Efficacy and safety of delgocitinib cream in adults with moderate to severe chronic hand eczema: pooled results of the phase 3 DELTA-1 and -2 trials

Robert Bissonnette,1 Margitta Worm,2 Richard B Warren,3,4 Tove Agner,5 Melinda Gooderham,6,7 Marie Louise Schuttelaar,8 Keith Baranowski,9 Ursula Plohberger,9 Laura Soerensen,9 Sibylle Schliemann10

1Innovaderm Research, Montreal, Quebec, CA; 2Division of Allergy and Immunology, Department of Dermatology, Venerology and Allergy, Charité Universitätsmedizin Berlin, DE; 3Dermatology Centre, Northern Care Alliance NHS Foundation Trust; 4NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, UK; 5Department of Dermatology, Bispebjerg Hospital, University of Copenhagen, Copenhagen, DK; 6Department of Dermatology, Queens University, Peterborough, Ontario, CA; 7SKiN Centre for Dermatology and Probity Medical Research, Peterborough, Ontario, CA; 8University Medical Centre Groningen, University of Groningen, NL; 9LEO Pharma A/S, Ballerup, DK; 10Department of Dermatology, University Hospital Jena, Jena, Germany

Introduction/Background: Chronic Hand Eczema (CHE) is a frequent inflammatory skin disease associated with pain, pruritus, and significant occupational, functional, social, and psychological burden. Delgocitinib is a topical pan-JAK inhibitor which showed a dose-dependent efficacy in adults with CHE in a Phase 2b trial.

Objectives: The objectives of this analysis were to study (1) the efficacy of twice-daily applications of delgocitinib cream 20 mg/g, as assessed by Investigator's Global Assessment for CHE treatment success (primary outcome), and the secondary outcomes ≥75%/≥90% improvement in Hand Eczema Severity Index and ≥4-point
improvement in the Dermatology Life Quality Index, and (2) the safety of twice-daily applications of delgocitinib cream 20 mg/g compared with cream vehicle in the treatment of adults with moderate to severe CHE in a pooled analysis of the DELTA-1 and DELTA-2 trials.

**Methods:** In the Phase 3 DELTA-1 (NCT04871711) and DELTA-2 (NCT04872101) trials, adults with moderate to severe CHE were randomized 2:1 to twice-daily delgocitinib cream 20 mg/g or cream vehicle for 16 weeks. The primary endpoint was the Investigator's Global Assessment for CHE (IGA-CHE) treatment success at Week 16, defined as IGA-CHE score of 0/1 (clear/almost clear, i.e., no/barely perceptible erythema and no other signs), with a ≥2-step improvement from baseline. Key secondary endpoints included ≥75%/≥90% improvement in Hand Eczema Severity Index (HECSI-75/90) and ≥4-point improvement in the Dermatology Life Quality Index (DLQI). This DELTA-1 and -2 pooled analysis included 639 patients treated with delgocitinib cream and 321 with cream vehicle.

**Results:** At Week 16, a significantly greater proportion of delgocitinib-treated patients, versus cream vehicle, achieved IGA-CHE treatment success (24.3% vs. 8.4%; \(P<0.001\)), HECSI-75 (49.4% vs. 20.9%; \(P<0.001\)), HECSI-90 (30.3% vs. 10.6%; \(P<0.001\)), and DLQI ≥4-point improvement (73.3% vs. 47.8%; \(P<0.001\)). Most frequent adverse events (occurring in ≥5% of patients) were COVID-19, nasopharyngitis, and headache with similar rates in both treatment groups.

**Conclusions:** In the DELTA-1 and -2 pooled analysis, delgocitinib cream twice-daily confirmed its clinical efficacy in patient- and clinician-reported efficacy outcomes versus
cream vehicle in adult CHE patients and suggests an innovative treatment option in this often difficult-to-treat patient population.

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

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