

## Association Between an Itch-Free State in Atopic Dermatitis Treated with Ruxolitinib Cream and Systemic Inflammatory Mediators

S Owens, K Sun, H Jones, M Kuligowski, MD Howell, Incyte Research Institute, Wilmington, DE

**Background:** Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by significant pruritus that can lead to an impaired quality of life and sleep disturbances. Ruxolitinib cream is a selective Janus kinase (JAK)1/2 inhibitor that previously demonstrated a significant therapeutic benefit in a Phase 2b trial (NCT03011892) of patients with mild to moderate AD.

**Objective:** To compare the proportions of ruxolitinib cream treated patients achieving an itch-free state versus vehicle, and to evaluate the relationship between achieving an itch-free state and circulating inflammatory mediators.

**Methods:** Data and sera from 89 participants in the intent-to-treat population from the phase 2b clinical trial of ruxolitinib cream in AD were analyzed. Patient-reported itch was assessed daily using a Numerical Rating Scale (NRS; 0 to 10) and an itch-free state was defined as an NRS score of 0/1 at week 8. Sera were analyzed for broad proteomic changes using the OLINK proximity extension assay. A two-sample t-test assessed unadjusted differences in change between participants achieving itch resolution versus those who did not. Significance was conferred at  $p < 0.05$ .

**Results:** At week 8, the proportion of itch-free patients included in this analysis was 7.1% for vehicle, and 14.3% for 0.15% once daily (QD), 29.4% for 0.5% QD, 27.3% for 1.5% QD, and 53.3% for 1.5% twice daily ruxolitinib cream. Expression of 1012 proteins was evaluated for each participant and comparisons were made between itch-free and non-itch-free participants. A total of 53 proteins were more down-regulated in itch-free participants ( $n = 22$ ) compared to those with NRS itch scores  $>1$  at week 8 ( $n = 67$ ), while 4 were more up-regulated.

**Conclusion:** Reduced pruritus following treatment with ruxolitinib cream correlated with regulation of selected inflammatory mediators.

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