



**Abstract N°: 5390**

**Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK 2) inhibitor, in patients with moderate to severe scalp psoriasis: patient-reported outcomes at Week 16 of a phase 3b/4 multicenter, randomized, double-blinded, placebo-controlled trial (PSORIATYK SCALP)**

Diamant Thaçi<sup>1</sup>, Matthias Augustin<sup>2</sup>, Christopher E. M. Griffiths<sup>3, 4, 5</sup>, Linda Stein Gold<sup>6</sup>, Michael Sebastian<sup>7</sup>, Anne-Bénédicte Duval-Modeste<sup>8</sup>, Andrew Napoli<sup>9</sup>, Eugene Balagula<sup>9</sup>, Priyanka Gaitonde<sup>9</sup>, Brandon Becker<sup>9</sup>, Ying-Ming Jou<sup>9</sup>, Mark Lebwohl<sup>10</sup>

<sup>1</sup>Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, <sup>2</sup>Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, <sup>3</sup>Centre for Dermatological Research, The University of Manchester, <sup>4</sup>Department of Dermatology, King's College Hospital, <sup>5</sup>King's College London, <sup>6</sup>Henry Ford Medical Center, <sup>7</sup>Mahlow Dermatology Practice, <sup>8</sup>Department of Dermatology, Rouen University Hospital, <sup>9</sup>Bristol Myers Squibb, <sup>10</sup>Icahn School of Medicine at Mount Sinai

**Introduction & Objectives:** Deucravacitinib (DEUC), an oral, selective, allosteric tyrosine kinase 2 inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy. PSORIATYK SCALP (NCT05478499), an ongoing 52-week, phase 3b/4 multicenter, randomized, double-blinded, placebo-controlled trial, assesses the efficacy and safety of DEUC in patients with moderate to severe scalp PsO, including those with more limited overall disease. We present patient-reported outcome results at Week 16.

**Materials & Methods:** Patients aged  $\geq 18$  years with scalp-specific Physician Global Assessment scores  $\geq 3$ , scalp surface area involvement  $\geq 20\%$ , Psoriasis Scalp Severity Index scores  $\geq 12$ , and body surface area involvement  $\geq 3\%$  were randomized 1:2 to receive once-daily placebo (PBO) or DEUC for 16 weeks. Randomization stratification factors were previous biologic use for PsO or other inflammatory diseases (yes/no) and body weight ( $\geq 90$  kg or  $< 90$  kg). Key secondary endpoints included Week 16 change from baseline in numeric rating scale (NRS) score for scalp-specific itch (11-point scale from 0 [none] to 10 [worst imaginable], rated over the preceding 24 hours). Exploratory endpoints included Week 16 change from baseline in scalp-specific pain and flaking, and whole-body itch NRS scores, as well as response rates for achieving the minimum clinically important difference (MCID;  $\geq 4$  points) on each NRS measure. For continuous measures, adjusted means and *P*-values (nominal in the case of exploratory endpoints) were determined with an analysis of covariance model using treatment and randomization stratification factors as fixed effects and the baseline value as a covariate. *P*-values for binary measures were generated using a stratified Cochran-Mantel-Haenszel test.

**Results:** The full analysis set included 154 patients (PBO, *n*=51; DEUC, *n*=103). Mean baseline scores for each NRS measure are presented in Table 1. At Week 16, patients receiving DEUC reported significantly greater mean change from baseline vs PBO in scalp-specific itch NRS score ( $-3.2$  vs  $-0.7$ , respectively;  $P < 0.0001$ ). Greater improvement was also reported by patients receiving DEUC vs PBO, respectively, for scalp-specific pain ( $-2.1$  vs  $-0.1$ ), flaking ( $-3.9$  vs  $-1.0$ ), and whole-body itch ( $-2.9$  vs  $-0.4$ ) NRS scores (all,  $P < 0.0001$ ; Figure 1). Patients receiving DEUC vs PBO had higher response rates, respectively, for achieving the MCID for scalp-specific itch (41.7% vs 9.8%;  $P < 0.0001$ ), pain (26.2% vs 11.8%;  $P = 0.0372$ ), and flaking (53.4% vs 19.6%;  $P < 0.0001$ ), and for whole-body itch (39.8% vs 13.7%;  $P = 0.0009$ ; Figure 2) NRS scores.

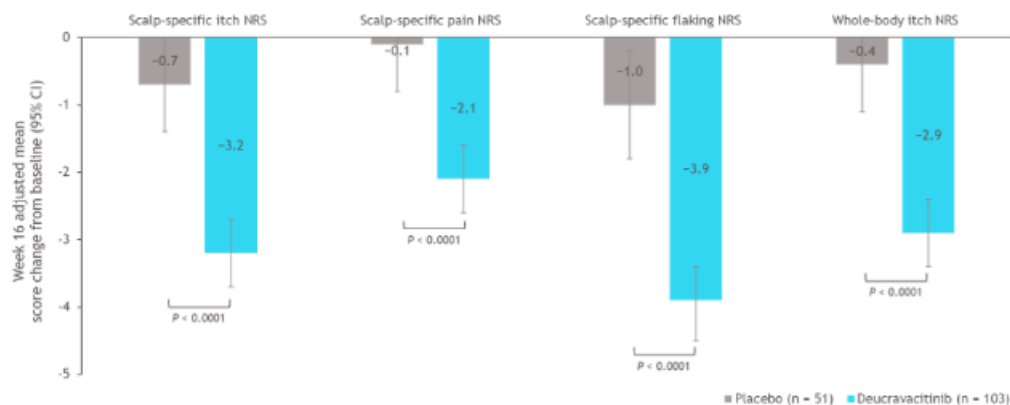
**Conclusion:** In this scalp-specific PsO trial, DEUC was efficacious\*\* and resulted in significantly greater improvement in scalp-specific symptoms of itch, pain, and flaking, and in whole-body itch. DEUC was also associated with clinically meaningful improvement in each of these NRS measures.

**Table 1. Mean baseline numeric rating scale scores**

NRS score, mean (SD)	Placebo (n = 51)	Deucravacitinib (n = 103)
Scalp-specific itch	6.4 (1.8)	6.4 (2.3)
Scalp specific pain	4.5 (3.0)	4.0 (2.8)
Scalp-specific flaking	6.7 (2.2)	7.0 (2.3)
Whole-body itch	5.8 (2.4)	5.8 (2.8)

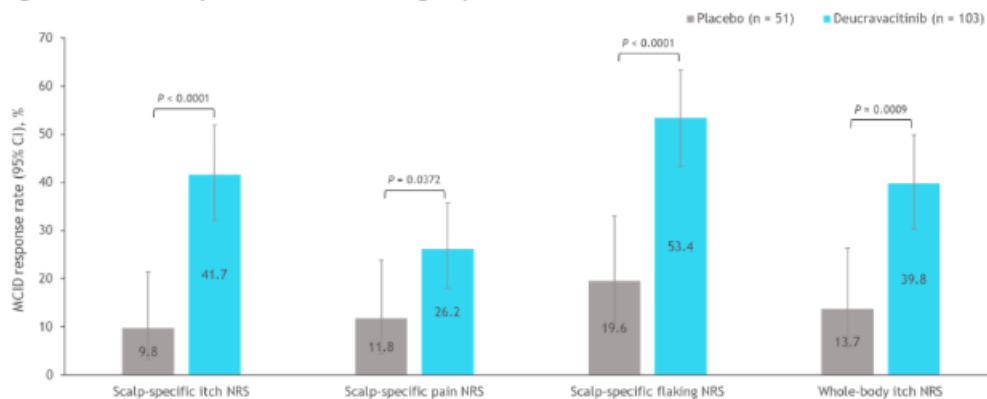
NRS, numeric rating scale; SD, standard deviation.

**Figure 1. Week 16 adjusted mean score change from baseline**



NRS, numeric rating scale.

**Figure 2. Week 16 response rates for achieving ≥4-point MCID**



MCID, minimum clinically important difference; NRS, numeric rating scale.

