Effect of deucravacitinib on quality of life in participants with plaque psoriasis in a community setting: 52-week data from the phase 4 ARTISTYK study

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Synopsis

- Deucravacitinib is a first-in-class, oral, selective, tyrosine kinase 2 inhibitor approved in multiple countries for the treatment of adults with moderate to severe plaque psoriasis[1-4]
- Deucravacitinib has demonstrated robust long-term efficacy and a consistent safety profile through 5 years of treatment in two global phase 3 studies in patients with moderate to severe plaque psoriasis[5-7]
- ARTISTYK (NCT05701995), a phase 4, placebo-controlled study evaluated the effect of deucravacitinib on quality of life (QoL) in patients with moderate to severe plaque psoriasis, a wide range of body surface area (BSA) involvement, and largely or extremely impaired QoL, who were treated in the community setting
  - At Week 16, deucravacitinib significantly improved QoL in this population, meeting the primary and all key secondary endpoints[8]

Objective

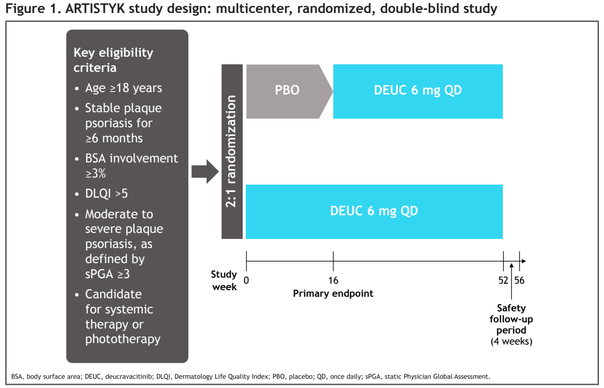
- To report ARTISTYK Week 52 patient-reported outcomes, and clinical efficacy and safety results

Methods

Study design

- Patients aged ≥18 years with ≥3% BSA involvement, static Physician Global Assessment (sPGA) score ≥3, and Dermatology Life Quality Index (DLQI) score >5 were randomized 2:1 to receive deucravacitinib or placebo for 16 weeks (**Figure 1**)
  - Randomization was stratified by body weight (≥90 kg vs <90 kg) and baseline BSA (3%-10% vs >10%)
- At Week 16, patients randomized to placebo switched to deucravacitinib; patients randomized to deucravacitinib continued treatment through Week 52
- This was a 52-week intervention study with an additional 4-week safety follow-up

Figure 1. ARTISTYK study design: multicenter, randomized, double-blind study



BSA, body surface area; DEUC, deucravacitinib; DLQI, Dermatology Life Quality Index; PBO, placebo; QD, once daily; sPGA, static Physician Global Assessment.

Primary endpoint (Week 16)

- Response rates for DLQI 0/1
  - DLQI 0/1 indicated no impact of disease on patient QoL

Key secondary endpoints (Week 16)

- Response rates for achieving DLQI meaningful change threshold (MCT; ≥4-point reduction from baseline)
- Change from baseline in whole-body itch numeric rating scale (NRS) score
- Response rates for sPGA 0/1 in subpopulation of patients with sPGA ≥3 at baseline
  - Proportion of patients achieving a score of 0 (clear) or 1 (almost clear) with at least a 2-point reduction from baseline at Week 16

Exploratory endpoints (up to Week 52)

- DLQI score 0/1
- ≥4-point reduction from baseline in DLQI
- Change from baseline in whole-body itch NRS score
- sPGA 0/1 with at least a 2-point reduction from baseline in subpopulation of patients with sPGA ≥3 at baseline

Safety endpoints

- Treatment-emergent adverse events (TEAEs), serious TEAEs, and deaths

Statistical analysis

- The analysis population included all randomized patients (full analysis set)
- The final efficacy analysis was performed after all participants completed the final safety follow-up visit at Week 56 or post-discontinuation follow-up visit
- The data analysis of the study followed the estimand framework, where intercurrent events (ICEs; eg, early discontinuation or use of protocol-prohibited therapy) were handled before missing data imputation
- For binary efficacy endpoints, nonresponder imputation (NRI) was used for patients with missing data
- For continuous endpoints, missing data were imputed using modified baseline observation carried forward (mBOCF)
- Endpoints were analyzed descriptively after Week 16 (ie, Week 20 through Week 52)
- For binary endpoints, 95% CIs were obtained using the Clopper-Pearson method

Results

Patient disposition

- A total of 180 patients were randomized (placebo: n = 60; deucravacitinib: n = 120) (**Table 1**)
- Of the 178 treated patients (deucravacitinib = 119; placebo = 59), 103 and 49 continued treatment after Week 16, with placebo patients switching to active treatment
- More than 80% of patients in each group completed treatment through Week 52
- Loss to follow-up, patient withdrawal from the trial, and lack of efficacy were the most common reasons for treatment discontinuation in patients who received continuous deucravacitinib

Table 1. End of treatment period status summary Week 0 through Week 52 (as-treated population)

Parameter, n (%)	Weeks 0-16		Weeks 16-52	
	PBO (n = 60)	DEUC (n = 120)	PBO-DEUC (n = 49)	DEUC-DEUC (n = 103)
Randomized and treated	59 (98.3)	119 (99.2)	49 (100.0)	103 (100.0)[a]
Completed treatment period	49 (81.7)	104 (86.7)	41 (83.7)	87 (84.5)
Did not complete treatment period	10 (16.7)	15 (12.5)	8 (16.3)	16 (15.5)
Reason for not completing treatment				
Withdrawal by patient	4 (6.7)	8 (6.7)	2 (4.1)	5 (4.9)
Lost to follow-up	3 (5.0)	2 (1.7)	4 (8.2)	5 (4.9)
Lack of efficacy	-	-	1 (2.0)	4 (3.9)
Adverse event	1 (1.7)	3 (2.5)	1 (2.0)	0
Other	1 (1.7)	1 (0.8)	0	1 (1.0)
Death	0	1 (1.7)[b]	0	1 (1.0)[c]

[a]One patient in the DEUC arm completed period 1 but did not enter period 2 due to lack of time for study visits. [b]The cause of death, suspected illicit drug overdose, was not treatment related. [c]The cause of death, pneumonia and congestive heart failure, was not treatment related. DEUC, deucravacitinib; PBO, placebo.

Patient demographics and baseline clinical characteristics

- In the overall population, the mean (standard deviation [SD]) age was 48.6 (14.5) years; 62.2% of patients were male (**Table 2**)

Table 2. Patient demographics and baseline characteristics

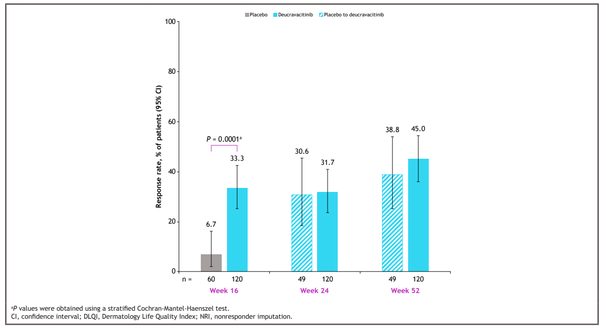
Characteristic	Overall population	
	PBO (n = 60)	DEUC (n = 120)
Age, years, mean (SD)	47.5 (13.6)	49.1 (14.9)
Female, n (%)	20 (33.3)	48 (40.0)
Race, n (%)		
White	50 (83.3)	108 (90.0)
Asian	1 (1.7)	5 (4.2)
Black or African American	6 (10.0)	3 (2.5)
Native Hawaiian or other Pacific Islander	0	1 (0.8)
Other	3 (5.0)	2 (1.7)
Hispanic or Latino ethnicity, n (%)	22 (36.7)	34 (28.3)
Weight, kg, mean (SD)	93.1 (23.1)	96.0 (25.0)
Psoriasis duration, years, mean (SD)	13.9 (9.9)	14.7 (12.6)
DLQI, mean (SD)	14.6 (6.1)	14.4 (6.0)
Whole-body itch NRS, mean (SD)	7.4 (2.2)	7.3 (2.1)
sPGA score, n (%)		
1 (almost clear)	0	2 (1.7)
2 (mild)	10 (16.7)	10 (8.3)
3 (moderate)	44 (73.3)	92 (76.7)
4 (severe)	5 (8.3)	15 (12.5)
BSA involvement, n (%)		
3%-10%	35 (58.3)	73 (60.8)
>10%	24 (40.0)	47 (39.2)
Not reported	1 (1.7)	0
BSA, mean (SD)	14.5 (13.4)	13.5 (13.5)
PASI, mean (SD)	12.3 (8.9)	11.2 (7.4)

BSA, body surface area; DEUC, deucravacitinib; DLQI, Dermatology Life Quality Index; NRS, numeric rating scale; PASI, Psoriasis Area and Severity Index; PBO, placebo; SD, standard deviation; sPGA, static Physician Global Assessment.

Efficacy

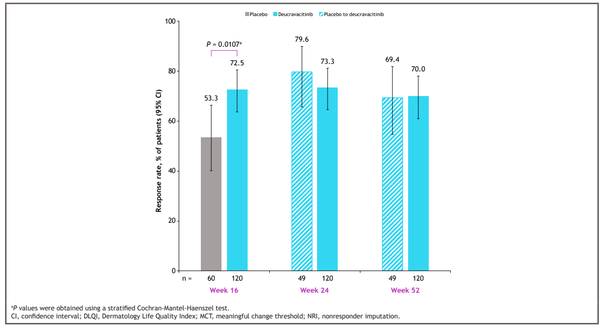
- In patients who continued treatment on deucravacitinib, DLQI 0/1 response rates were maintained through Week 52 across all endpoints (DLQI, DLQI MCT, itch NRS, and sPGA) (**Figures 2-5**)
- After switching from placebo to deucravacitinib, patients achieved Week 52 responses (DLQI 0/1: 38.8%; DLQI MCT: 69.4%; itch NRS: -4.4; sPGA: 42.9%) that were similar to those observed in patients who received continuous deucravacitinib (**Figures 2-5**)

Figure 2. DLQI 0/1 response rates (NRI)



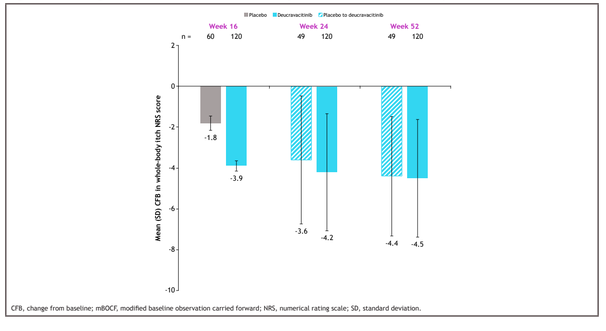
[a]P values were obtained using a stratified Cochran-Mantel-Haenszel test.
CI, confidence interval; DLQI, Dermatology Life Quality Index; NRI, nonresponder imputation.

Figure 3. DLQI MCT (≥4-point reduction) response rates (NRI)



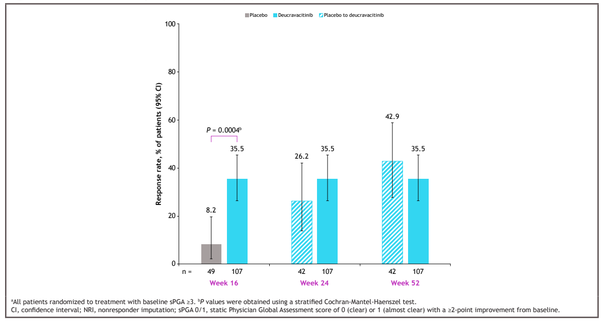
[a]P values were obtained using a stratified Cochran-Mantel-Haenszel test.
CI, confidence interval; DLQI, Dermatology Life Quality Index; MCT, meaningful change threshold; NRI, nonresponder imputation.

Figure 4. Change from baseline in whole-body itch NRS score (mBOCF)



CFB, change from baseline; mBOCF, modified baseline observation carried forward; NRS, numerical rating scale; SD, standard deviation.

Figure 5. sPGA 0/1 response rates (NRI[a])



[a]All patients randomized to treatment with baseline sPGA ≥3. [b]P values were obtained using a stratified Cochran-Mantel-Haenszel test.
CI, confidence interval; NRI, nonresponder imputation; sPGA 0/1, static Physician Global Assessment score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline.

Safety

- The most frequent TEAEs through Week 52 in patients treated with deucravacitinib were COVID-19, acne, and nasopharyngitis; serious TEAEs related to treatment occurred in 1.2% of patients (**Table 3**)

Table 3. Overall safety summary, Weeks 0 to 52

TEAE category, n (%)	PBO (Weeks 0-16) (n = 59)	DEUC (Weeks 0-52)[a] (n = 168)
Deaths	0	2 (1.2)[b]
Serious TEAEs	1 (1.7)	10 (6.0)
Related serious TEAEs	0	2 (1.2)
TEAEs	25 (42.4)	112 (66.7)
Related TEAEs	4 (6.8)	34 (20.2)
Discontinued treatment due to TEAEs	1 (1.7)	3 (1.8)
Most frequent TEAEs (≥5% in the DEUC group) by PT		
COVID-19	2 (3.4)	19 (11.3)
Acne	0	14 (8.3)
Nasopharyngitis	2 (3.4)	13 (7.7)
Upper respiratory tract infection	3 (5.1)	13 (7.7)

[a]Includes PBO-DEUC. [b]One death (suspected illicit drug overdose) occurred during the Week 0-16 period, and 1 death (pneumonia/congestive heart failure) occurred during the Week 16-52 period. Both were assessed as not related to the study treatment by the investigator. Treatment associated with the event is the treatment the patient was taking on the event start date. Patients can be included in both "deucravacitinib" and "placebo" columns as patients completed the placebo-controlled period and were reassigned to DEUC for the open-label period.
DEUC, deucravacitinib; PBO, placebo; PT, preferred term; TEAEs, treatment-emergent adverse events.

Conclusions

- This phase 4 trial included patients spanning a range of BSA involvement and with largely or extremely impaired QoL, treated in a community setting
- Deucravacitinib improved QoL and itch symptoms through Week 52 in these patients with moderate to severe plaque psoriasis
- Safety findings were consistent with previous studies
- These results support the efficacy and safety of once-daily oral deucravacitinib in patients with moderate to severe plaque psoriasis

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