Long-term safety and efficacy of delgocitinib cream for up to 36 weeks in adults with chronic hand eczema: results of the phase 3 open-label extension DELTA-3 trial

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Introduction/Background: In patients with moderate to severe Chronic Hand Eczema (CHE), delgocitinib cream, a topical pan-Janus kinase inhibitor, was well tolerated and demonstrated significant improvement in all efficacy endpoints in DELTA-1 and -2.

Objectives: The objectives of this study were to evaluate the long-term safety and efficacy of twice-daily applications of delgocitinib cream 20 mg/g as needed for up to 36 weeks in adults with CHE in the Phase 3 open-label DELTA-3 trial (NCT04949841), an
extension trial of the 16-week DELTA-1 (NCT04871711) and DELTA-2 (NCT04872101) trials.

**Methods:** In DELTA-3, subjects who completed the 16-week (W) treatment period in DELTA-1 and DELTA-2 were treated on an as-needed basis with twice-daily delgocitinib cream 20 mg/g for 36 weeks (n=801). Subjects with Investigator's Global Assessment for CHE (IGA-CHE) ≥2 received delgocitinib cream until symptoms resolved (i.e., IGA-CHE 0/1 [clear/almost clear]). Primary endpoint was number of treatment-emergent adverse events (TEAEs). Key secondary endpoints were IGA-CHE 0/1 and ≥75%/≥90% improvement in Hand Eczema Severity Index (HECSI-75/90) scores; Hand Eczema Symptom eDiary captured patient-reported worst severity of itch/pain over the past 24 hours.

**Results:** No safety concerns were identified during delgocitinib cream treatment in DELTA-1 (n=325; R=305.4; PYO=100.9), DELTA-2 (n=313; R=280.6; PYO=95.9) and DELTA-3 (n=801; R=231.1; PYO=535.7). In DELTA-3, the most frequent TEAEs were COVID-19 and nasopharyngitis. In DELTA-3, IGA-CHE 0/1, HECSI-75, HECSI-90 and ≥4-point itch/pain reduction were maintained from baseline (24.6%, 51.8%, 31.8%, and 50.6%/51.9%, respectively) to W36 (30.0%, 58.6%, 36.6%, and 52.4%/55.4%, respectively) among delgocitinib cream-treated subjects in the parent trials. Among those treated with cream vehicle in parent trials, response rates improved from baseline (9.1%, 23.7%, 12.0%, and 26.3%/32.3%, respectively) to W36 (29.5%, 51.5%, 35.7%, and 41.3%/43.3%, respectively).
**Conclusions:** Overall, with delgocitinib cream 20 mg/g treatment no safety concerns were identified and efficacy further improved, supporting the benefit of long-term as-needed use of delgocitinib cream in patients with moderate to severe CHE.

**Keywords:** chronic hand eczema, delgocitinib, JAK

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