

A new ERA for global Dermatology 10 - 15 JUNE 2019 MILAN, ITALY

ATOPIC ECZEMA/DERMATITIS

EFFICACIOUS AND WELL-TOLERATED TREATMENT OF CHRONIC HAND ECZEMA AND RELATED ITCH WITH TOPICAL DELGOCITINIB

M Worm (1) - A Bauer (2) - P Elsner (3) - V Mahler (4) - S Molin (5) - T Nielsen (6)

Allergy Center Charité, Department Of Dermatology, Allergology And Venereology, Berlin, Germany (1) - University Hospital Carl Gustav Carus, Department Of Dermatology, Dresden, Germany (2) - Friedrich Schiller University Jena, Clinic Of Dermatology And Allergology, Jena, Germany (3) - University Hospital Erlangen, Department Of Dermatology, Erlangen, Germany (4) - Queen's University, Department Of Medicine, Kingston, Canada (5) - Leo Pharma A/s, Biostatistics, Ballerup, Denmark (6)

Background: Chronic hand eczema (CHE) is an inflammatory skin disease with multifactorial etiology (eg, irritant or allergic contact dermatitis or atopic hand dermatitis). Itch is one of the most significant symptoms experienced by patients with CHE. Although the molecular mechanisms underlying CHE are not fully understood, cytokines and the JAK-STAT signalling pathway have been implicated in the pathophysiology. Topical delgocitinib is a novel, pan-JAK inhibitor that blocks several cytokine-mediated signalling cascades, thereby inhibiting inflammation.

Objectives: To evaluate the efficacy/safety of delgocitinib ointment over 8 weeks in adults with CHE.

Methods: In this multicenter, randomized, double-blind, Phase 2a proof-of-concept study (NCT02664805), trial patients aged 18-65 years were randomized 2:1 to delgocitinib ointment (30 mg/g) or vehicle ointment applied twice daily. Efficacy was assessed at Week 8 using Physician's Global Assessment of Disease Severity (PGA), which defined treatment success as achieving 'clear/almost clear' skin with \geq 2-step improvement from baseline. A post-hoc responder analysis of a \geq 4 numerical rating scale (NRS) score change from baseline to Week 8 in itch, among patients with baseline NRS score of \geq 4, was explored.

Results: 91 patients were randomized. Treatment success by PGA was achieved in 45.7% of delgocitinib patients versus 14.9% in the vehicle group (OR=4.89, 95% CI 1.49-16.09; P=0.009); success rates for delgocitinib did not reach a plateau. In 50 patients with a baseline NRS itch score ≥4, a reduction of ≥4 was observed in a greater proportion of delgocitinib than vehicle patients at Week 8 (OR=4.01, 95% CI 1.14-14.09; P=0.0287). Overall, 34 (56.7%) delgocitinib patients and 14 (45.2%) vehicle patients experienced adverse events (AEs), most of which were of mild intensity; 3 (5.0%) and 8 (25.8%) patients











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experienced treatment-related AEs, respectively.

Conclusions: Delgocitinib ointment is an efficacious and well-tolerated treatment for CHE and decreases related itch in affected patients.





