Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, in patients with moderate to severe scalp psoriasis: the association between patient-reported and clinician-reported outcomes at Week 16 in a phase 3b/4 multicenter, randomized, double-blinded, placebo-controlled study (PSORIATYK SCALP)

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Introduction

- Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy[1-5]
- Scalp involvement may occur in up to ~80% of patients with psoriasis and disproportionately impacts patients' quality of life (QoL)[6-10]
  - The scalp is frequently the first area affected by psoriasis[6-9]
  - Treatment with topical agents may be challenging[8,9,11]
- PSORIATYK SCALP, a phase 3b/4 multicenter, randomized, double-blinded, placebo-controlled study assessed the efficacy and safety of deucravacitinib in patients with moderate to severe scalp psoriasis, including those with less extensive overall psoriasis (body surface area [BSA] involvement ≥3%)
  - At Week 16, deucravacitinib achieved superiority vs placebo for the primary and all key secondary endpoints
- Patient-reported outcomes (PROs) provide additional information on treatment efficacy, capturing patients' experiences and impact on their QoL[12]
  - The association between scalp-specific PROs and clinician-reported outcomes (CROs) may vary depending on specific measures used and has not been evaluated in patients with moderate to severe scalp psoriasis

Objective

- To evaluate the association between PROs and CROs in patients treated with deucravacitinib vs placebo in patients with moderate to severe scalp psoriasis

Methods

Study design

- Patients with moderate to severe scalp psoriasis were randomized 1:2 to once-daily (QD) placebo or deucravacitinib 6 mg
  - At Week 16, all patients were switched to open-label deucravacitinib 6 mg QD through Week 52

Study eligibility

- Participants were eligible for study inclusion if they:
  - Were age ≥18 years
  - Were a candidate for systemic therapy or phototherapy
  - Had moderate to severe scalp psoriasis (must meet all 3)
    - Scalp-specific Physician Global Assessment score ≥3
    - Scalp surface area involvement ≥20%
    - Psoriasis Scalp Severity Index score ≥12
  - BSA involvement ≥3%
  - Evidence of plaque psoriasis in a non-scalp area
  - Failed to respond to, or intolerant of, ≥1 topical therapy for scalp psoriasis

PRO endpoints

- Scalp-specific itch, pain, and flaking numeric rating scales (NRS)
  - A patient-administered, 11-point horizontal symptom severity scale anchored at 0 and 10; higher scores represent greater symptom severity (24-hour recall)
- Scalpdex
  - A 23-item scalp dermatitis-specific QoL tool, with emotions, symptoms, and function subscales; higher scores indicate worse QoL
- Dermatology Life Quality Index (DLQI)
  - A 10-question, 3-point, patient-reported QoL impairment index with summed scores ranging from 0 to 30; higher scores denote greater QoL impairment (7-day recall)

CRO endpoints

- Scalp-specific Physician Global Assessment (ss-PGA)
  - Scalp lesions are evaluated in terms of clinical signs of redness, thickness, and scaliness
  - Scored on a 5-point scale: 0 = absence of disease; 1 = very mild disease; 2 = mild disease; 3 = moderate disease; 4 = severe disease
- Psoriasis Scalp Severity Index (PSSI)
  - A 5-point, Likert-type clinical scale assessing clinical parameters of erythema, induration, and desquamation to evaluate scalp disease severity
  - Summed scores are multiplied by an integer from 0 to 6 that represents the area of affected scalp, yielding a score ranging from 0 to 72; higher scores indicate worse disease severity

Analysis

- The correlation between PROs and CROs was evaluated using Spearman correlation coefficients for absolute scores at baseline and Week 16
- Descriptive analyses of changes in PROs from baseline and response rates by CRO response groups were calculated for deucravacitinib-treated patients

Results

Baseline characteristics

- This analysis included 154 patients (placebo: n = 51; deucravacitinib: n = 103)
- Baseline demographic and clinical characteristics are summarized in **Table 1**
  - Baseline demographics, clinician-assessed disease severity, scalp-specific symptoms, and QoL scores were similar between treatment groups
- Correlations were weak between PRO and CRO absolute values at baseline (data not shown)

Table 1. Demographics and baseline clinical characteristics

Characteristic	Placebo (n = 51)	Deucravacitinib (n = 103)
Age, years, mean (SD)	43.2 (13.1)	42.8 (15.7)
Female, n (%)	20 (39.2)	45 (43.7)
White, n (%)	47 (92.2)	93 (90.3)
Weight, kg, mean (SD)	88.2 (27.6)	89.3 (23.8)
Scalp psoriasis duration, years, mean (SD)	12.4 (9.6)	16.4 (11.7)
BSA involvement, n (%)		
3%-10%	38 (74.5)	70 (68.0)
>10%	13 (25.5)	33 (32.0)
sPGA, n (%)		
2	4 (7.8)	7 (6.8)
3	42 (82.4)	81 (78.6)
4	5 (9.8)	15 (14.6)
PASI, mean (SD)	9.4 (5.6)	10.2 (6.7)
ss-PGA, n (%)		
3	32 (62.7)	76 (73.8)
4	19 (37.3)	27 (26.2)
PSSI, mean (SD)	32.2 (13.7)	33.5 (12.5)
SSA involvement, %, mean (SD)	53.0 (24.0)	57.6 (23.1)
Scalp-specific itch NRS, mean (SD)	6.4 (1.8)	6.4 (2.3)
Scalp-specific pain NRS, mean (SD)	4.5 (3.0)	4.0 (2.8)
Scalp-specific flaking NRS, mean (SD)	6.7 (2.2)	7.0 (2.3)
Scalpdex, mean (SD)		
Emotions	54.0 (22.2)	56.8 (23.4)
Symptoms	55.4 (19.4)	52.1 (21.3)
Function	54.9 (24.3)	53.7 (26.1)
Total	54.4 (20.4)	55.5 (22.4)
DLQI, mean (SD)	10.2 (5.6)	11.3 (6.3)

BSA, body surface area; DLQI, Dermatology Life Quality Index; NRS, numeric rating scale; PASI, Psoriasis Area and Severity Index; PSSI, Psoriasis Scalp Severity Index; SD, standard deviation; sPGA, static Physician Global Assessment; SSA, scalp surface area; ss-PGA, scalp-specific Physician Global Assessment.

Spearman correlation between PROs and CROs

- At Week 16, correlations were stronger in deucravacitinib-treated patients than those receiving placebo (**Table 2**)
  - All correlations were statistically significant across CRO measures within this treatment group
- In the deucravacitinib treatment group, PSSI and ss-PGA were most strongly correlated with scalp-specific NRS items and Scalpdex symptoms (≥0.6; $P < 0.0001$), except for PSSI and scalp-specific pain, which were moderately correlated (**Table 2**)
  - Scalpdex total scores and DLQI scores were moderately correlated with PSSI and ss-PGA ($P < 0.0001$)

Table 2. Spearman correlation coefficients between PROs and CROs

	Placebo (n = 51)		Deucravacitinib (n = 103)	
Measure	ss-PGA	PSSI	ss-PGA	PSSI
Scalp-specific itch NRS	0.418[a]	0.436[a]	0.636[b]	0.656[a]
Scalp-specific pain NRS	0.336[a]	0.324[a]	0.605[b]	0.591[b]
Scalp-specific flaking NRS	0.489[b]	0.443[a]	0.747[b]	0.721[b]
Scalpdex: Emotions	0.308[a]	0.396[a]	0.497[b]	0.473[b]
Scalpdex: Symptoms	0.250	0.308[a]	0.645[b]	0.660[b]
Scalpdex: Function	0.224	0.252	0.441[b]	0.432[b]
Scalpdex: Total	0.308[a]	0.387[a]	0.536[b]	0.520[b]
DLQI	0.345[a]	0.293	0.547[b]	0.565[b]

Weak correlation | Moderate correlation | Strong correlation

[a]$P < 0.05$. [b]$P < 0.0001$.
CRO, clinician-reported outcome; DLQI, Dermatology Life Quality Index; NRS, numeric rating scale; PRO, patient-reported outcome; PSSI, Psoriasis Scalp Severity Index; ss-PGA, scalp-specific Physician Global Assessment.

Correlations between scalp-specific NRS items and DLQI

- The correlations between scalp-specific NRS items and DLQI were strong and statistically significant in deucravacitinib-treated patients, ranging from 0.693 to 0.780 ($P < 0.0001$), and moderate in placebo-treated patients (**Table 3**)

Table 3. Spearman correlation coefficients between scalp-specific symptoms and DLQI

	DLQI	
Measure	Placebo (n = 51)	Deucravacitinib (n = 103)
Scalp-specific itch NRS	0.512[a]	0.780[b]
Scalp-specific pain NRS	0.459[a]	0.711[b]
Scalp-specific flaking NRS	0.488[a]	0.693[b]

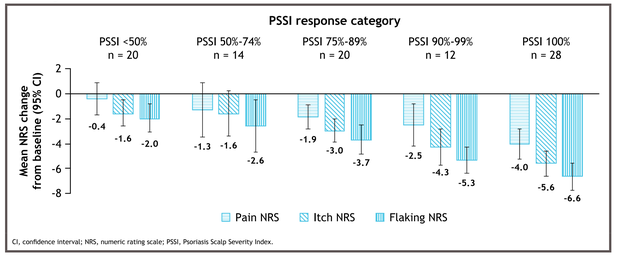
Moderate correlation | Strong correlation

[a]$P < 0.001$; [b]$P < 0.0001$.
DLQI, Dermatology Life Quality Index; NRS, numeric rating scale.

Change from baseline in NRS response

- Overall, scalp-specific NRS outcomes continued to improve with higher PSSI response (**Figure 1**)
  - Patients achieving PSSI 90 at Week 16 experienced substantial improvements in scalp-specific symptoms when treated with deucravacitinib
- Similar trends were observed for change from baseline in NRS measures by change in ss-PGA categories (data not shown)

Figure 1. Change from baseline in NRS measures by PSSI response category in patients receiving deucravacitinib

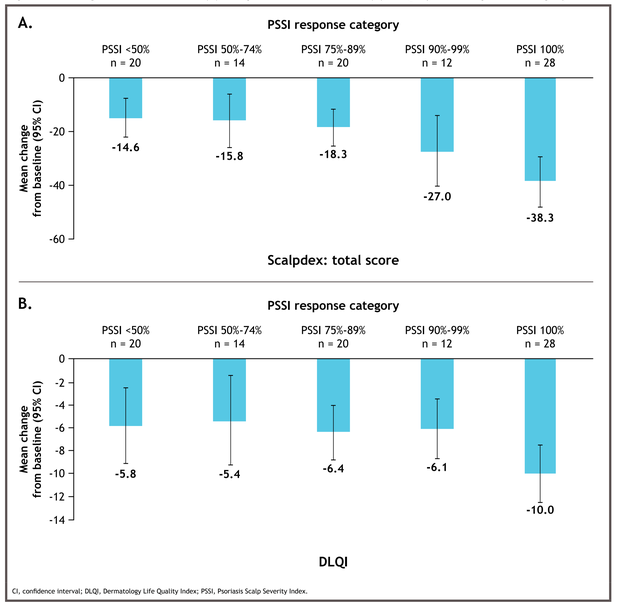


CI, confidence interval; NRS, numeric rating scale; PSSI, Psoriasis Scalp Severity Index.

Change from baseline in Scalpdex total scores and DLQI

- At Week 16, patients treated with deucravacitinib experienced progressively greater improvements in Scalpdex total scores with greater reductions in scalp disease severity, as measured by PSSI (**Figure 2A**)
- Patients treated with deucravacitinib experienced improvements in DLQI across all PSSI response categories (**Figure 2B**)
  - DLQI improvements were largest among those who achieved PSSI 100, with mean reductions of 10.0 points
- Similar trends were observed for Scalpdex total score and DLQI reductions by ss-PGA change categories (data not shown)

Figure 2. Change from baseline in (A) Scalpdex total score and (B) DLQI by PSSI response category



CI, confidence interval; DLQI, Dermatology Life Quality Index; PSSI, Psoriasis Scalp Severity Index.

PRO response rates by ss-PGA and PSSI response level

- At Week 16, between 76.2% and 89.5% of patients achieving ss-PGA 0/1 reported clinically meaningful (≥4-point[13]) improvements in scalp-specific NRS measures (**Table 4**)
  - Similar improvements were reported among those who achieved PSSI 90
- A large proportion of patients treated with deucravacitinib also reported a 20-point reduction in Scalpdex total score with achievement of ss-PGA 0/1 and PSSI 90 (**Table 4**)
- Meaningful improvement in DLQI (≥4 points[14]) was reported by 82.6% and 83.3% of patients achieving ss-PGA 0/1 and PSSI 90, respectively

Table 4. Response rates in patient-reported outcomes by ss-PGA and PSSI response level at Week 16 in patients receiving deucravacitinib

Measure	ss-PGA 0/1[a]	PSSI 90[b]
≥4-pt reduction in scalp-specific NRS		
Itch	76.2%	86.1%
Pain	89.5%	89.5%
Flaking	88.4%	88.9%
≥20-pt reduction in Scalpdex		
Emotions	69.6%	75.7%
Symptoms	69.4%	77.5%
Function	84.1%	88.9%
Total	75.6%	83.3%
≥4-pt reduction in DLQI	82.6%	86.8%

[a]Patients achieving ss-PGA score of 0 or 1. [b]≥90% improvement in PSSI from baseline.
DLQI, Dermatology Life Quality Index; NRS, numeric rating scale; PSSI, Psoriasis Scalp Severity Index; pt, point; ss-PGA, scalp-specific Physician Global Assessment.

Conclusions

- In patients treated with deucravacitinib, a strong correlation was found between patient-reported scalp symptoms and scalp-specific CROs at Week 16, confirming the treatment benefit from the patient perspective
  - Scalp-specific itch and flaking were the NRS measures most strongly correlated with scalp-specific CROs, suggesting that clinical improvement of lesions is accompanied by symptom improvement experienced by patients
- DLQI correlations with scalp-specific CROs were similar to those observed with non-scalp-specific CROs in patients with psoriasis[15,16]

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