Rapid, substantial, and sustained reduction of itch in adults with atopic dermatitis applying ruxolitinib cream

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Background: Atopic dermatitis (AD) is a chronic, recurring, highly pruritic inflammatory skin disease. Ruxolitinib cream is approved in the US for the treatment of mild to moderate AD in patients ≥12 years old. In pivotal phase 3 trials (TRuE-AD1/TRuE-AD2) in adolescents and adults with AD, ruxolitinib cream 1.5% demonstrated significant improvement in itch versus vehicle, as early as 12 hours after initial application.

Objective: A phase 2, open-label, single-site study (SCRATCH-AD/NCT04839380) to further understand the short-term clinical benefits of ruxolitinib cream to control pruritus and reduce disease severity in AD.

Methods: Participants were aged 18–65 years with AD for ≥6 months, chronic itch related to AD for ≥3 months, 1%–20% affected body surface area (BSA), Investigator's Global Assessment (IGA) of ≥2, and a peak pruritus numerical rating scale (PP-NRS) score ≥4 at baseline. Participants applied ruxolitinib cream 1.5% twice daily to all baseline lesions and any new lesions for 28 days. The primary endpoint was change from baseline in PP-NRS at Day 2 (24 hours after first ruxolitinib cream application). Secondary endpoints included change from baseline in modified PP-NRS (mPP-NRS; current itch intensity) at 15 and 30 minutes and 1, 2, 4, 6, and 12 hours post-treatment on Day 1, and change from baseline in PP-NRS from Days 3–29, change from baseline in IGA at Days 8, 15, and 29, and safety.

Results: The primary analysis included 46 participants (modified intent-to-treat population). Median age (range) was 30 (18–64) years; 69.6% were female, and 89.1% were White. At baseline, mean (SD) affected BSA was 9.5% (4.94%), mean (SD) 7-day average PP-NRS score was 6.7 (1.36), mean (SD) pre-treatment mPP-NRS score was 6.4 (1.72), and 89.1% had an IGA score of 3. The mean (SD) change from baseline in

PP-NRS on Day 2 (24 hours after first cream application) was –3.4 (1.85). The mean (SD) change from baseline in mPP-NRS at 15 minutes post-treatment was –2.3 (2.34), peaking at –4.2 (2.12) at 4 hours post-treatment, and was –3.1 (2.00) at 12 hours post-treatment. The mean (SD) change from baseline PP-NRS continued to increase through Day 29 (–5.7 [1.60]). The mean (SD) changes from baseline in IGA score on Days 8, 15, and 29 were –1.4 (0.73), –2.0 (0.87), and –2.2 (0.90), respectively. Treatment-emergent adverse events (TEAEs) were reported in 15/49 (30.6%) participants (none were serious); 1 participant had a treatment-related TEAE (grade 1 application site reaction [acne]). No participant discontinued treatment due to TEAE. Lesional skin treated with ruxolitinib cream 1.5% twice daily, showed substantial decrease in transepidermal water loss (TEWL) from a baseline mean (SD) score of 35.0 (17.47) to 13.1 (4.42) over 4 weeks, thus reaching similar levels to the non-lesional skin score of 12.7 (4.56) at day 29.

Conclusion: Application of 1.5% ruxolitinib cream in participants with AD was associated with rapid and sustained reduction in itch occurring as early as 15 minutes with peak reduction noted at 4 hours after first application; itch improvement was sustained over 28 days of treatment.

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