organization. (2016). Global report on psoriasis. World Health Organization. https://apps.who.int/iris/ha.
11. Tan KW, Griffiths CE. Novel systemic therapies for the treatment of psoriasis. Expert Opin Pharmacother. 2016;17(1):79-92.
12. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. J Am Acad Dermatol. 2008;58(5):826-50.
13. Papp K, Berth-Jones J, Kragballe K, Wozel G, de la Brassinne M. Scalp psoriasis: a review of current topical treatment options. J Eur Acad Dermatol Venereol JEADV. 2007;21(9):1151-60.
14. Kivelevitch D, Frieder J, Watson I, Paek SY, Menter MA. Pharmacotherapeutic approaches for treating psoriasis in difficult-to-treat areas. Expert Opin Pharmacother. 2018;19(6):561-75.
15. Zampieron A, Buja A, Fusco M, Linder D, Bortune M, Piaserico S, et al. Quality of life in patients with scalp psoriasis. G Ital Dermatol E Venereol Organo Uff Soc Ital Dermatol E Sifilogr. 2015;150(3):309-16.
16. Lebwohl MG, Bachelez H, Barker J, Girolomoni G, Kavanaugh A, Langley RG, et al. Patient perspectives in the management of psoriasis: results from the population-based Multinational Assessment of Psoriasis and Psoriatic Arthritis Survey. J Am Acad

Document Ref: 6LDXK-7CS8F-HSUJL-FHFJH

Dermatol. 2014;70(5):871-881.e1-30.
17. Chan CS, Van Voorhees AS, Lebwohl MG, Korman NJ, Young M, Bebo BF, et al. Treatment of severe scalp psoriasis: from the Medical Board of the National Psoriasis Foundation. J Am Acad Dermatol. 2009;60(6):962-71.
18. Zeichner JA, Lebwohl MG, Menter A, Bagel J, Del Rosso JQ, Elewski BE, et al. Optimizing topical therapies for treating psoriasis: a consensus conference. Cutis. 2010;86(3 Suppl):5-31; quiz 32.
19. Langley RG, Ellis CN. Evaluating psoriasis with Psoriasis Area and Severity Index, Psoriasis Global Assessment, and Lattice System Physician's Global Assessment. J Am Acad Dermatol. 2004;51(4):563-9.
20. Langley RGB, Feldman SR, Nyirady J, van de Kerkhof P, Papavassilis C. The 5-point Investigator's Global Assessment (IGA) Scale: A modified tool for evaluating plaque psoriasis severity in clinical trials. J Dermatol Treat. 2015;26(1):23-31.
21. Mrowietz U, Kragballe K, Reich K, Spuls P, Griffiths CEM, Nast A, et al. Definition of treatment goals for moderate to severe psoriasis: a European consensus. Arch Dermatol Res. 2011;303(1):1-10.
22. Stein Gold LF. Topical Therapies for Psoriasis: Improving Management Strategies and Patient Adherence. Semin Cutan Med Surg. 2016;35(2 Suppl 2):S36-44; quiz S45.
23. Psoriasis: assessment and management. Clinical Guideline CG153. NICE, 2012 (last updated: September 2017). [Internet].
24. Daudén E, Bewley A, Lambert J, Girolomoni G, Cambazard F, Reich K. Expert recommendations: the use of the fixed combination calcipotriol and betamethasone dipropionate gel for the topical treatment of psoriasis. J Eur Acad Dermatol Venereol JEADV. 2014;28 Suppl 2:22-32.
25. Samarasekera E, Sawyer L, Parnham J, Smith CH, Guideline Development Group. Assessment and management of psoriasis: summary of NICE guidance. BMJ. 2012;345:e6712.
26. Papp K, Gulliver W, Lynde C, Poulin Y, Ashkenas J, Canadian Psoriasis Guidelines Committee. Canadian guidelines for the management of plaque psoriasis: overview. J Cutan Med Surg. 2011;15(4):210-9.
27. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol. 2009;60(4):643-59.
28. Megna M, Cinelli E, Camela E, Fabbrocini G. Calcipotriol/betamethasone dipropionate formulations for psoriasis: an overview of the options and efficacy data. Expert Rev Clin Immunol. 2020;16(6):599-620.
29. Rajabi-Estarabadi A, Hasanzadeh H, Taheri A, Feldman SR, Firooz A. The efficacy of short-term clobetasol lotion in the treatment of scalp psoriasis. J Dermatol Treat. 2018;29(2):111-5.
30. Campanati A, Atzori L, Potenza C, Damiani G, Bianchi L, Corazza M, et al. Patient satisfaction with calcipotriol/betamethasone dipropionate cutaneous foam for the treatment of plaque psoriasis: The LION real-life multicenter prospective observational

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cohort study. Dermatol Ther. 2021;34(5):e15077.
31. Taneja A, Racette A, Gourgouliatos Z, Taylor CR. Broad-band UVB fiber-optic comb for the treatment of scalp psoriasis: a pilot study. Int J Dermatol. 2004;43(6):462-7.
32. Krell J, Nelson C, Spencer L, Miller S. An open-label study evaluating the efficacy and tolerability of alefacept for the treatment of scalp psoriasis. J Am Acad Dermatol. 2008;58(4):609-16.
33. Langley RGB, Feldman SR, Nyirady J, van de Kerkhof P, Papavassilis C. The 5-point Investigator's Global Assessment (IGA) Scale: A modified tool for evaluating plaque psoriasis severity in clinical trials. J Dermatol Treat. 2015;26(1):23-31.
34. Kimball AB, Naegeli AN, Edson-Heredia E, Lin CY, Gaich C, Nikaï E, et al. Psychometric properties of the Itch Numeric Rating Scale in patients with moderate-to-severe plaque psoriasis. Br J Dermatol. 2016;175(1):157-62.
35. Reich A, Chatzigeorkidis E, Zeidler C, Osada N, Furue M, Takamori K, et al. Tailoring the Cut-off Values of the Visual Analogue Scale and Numeric Rating Scale in Itch Assessment. Acta Derm Venereol. 2017;97(6):759-60.
36. Bharmal M, Payne K, Atkinson MJ, Desrosiers MP, Morisky DE, Gemmen E. Validation of an abbreviated Treatment Satisfaction Questionnaire for Medication (TSQM-9) among patients on antihypertensive medications. Health Qual Life Outcomes. 2009;7:36.
37. Chen SC, Yeung J, Chren MM. Scalpdex: a quality-of-life instrument for scalp dermatitis. Arch Dermatol. 2002;138(6):803-7.
38. Reich K, Zschocke I, Bachelez H, de Jong EMGJ, Gisondi P, Puig L, et al. Efficacy of a fixed combination of calcipotriol/betamethasone dipropionate topical gel in adult patients with mild to moderate psoriasis: blinded interim analysis of a phase IV, multicenter, randomized, controlled, prospective study. J Eur Acad Dermatol Venereol JEADV. 2015;29(6):1156-63.
39. Zschocke I, Mrowietz U, Lotzin A, Karakasili E, Reich K. Assessing adherence factors in patients under topical treatment: development of the Topical Therapy Adherence Questionnaire (TTAQ). Arch Dermatol Res. 2014;306(3):287-97.
40. Atkinson MJ, Kumar R, Cappelleri JC, Hass SL. Hierarchical construct validity of the treatment satisfaction questionnaire for medication (TSQM version II) among outpatient pharmacy consumers. Value Health J Int Soc Pharmacoeconomics Outcomes Res. 2005;8 Suppl 1:S9-24.

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9 APPENDICES

Appendix A: Study Schedule of Events

Appendix B: List of Tables for Interim Analysis

Appendix C: Select Study Questionnaires

Appendix D: Signature Page

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APPENDIX A: STUDY SCHEDULE OF EVENTS

Visit	Baseline	Additional Visit	EOS visit	Early Termination Visit^
Week†	0	4 ± 2 weeks	8 ± 4 weeks, as per routine practice**	-
Informed consent*	x			
Selection criteria	x			
Demographics/baseline characteristics[1]	x			
Physical examination[2]	x			
Psoriasis medical history and relevant comorbidities[3]	x			
Prior skin and scalp/plaque psoriasis medication (including topicals for scalp)	x			
Concomitant general medication	x		x	x
Photography	x	x	x	x
Physician's assessments (Scalp PGA, S-mPASI)	x	x	x	x
Physician satisfaction with medication			x	x
Patients' questionnaires				
Scalpdex, WI-NRS, Sleep quality, and Psychosocial effects	x		x	x
TSQM-9, PPQ, MMAS-4, self-reported VAS for treatment adherence, CUSP-Q			x	x
(S)AEs/(S)ADRs[4], special situation reports		x	x	x
Reason to continue CAL/BDP PAD cream (if applicable)			x	
Reasons for premature study withdrawal				x

† Expected visit schedule based on routine clinical practice, and index date (date of first administration of CAL/BDP PAD cream).

*The cream start date should be the same day of the study inclusion date or 24-hour prior to the study inclusion date as a maximum.

**If more than one visit is conducted (post-baseline) as per clinical practice, all routine assessments will be collected in the eCRF at EOS visit.

^Conducted (if feasible) as result of patient discontinuation from study for reasons other than achievement of scalp psoriasis disease control; this will be serve as the EOS visit for these patients. If this visit is not feasible to conduct earlier (closer to actual date of discontinuation), data collection will be performed the original EOS visit timeframe. Clinician assessments and patient surveys completed, if feasible.

[1] Age, gender, alcohol intake, smoking status, other demographic data, and patient clinical characteristics.

[2] Height/weight measurements, if documented per usual care.

[3] Disease information (date of diagnosis and baseline severity), comorbidities.

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[4] All AE/ADR information will be reported in the eCRF. If the (S)AE/(S)ADR has not resolved or stabilized by the time the subject completed the EOS visit or at the time of Subject's premature termination from the study, the Investigator may subsequently follow-up with the Subject to check the status of SAE/SADR, prior to completing the eCRF for EOS visit/ETV, if feasible.

ADR: Adverse drug reaction; AE, adverse event; BDP, betamethasone dipropionate; CAL, calcipotriene; CUSP-Q, cream usability in scalp psoriasis questionnaire; eCRF, electronic Case Report Form; EOS, End of Study; ETV, Early Termination Visit; MMAS, Morisky Medication Adherence Scale; PGA, physician's global assessment; PPQ, patient preference questionnaire; SAE, serious adverse event; SADR, Serious adverse drug reaction; TSQM, treatment satisfaction questionnaire for medication; V, visit; VAS, visual analogue scale; WI-NRS: Worst Itch Numerical Rating Scale.

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APPENDIX B: LIST OF TABLES FOR INTERIM ANALYSIS

The following tables will be considered for interim analyses.

Table 1.1 Population

Table 1.2 Patient Demographic Characteristics

Table 1.3 Scalp Worst Itch – Numerical Rating Scale (Scalp WI-NRS) Patient Scores

Table 1.5 SCALPDEX: Patient Response Summary

Table 1.7 SCALPDEX: Domain Scores

Table 1.9 Patient Evaluation of Sleep Quality Questionnaire

Table 1.11 Patient Psychosocial Effects (PSY-SCALP) Evaluation

Table 1.13 Abbreviated Patient Treatment Satisfaction Questionnaire for Medication

Table 1.15 Patient Preference Questionnaire (PPQ)

Table 1.16 Patient Preference Questionnaire (PPQ) – Composite Score

Table 1.18 Patient Treatment Behaviours

Table 1.19 Morisky Medication Adherence Scale (MMAS-4) – Composite Score

Table 1.22 Self-reported Visual Analogic Scale (VAS) for treatment adherence

Table 1.24 Cream Usability Scalp Psoriasis Questionnaire (CUSP-Q)

Table 2.1 Site Characteristics

Table 2.2 Study Subject Selection Criteria

Table 2.3 Patient Clinical Characteristics from Medical Chart

Table 2.4 Clinician Evaluation of Current Scalp Severity - Scalp-PGA

Table 2.5 CFB for Clinician Evaluation of Current Scalp Severity - Scalp-PGA

Table 2.6 Scalp-PGA Success

Table 2.9 S-mPASI Score

Table 2.11 CAL/BDP PAD cream (Wynzora®) Treatment Characteristics

Table 2.16 Treatment Satisfaction Questionnaire for Medication: Clinician Scores

Table 3.1 Safety Analysis Population

Table 3.2 Study Subject Selection Criteria, Safety Population

Table 3.3 Patient Demographic Characteristics, Safety Population

Table 3.4 Patient Clinical Characteristics from Medical Chart, Safety Population

Table 3.5 Wynzora® Treatment Characteristics for the Original Treated Area, Safety Population

Table 3.10 Patient Disposition Throughout the Study

Table 3.11 Reason for Discontinuation

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APPENDIX C: SELECT STUDY QUESTIONNAIRES

TSQM-9

Abbreviated Treatment Satisfaction Questionnaire for Medication

Instructions: Please take some time to think about how satisfied or dissatisfied you are with the medication you are taking in this clinical trial. We are interested in what you think about the effectiveness and convenience experienced when using the medication over the last two to three weeks, or since you last used it. For each question, please select the response that most closely corresponds to your own experiences.

1. How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?

☐1 Extremely Dissatisfied
☐2 Very Dissatisfied
☐3 Dissatisfied
☐4 Somewhat Satisfied
☐5 Satisfied
☐6 Very Satisfied
☐7 Extremely Satisfied

2. How satisfied or dissatisfied are you with the way the medication relieves your symptoms?

☐1 Extremely Dissatisfied
☐2 Very Dissatisfied
☐3 Dissatisfied
☐4 Somewhat Satisfied
☐5 Satisfied
☐6 Very Satisfied
☐7 Extremely Satisfied

3. How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?

☐1 Extremely Dissatisfied
☐2 Very Dissatisfied
☐3 Dissatisfied
☐4 Somewhat Satisfied

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☐5 Satisfied
☐6 Very Satisfied
☐7 Extremely Satisfied

4. How easy or difficult is it to use the medication in its current form?

☐1 Extremely Difficult
☐2 Very Difficult
☐3 Difficult
☐4 Somewhat Easy
☐5 Easy
☐6 Very Easy
☐7 Extremely Easy

5. How easy or difficult is it to plan when you will use the medication each time?

☐1 Extremely Difficult
☐2 Very Difficult
☐3 Difficult
☐4 Somewhat Easy
☐5 Easy
☐6 Very Easy
☐7 Extremely Easy

6. How convenient or inconvenient is it to take the medication as instructed?

☐1 Extremely Inconvenient
☐2 Very Inconvenient
☐3 Inconvenient
☐4 Somewhat Convenient
☐5 Convenient
☐6 Very Convenient
☐7 Extremely Convenient

7. Overall, how confident are you that taking this medication is a good thing for you?

☐1 Not at All Confident
☐2 A Little Confident
☐3 Somewhat Confident
☐4 Very Confident
☐5 Extremely Confident

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8. How certain are you that the good things about your medication outweigh the bad things?

☐1 Not at All Certain
☐2 A Little Certain
☐3 Somewhat Certain
☐4 Very Certain
☐5 Extremely Certain

9. Taking all things into account, how satisfied or dissatisfied are you with this medication?

☐1 Extremely Dissatisfied
☐2 Very Dissatisfied
☐3 Dissatisfied
☐4 Somewhat Satisfied
☐5 Satisfied
☐6 Very Satisfied
☐7 Extremely Satisfied

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SCALPDEX

These questions concern your feelings over the past 4 weeks about **your scalp condition.** Check the answer that comes closest to the way you have been feeling.

HOW OFTEN DURING THE PAST 4 WEEKS DO THESE STATEMENTS DESCRIBE YOU?	NEVER	RARELY	SOMETIMES	OFTEN	ALL THE TIME
1. My scalp hurts	☐1	☐2	☐3	☐4	☐5
2. My scalp condition makes me feel depressed	☐1	☐2	☐3	☐4	☐5
3. My scalp itches	☐1	☐2	☐3	☐4	☐5
4. I am ashamed of my scalp condition	☐1	☐2	☐3	☐4	☐5
5. I am embarrassed by my scalp condition	☐1	☐2	☐3	☐4	☐5
6. I am frustrated by my scalp condition	☐1	☐2	☐3	☐4	☐5
7. I am humiliated by my scalp condition	☐1	☐2	☐3	☐4	☐5
8. My scalp condition bleeds	☐1	☐2	☐3	☐4	☐5
9. I am annoyed by my scalp condition	☐1	☐2	☐3	☐4	☐5
10. I am bothered by the appearance of my scalp condition	☐1	☐2	☐3	☐4	☐5
11. My scalp condition makes me feel self-conscious.	☐1	☐2	☐3	☐4	☐5
12. I am bothered that my scalp condition is incurable.	☐1	☐2	☐3	☐4	☐5
13. My scalp condition affects how I wear my hair (hairstyle, hats)	☐1	☐2	☐3	☐4	☐5
14. I am bothered by people's questions about my scalp condition.	☐1	☐2	☐3	☐4	☐5
15. My scalp condition affects the color of clothes I wear.	☐1	☐2	☐3	☐4	☐5
16. I am bothered by the persistence/reoccurrence of my scalp condition.	☐1	☐2	☐3	☐4	☐5
17. I feel stressed about my scalp condition.	☐1	☐2	☐3	☐4	☐5
18. Caring for my scalp condition is inconvenient for me.	☐1	☐2	☐3	☐4	☐5
19. I feel that my knowledge for caring for my scalp is adequate	☐1	☐2	☐3	☐4	☐5
20. The cost of caring for my scalp condition bothers me.	☐1	☐2	☐3	☐4	☐5
21. My scalp condition makes my daily life difficult.	☐1	☐2	☐3	☐4	☐5
22. My scalp condition makes me feel different from others.	☐1	☐2	☐3	☐4	☐5
23. My scalp condition makes it hard to go to the hairdresser/barber.	☐1	☐2	☐3	☐4	☐5

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APPENDIX D: SIGNATURE PAGE

The signature below constitutes the approval of this SAP and the attachments and provides the necessary assurances that this study analyses will be conducted according to all stipulations of the SAP.

Study CRO:

PPD PPD 11 / 07 / 2024

Signature Date

Almirall Approvals:

PPD PPD 11 / 08 / 2024

Signature Date

PPD

PPD PPD 11 / 27 / 2024

Signature Date

PPD

PPD PPD 11 / 08 / 2024

Signature Date

PPD

Document Ref: 6LDXK-7CS8F-HSUJL-FHFJH

Signature Certificate

PPD

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