EADV CONGRESS
AMSTERDAM 25-28 SEPTEMBER 2024
EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 3804

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 Sørensen[9], Sibylle Schliemann[10]

[1]Innovaderm Research, Montreal, Canada, [2]Division of Allergy and Immunology, Department of Dermatology, Venerology and Allergy, Charité Universitätsmedizin Berlin, Berlin, Germany, [3]Dermatology Centre, Northern Care Alliance NHS Foundation Trust, Manchester, United Kingdom, [4]NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Science Centre, Manchester, United Kingdom, [5]Department of Dermatology, Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark, [6]Department of Dermatology, Queens University, Kingston, Canada, [7]SKiN Centre for Dermatology and Probity Medical Research, Peterborough, Canada, [8]University Medical Centre Groningen, University of Groningen, Groningen, Netherlands, [9]LEO Pharma A/S, Ballerup, Denmark, [10]Department of Dermatology, University Hospital Jena, Jena, Germany

Introduction & Objectives: 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. The objectives of this analysis were to study (1) the efficacy, as assessed by Investigator's Global Assessment for CHE (IGA-CHE) treatment success (primary outcome), and the secondary outcomes ≥75%/≥90% improvement in Hand Eczema Severity Index (HECSI-75/90) and ≥4-point improvement in the Dermatology Life Quality Index (DLQI), 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.

Materials & 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 IGA-CHE treatment success at Week 16, defined as IGA-CHE score of 0/1 (clear / almost clear, i.e., no or barely perceptible erythema and no other signs), with a ≥2-step improvement from baseline. Key secondary endpoints included HECSI-75/90 and ≥4-point improvement in the 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.

Conclusion: 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.