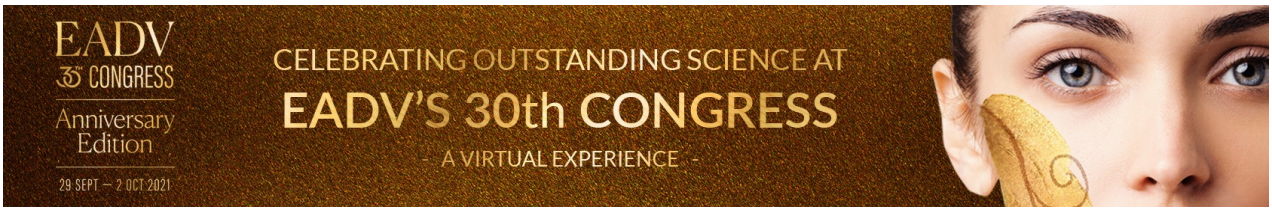

Abstract N°: 725

Title: The topical pan-JAK inhibitor delgocitinib in a cream formulation reduces itch and pain in chronic hand eczema

Andrea Bauer[1], Jacob Thyssen[2], Timo Buhl[3], Thor Schütt Svane Nielsen[4], Lotte Seiding Larsen[5], Anne Birk Oesterskov[5], Tove Agner[6]

[1] Technical University Dresden, University Hospital Carl Gustav Carus, Dresden, Germany, [2] University Of Copenhagen, Gentofte Hospital, Hellerup, Denmark, [3] Department Of Dermatology, Venereology And Allergology, University Medical Center Göttingen,, Gottingen, Germany, [4] Biostatistics, Leo Pharma A/S, Ballerup, Denmark, [5] Leo Pharma A/S, Ballerup, Denmark, [6] Dept. Of Dermatology, Bispebjerg University Hospital, Copenhagen Nv, Denmark

Introduction

Chronic hand eczema (CHE) is a multifactorial inflammatory skin disorder associated with high socio-economical and psychological burden. Hand eczema is characterized by signs of erythema, vesicles, papules, scaling, fissures, hyperkeratosis, and symptoms of itch and pain. There is a need for additional, efficacious, safe, non-steroidal treatments developed specifically for CHE. Twice-daily application of delgocitinib cream for 16 weeks was efficacious and had a favourable safety profile in adults with mild to severe CHE treated in a phase 2b dose-ranging trial. From this trial, we here report the effect of delgocitinib cream in reducing severity of itch and pain in patients with mild to severe CHE, using the Hand Eczema Symptom Diary (HESD); an electronic symptom diary.

Material and Methods

A total of 258 adult patients with mild to severe CHE were randomized 1:1:1:1:1 to delgocitinib cream 1, 3, 8, 20 mg/g, or vehicle cream twice-daily for 16 weeks in a phase 2b dose-ranging trial (NCT03683719). The eligibility criteria included mild to severe disease according to the Investigator's Global Assessment for CHE (IGA-CHE) and a recent history of inadequate response or contraindication to topical corticosteroids. Patients assessed the worst severity of itch and pain for the past 24 hours using an 11-point numeric rating scale (NRS) from 0 indicating 'no itch'/'no pain' to 10 indicating 'severe itch'/'severe pain' daily captured through HESD. The weekly average itch and pain NRS scores from baseline to Week 16 for all patients were analysed. In addition, the proportion of responders, defined as patients with a reduction in itch or pain NRS score [*post-hoc*] (weekly average) of ≥4 points from baseline among patients with baseline itch/pain NRS score ≥4 points, were analysed.

Results

The changes in itch and pain NRS scores from baseline to Week 16 were greater in the delgocitinib 1, 8, and 20 mg/g dose groups for itch, and for all active delgocitinib dose groups for pain compared to vehicle ($p<0.05$, **Table 1**). For the delgocitinib 20 mg/g dose group, a treatment effect for itch and pain NRS was already present at Day 3 and Day 5, respectively (*post-hoc*; $p<0.05$), indicating an early onset of action in the highest dose group. Additionally, there was a higher proportion of itch and pain NRS responders in all active delgocitinib dose groups compared to the vehicle group at Week 16 (**Table 1**).

Discussion

Delgocitinib cream twice-daily for 16 weeks reduced itch and pain NRS severity compared with vehicle in patients

with mild to severe CHE (1, 8, and 20 mg/g). An early onset of treatment effect on itch and pain NRS was observed as early as Day 3 and Day 5, respectively, for the highest dose group (20 mg/g).