Deucravacitinib is associated with improvements in Dermatology Life Quality Index in patients with moderate to severe scalp psoriasis: an analysis of PSORIATYK SCALP, a randomized, double-blinded, placebo-controlled, phase 3b/4 trial

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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[1-4]
- Scalp involvement occurs in up to ~80% of patients with psoriasis and may disproportionately affect patient quality of life[5-7]
  - Under guidelines jointly issued by the American Academy of Dermatology and the National Psoriasis Foundation, psoriasis may be considered severe when it occurs in certain regions of the body, including the scalp[8]
  - In 2020, the International Psoriasis Council classified patients with scalp psoriasis as candidates for systemic therapy but observed a paucity of evidence from clinical trials demonstrating treatment efficacy in patients with lower body surface area (BSA) involvement[9]
- PSORIATYK SCALP (NCT05478499), a 52-week, phase 3b/4, multicenter, randomized, double-blinded, placebo-controlled trial, assessed the efficacy and safety of deucravacitinib in patients with moderate to severe scalp psoriasis and total BSA involvement ≥3%
  - 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 endpoints (≥90% improvement from baseline in Psoriasis Scalp Severity Index [PSSI], change from baseline in the patient-reported scalp-specific itch numeric rating scale, and static Physician Global Assessment score of 0 or 1)[10]

Objectives

- To evaluate improvements in quality of life (QoL), measured by the Dermatology Life Quality Index (DLQI), in patients treated with deucravacitinib vs placebo in the PSORIATYK SCALP trial
- To evaluate DLQI improvements in subgroups of patients with total BSA 3%–10% and BSA >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 involvement ≥3%
- Patients were randomized 1:2 to placebo or deucravacitinib 6 mg once daily for 16 weeks
  - Randomization was stratified by previous biologic use (yes/no) and body weight (<90 or ≥90 kg)

Outcomes and analyses

- DLQI
  - Skin disease–specific measure assessing 6 QoL domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment
  - Range: 0–30, with higher scores indicating worse QoL[11]
    - 0-1: no effect on QoL
    - 2-5: small effect on QoL
    - 6-10: moderate effect on QoL
    - 11-20: very large effect on QoL
    - 21-30: extremely large effect on QoL
  - Meaningful change threshold (MCT): ≥4-point reduction from baseline[12]
  - Patients completed the DLQI at baseline, Weeks 1, 2, and 4, and every 4 weeks thereafter through Week 16
- Overall analysis
  - Adjusted mean change from baseline in DLQI score was assessed using an analysis of covariance (ANCOVA) model with treatment and randomization stratification factors as fixed effects and the baseline value as a covariate
  - Response rates for achieving DLQI of 0 or 1 (DLQI 0/1) were assessed in patients with baseline DLQI ≥2 using a Cochran-Mantel-Haenszel test stratified by randomization factors
  - Response rates for achieving clinically meaningful improvement in DLQI (≥4-point reduction from baseline) in patients with baseline DLQI ≥4 were compared using a Cochran-Mantel-Haenszel test stratified by randomization factors
  - Mean DLQI subdomain scores at baseline and Week 16 in patients treated with deucravacitinib
- Subgroup analysis by BSA 3%–10% or BSA >10%
  - Adjusted mean change from baseline in DLQI score was assessed using an ANCOVA model with treatment as a fixed effect and the baseline value as a covariate
  - Response rates for achieving DLQI 0/1 were assessed in patients with baseline DLQI ≥2 using an unstratified Chi-squared test
  - Response rates for achieving clinically meaningful improvement in DLQI (≥4-point improvement from baseline) in patients with baseline DLQI ≥4 were compared using an unstratified Chi-squared test
- Missing data were imputed with a modified baseline observation carried forward (mBOCF) approach for continuous variables and nonresponder imputation (NRI) for binary variables
- *P* values are nominal

Results

Patient population

- The study population included 51 patients in the placebo group and 103 in the deucravacitinib group
- Mean (SD) baseline DLQI was 10.2 (5.6) in the placebo group and 11.3 (6.3) in the deucravacitinib group (**Table**)
  - BSA 3%–10% placebo (n = 38): 10.4 (5.7)
  - BSA 3%–10% deucravacitinib (n = 70): 11.0 (6.3)
  - BSA >10% placebo (n = 13): 9.5 (5.5)
  - BSA >10% deucravacitinib (n = 33): 12.1 (6.4)

Table. Demographics and baseline clinical characteristics

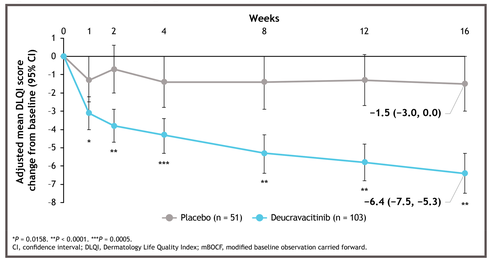
Characteristic	Overall population		BSA 3%–10% subgroup		BSA >10% subgroup	
	Placebo (n = 51)	Deucravacitinib (n = 103)	Placebo (n = 38)	Deucravacitinib (n = 70)	Placebo (n = 13)	Deucravacitinib (n = 33)
Age, years, mean (SD)	43.2 (13.1)	42.8 (15.7)	41.8 (13.1)	42.0 (15.2)	47.5 (12.5)	44.3 (16.9)
Sex, female, n (%)	20 (39.2)	45 (43.7)	18 (47.4)	33 (47.1)	2 (15.4)	12 (36.4)
Race, White, n (%)	47 (92.2)	93 (90.3)	36 (94.7)	64 (91.4)	11 (84.6)	29 (87.9)
Weight, kg, mean (SD)	88.2 (27.6)	89.3 (23.8)	86.3 (24.3)	88.7 (25.0)	93.8 (36.2)	90.6 (21.3)
PSSI, mean (SD)	32.2 (13.7)	33.5 (12.5)	32.4 (13.8)	32.1 (11.8)	31.5 (14.0)	36.5 (13.7)
SSA, mean (SD)	53.0 (24.0)	57.6 (23.1)	54.4 (24.4)	53.8 (22.5)	48.8 (23.0)	65.6 (22.7)
ss-PGA, n (%)						
3	32 (62.7)	76 (73.8)	23 (60.5)	56 (80.0)	9 (69.2)	20 (60.6)
4	19 (37.3)	27 (26.2)	15 (39.5)	14 (20.0)	4 (30.8)	13 (39.4)
BSA, %, mean (SD)	10.0 (8.1)	10.5 (9.6)	6.1 (2.1)	5.8 (2.0)	21.5 (8.1)	20.5 (11.5)
PASI, mean (SD)	9.4 (5.6)	10.2 (6.7)	7.0 (3.1)	6.9 (3.1)	16.5 (5.1)	17.4 (6.6)
sPGA, n (%)						
2	4 (7.8)	7 (6.8)	4 (10.5)	6 (8.6)	0	1 (3.0)
3	42 (82.4)	81 (78.6)	31 (81.6)	56 (80.0)	11 (84.6)	25 (75.8)
4	5 (9.8)	15 (14.6)	3 (7.9)	8 (11.4)	2 (15.4)	7 (21.2)
DLQI, mean (SD)	10.2 (5.6)	11.3 (6.3)	10.4 (5.7)	11.0 (6.3)	9.5 (5.5)	12.1 (6.4)
Scalp-specific itch NRS, mean (SD)	6.4 (1.8)	6.4 (2.3)	6.4 (1.8)	6.3 (2.4)	6.5 (2.0)	6.5 (2.0)
Whole-body itch NRS, mean (SD)	5.8 (2.4)	5.8 (2.8)	5.4 (2.2)	5.2 (2.9)	7.1 (2.5)	7.0 (2.4)

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; ss-PGA, scalp-specific Physician Global Assessment; SSA, scalp surface area.

Overall analysis

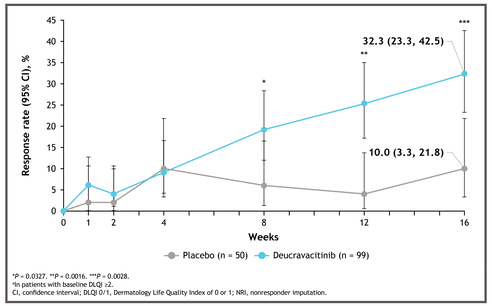
- At Week 16, adjusted mean (95% CI [confidence interval]) change from baseline in DLQI was greater in patients receiving deucravacitinib (−6.4 [−7.5, −5.3]) vs placebo (−1.5 [−3.0, 0.0]; *P* < 0.0001; **Figure 1**)
- At Week 16, DLQI 0/1 response rates (95% CI) were greater for patients receiving deucravacitinib (32.3% [23.3, 42.5]) vs placebo (10.0% [3.3, 21.8]; *P* = 0.0028; **Figure 2**)
- At Week 16, response rates (95% CI) for achieving clinically meaningful improvement in DLQI were greater in patients receiving deucravacitinib (69.5% [59.2, 78.5] vs placebo (29.8% [17.3, 44.9]; *P* < 0.0001; **Figure 3**)
- Patients receiving deucravacitinib reported improvement from baseline in each DLQI subdomain (**Figure 4**)

Figure 1. Mean DLQI change from baseline, overall population (mBOCF)



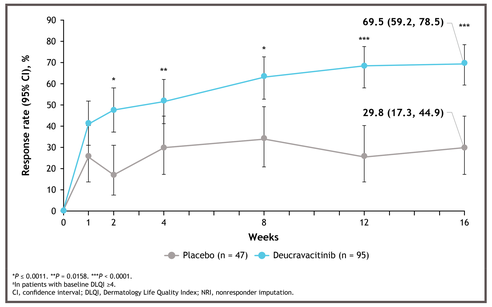
*P = 0.0158. **P < 0.0001. ***P = 0.0005.
CI, confidence interval; DLQI, Dermatology Life Quality Index; mBOCF, modified baseline observation carried forward.

Figure 2. DLQI 0/1 response rate, overall population[a] (NRI)



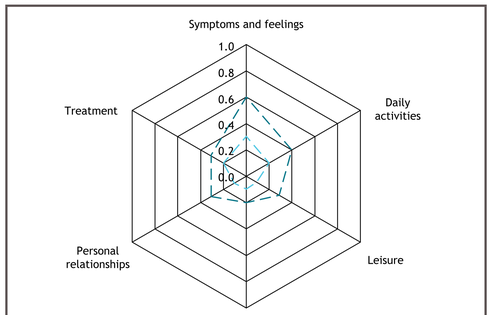
*P = 0.0327. **P = 0.0016. ***P = 0.0028.
[a]In patients with baseline DLQI ≥2.
CI, confidence interval; DLQI 0/1, Dermatology Life Quality Index of 0 or 1; NRI, nonresponder imputation.

Figure 3. DLQI MCT (≥4-point reduction from baseline) response rates,[a] overall population (NRI)



*P ≤ 0.0011. **P = 0.0158. ***P < 0.0001.
[a]In patients with baseline DLQI ≥4.
CI, confidence interval; DLQI, Dermatology Life Quality Index; NRI, nonresponder imputation.

Figure 4. DLQI subdomain scores[a] at baseline and Week 16 in patients treated with deucravacitinib

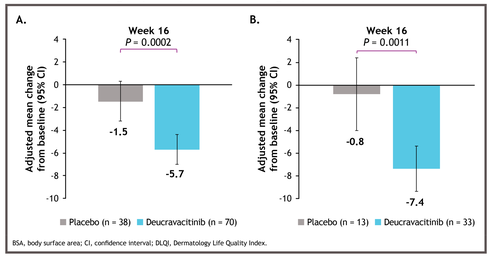


[a]The scale was unified from 0-1 to compare scores across the DLQI subdomains. Scores for the symptoms and feelings, daily activities, leisure, and personal relationships domains were divided by 6 (the maximum possible score), while scores for the work or school performance and treatment domains were divided by 3 (the maximum possible score).
DLQI, Dermatology Life Quality Index.

Subgroup analysis by BSA 3%–10% or BSA >10%

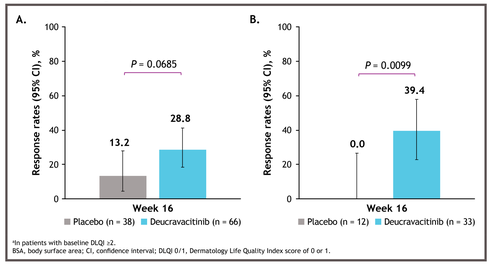
- At Week 16, adjusted mean (95% CI) change from baseline in DLQI was greater in patients receiving deucravacitinib vs placebo in each BSA subgroup
  - BSA 3%–10%: −5.7 (−7.0, −4.4) vs −1.5 (−3.2, 0.3); *P* = 0.0002 (**Figure 5A**)
  - BSA >10%: −7.4 (−9.4, −5.4) vs −0.8 (−4.0, 2.4); *P* = 0.0011 (**Figure 5B**)
- At Week 16, DLQI 0/1 response rates (95% CI) in patients receiving deucravacitinib vs placebo were numerically greater in the BSA 3%–10% subgroup and significantly greater in the BSA >10% subgroup
  - BSA 3%–10%: 28.8% (18.3, 41.3) vs 13.2% (4.4, 28.1); *P* = 0.0685 (**Figure 6A**)
  - BSA >10%: 39.4% (22.9, 57.9) vs 0.0 (0.0, 26.5); *P* = 0.0099 (**Figure 6B**)
- At Week 16, response rates (95% CI) for achieving clinically meaningful improvement in DLQI were greater for patients receiving deucravacitinib vs placebo in each BSA subgroup
  - BSA 3%–10%: 66.1% (53.0, 77.7) vs 33.3% (18.6, 51.0); *P* = 0.0017 (**Figure 7A**)
  - BSA >10%: 75.8% (57.7, 88.9) vs 18.2% (2.3, 51.8); *P* = 0.0007 (**Figure 7B**)

Figure 5. Adjusted mean DLQI change from baseline at Week 16 in the (A) BSA 3%–10% subgroup and (B) BSA >10% subgroup



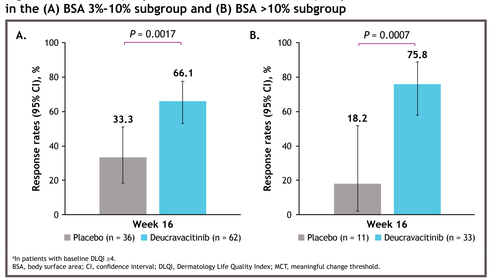
BSA, body surface area; CI, confidence interval; DLQI, Dermatology Life Quality Index.

Figure 6. DLQI 0/1 response rates[a] at Week 16 in the (A) BSA 3%–10% subgroup and (B) BSA >10% subgroup



[a]In patients with baseline DLQI ≥2.
BSA, body surface area; CI, confidence interval; DLQI 0/1, Dermatology Life Quality Index score of 0 or 1.

Figure 7. DLQI MCT (≥4-point reduction from baseline) response rates[a] at Week 16 in the (A) BSA 3%–10% subgroup and (B) BSA >10% subgroup



[a]In patients with baseline DLQI ≥4.
BSA, body surface area; CI, confidence interval; DLQI, Dermatology Life Quality Index; MCT, meaningful change threshold.

Conclusions

- Patients with moderate to severe scalp psoriasis receiving deucravacitinib reported greater improvements in skin-related QoL than those receiving placebo
  - Greater DLQI change from baseline was reported from Week 1 with deucravacitinib than with placebo
  - Greater proportions of patients receiving deucravacitinib reported no impact of psoriasis on QoL by Week 16, with higher DLQI 0/1 response rates observed from Week 8 in the deucravacitinib group
  - Patients receiving deucravacitinib experienced improvement from baseline in each DLQI subdomain
- Improvements in patient QoL with deucravacitinib were also observed in patients with less extensive overall psoriasis (BSA 3%–10%), as well as in those with BSA >10%
  - In both BSA subgroups, response rates for clinically meaningful improvement in QoL at Week 16 were greater in the deucravacitinib group than in the placebo group

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