Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, in patients with moderate to severe scalp psoriasis: improvement in scalp-related quality of life and symptoms in the phase 3b/4 multicenter, randomized, double-blinded, placebo-controlled PSORIATYK SCALP trial

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Synopsis

- 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[1-4]
- Scalp psoriasis carries a profound symptom burden and may have severe impact on patients' quality of life[5]
- PSORIATYK SCALP (NCT05478499), an ongoing 52-week, phase 3b/4, multicenter, randomized, double-blinded, placebo-controlled trial assesses the efficacy and safety of deucravacitinib in patients with moderate to severe scalp psoriasis and total body surface area (BSA) involvement ≥3%[6]
- At Week 16, deucravacitinib achieved statistical superiority vs placebo for the primary endpoint (scalp-specific Physician Global Assessment [ss-PGA] score of 0 or 1) and all key secondary efficacy endpoints (≥90% improvement from baseline in Psoriasis Scalp Severity Index [PSSI], change from baseline in the patient-reported scalp-specific itch numeric rating scale [NRS], and static Physician Global Assessment score of 0 or 1)[6]
- At Week 16, deucravacitinib was efficacious in improving scalp-specific quality of life and symptoms

Objective

- To assess patient-reported outcomes (PROs) through Week 16 of PSORIATYK SCALP, overall and in subgroups of patients with baseline BSA 3–10% and >10%

Methods

Study design

- Eligible patients were aged ≥18 years with moderate to severe scalp psoriasis
  - PSSI ≥12
  - ss-PGA ≥3
  - Scalp surface area involvement ≥20%
  - Total BSA ≥3%
- Patients were randomized 1:2 to placebo or deucravacitinib 6 mg for 16 weeks

Outcomes and analysis

- The following PROs were completed at baseline, Weeks 1, 2, and 4, and every 4 weeks thereafter:
  - Scalpdex, a validated scalp-dermatitis–specific quality-of-life instrument based on the Skindex instrument, includes emotions, function, and symptom subscales[7]
    - Range: 0–100, with higher scores indicating worse quality of life
  - Three NRS measures for scalp-specific flaking, itch, and pain
    - NRS describes a symptom's worst level of severity over the preceding 24 hours
    - Range: 0–10, with 0 indicating "none" and 10 indicating "worst imaginable"
- In the overall population, Scalpdex and scalp-specific flaking, itch, and pain NRS score changes from baseline were assessed with an analysis of covariance (ANCOVA) model, with treatment and randomization stratification factors as fixed effects and the baseline value as a covariate
  - Randomization stratification factors: previous biologic use (yes/no) and body weight (<90 or ≥90 kg)
- Subgroup analyses assessed change from baseline in Scalpdex score in BSA subgroups (BSA 3–10%, BSA >10%) using an ANCOVA model, with treatment as a fixed effect and the baseline value as a covariate
- Missing data were imputed with a modified baseline observation carried forward (mBOCF) approach
  - Patients who discontinued due to lack of efficacy or adverse events had their baseline observation carried forward for subsequent analysis weeks
  - Patients with missing values for other reasons had their last valid observation carried forward
- *P* values are nominal

Results

Patient population

- The trial included 154 patients (placebo: n = 51; deucravacitinib: n = 103)
- Mean baseline scores in the overall population were balanced across treatment arms (**Table**)
  - Mean Scalpdex total scores indicated severe impact on quality of life (>44.0, based on interpretation bands for Skindex,[8] from which Scalpdex was adapted)
  - Mean NRS scores for scalp-specific flaking, itch, and pain indicated moderate to severe symptoms (≥4.0[9,10])

Table. Baseline PRO scores, overall and by BSA subgroups

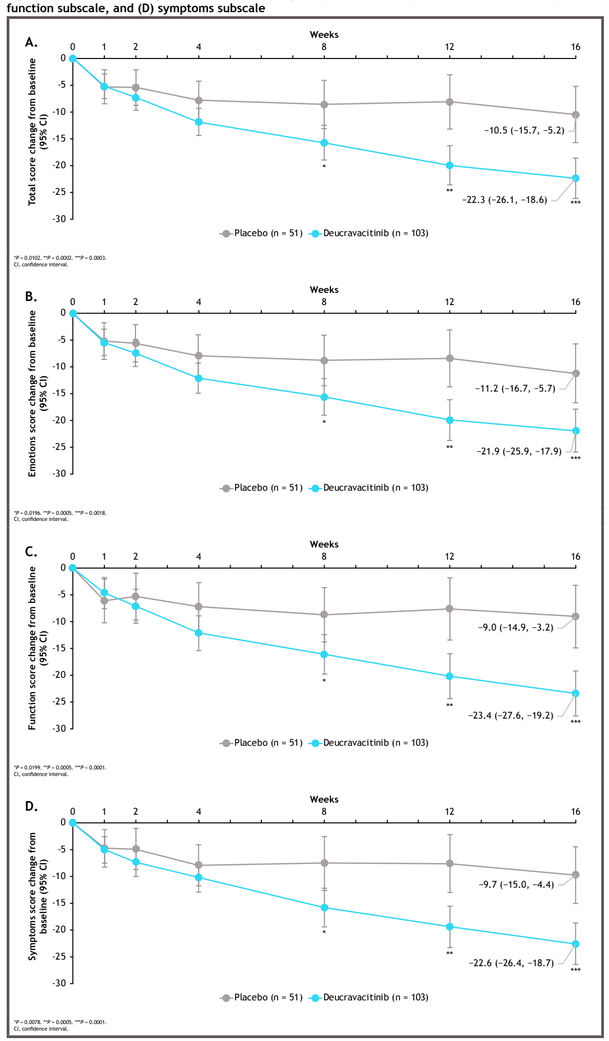
	Overall population		BSA 3–10%		BSA >10%	
PRO measure, mean (SD)	Placebo (n = 51)	Deucravacitinib (n = 103)	Placebo (n = 38)	Deucravacitinib (n = 70)	Placebo (n = 13)	Deucravacitinib (n = 33)
Scalpdex						
Emotions	54.0 (22.2)	56.8 (23.4)	57.8 (20.7)	58.9 (23.3)	42.8 (23.7)	52.6 (23.4)
Function	54.9 (24.3)	53.7 (26.1)	57.6 (23.8)	55.0 (27.0)	46.9 (25.1)	50.9 (24.0)
Symptoms	55.4 (19.4)	52.1 (21.3)	58.8 (17.1)	53.1 (20.5)	45.5 (23.0)	50.0 (23.1)
Total	54.4 (20.4)	55.5 (22.4)	57.9 (18.7)	57.3 (22.5)	44.1 (22.3)	51.9 (22.2)
Scalp-specific flaking NRS	6.7 (2.2)	7.0 (2.3)	6.9 (2.1)	7.0 (2.3)	5.9 (2.3)	6.8 (2.4)
Scalp-specific itch NRS	6.4 (1.8)	6.4 (2.3)	6.4 (1.8)	6.3 (2.4)	6.5 (2.0)	6.5 (2.0)
Scalp-specific pain NRS	4.5 (3.0)	4.0 (2.8)	4.9 (2.9)	3.8 (2.8)	3.3 (2.9)	4.2 (2.9)

BSA, body surface area; NRS, numeric rating scale; PRO, patient-reported outcome; SD, standard deviation.

Scalpdex score change from baseline, overall population

- Significantly greater change from baseline with deucravacitinib vs placebo was observed from Week 8 for Scalpdex total score (**Figure 1A**) and for each Scalpdex subscale (**Figure 1B-D**)

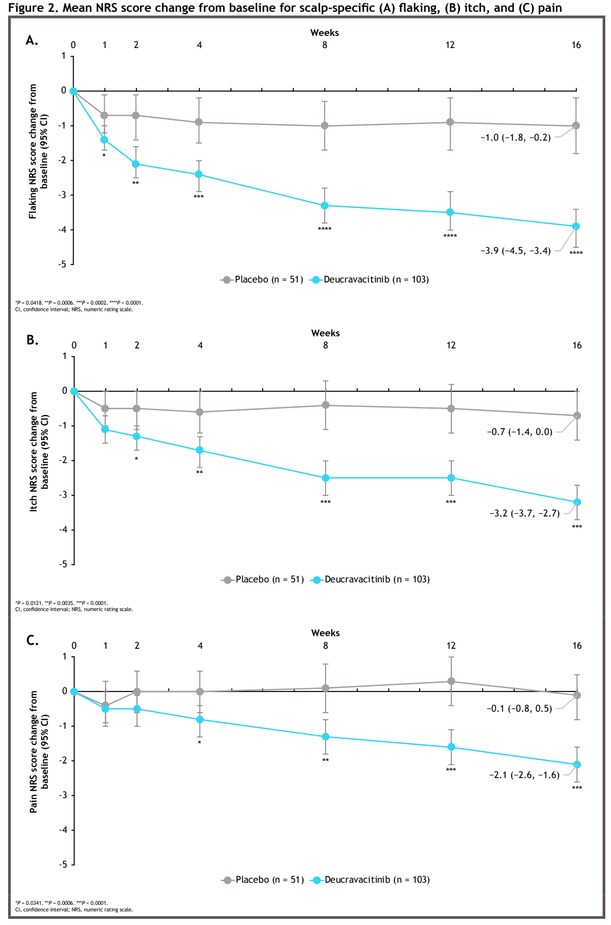
Figure 1. Mean score change from baseline in Scalpdex (A) total score, (B) emotions subscale, (C) function subscale, and (D) symptoms subscale



NRS score changes from baseline, overall population

- Significantly greater NRS score change from baseline with deucravacitinib vs placebo was observed from:
  - Week 1 for scalp-specific flaking (**Figure 2A**)
  - Week 2 for scalp-specific itch (**Figure 2B**)
  - Week 4 for scalp-specific pain (**Figure 2C**)

Figure 2. Mean NRS score change from baseline for scalp-specific (A) flaking, (B) itch, and (C) pain



Scalpdex score changes from baseline, subgroup analysis

- Significantly greater change from baseline in Scalpdex total score with deucravacitinib vs placebo was observed from:
  - Week 12 in the BSA 3–10% subgroup (**Figure 3A**)
  - Week 8 in the BSA >10% subgroup (**Figure 3B**)
- Week 16 change from baseline was significantly greater for patients receiving deucravacitinib vs placebo:
  - On each Scalpdex subscale in the BSA 3–10% subgroup (**Figure 4**)
  - On the emotions and function subscales in the BSA >10% subgroup (**Figure 4**)

Figure 3. Mean score change from baseline in Scalpdex total score in the subgroups (A) BSA 3–10% and (B) BSA >10%

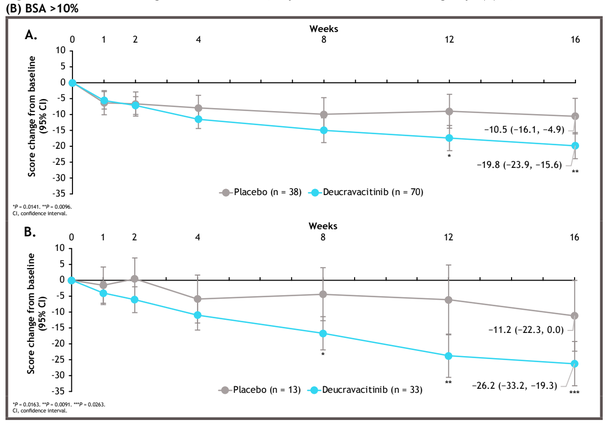
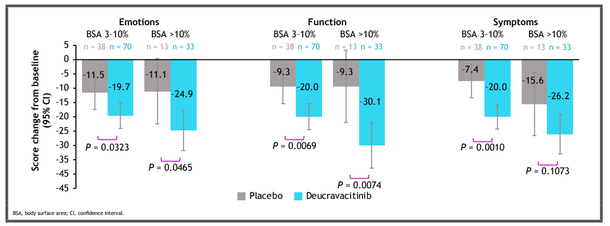


Figure 4. Week 16 Scalpdex subscale score change from baseline by BSA subgroup



Conclusions

- Deucravacitinib was efficacious in improving scalp-specific quality-of-life measures and symptoms
- Patient-reported scalp-specific quality-of-life outcomes were improved in patients receiving deucravacitinib in both BSA subgroups

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