Ruxolitinib Cream Monotherapy Use Demonstrates Maintenance of Disease and Symptom Control With Use As Needed in Adults and Adolescents With Atopic Dermatitis: Pooled Analysis From the Long Term Safety Periods of Two Phase 3 Studies

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Background: Atopic dermatitis (AD) is a pruritic inflammatory skin disease. Ruxolitinib cream (RUX) is a topical formulation of ruxolitinib, a Janus kinase (JAK) 1/JAK2 inhibitor. Herein, we evaluated the long-term maintenance of disease and symptom control in adolescent and adult patients with AD applying ruxolitinib cream as needed using pooled data from the long-term safety (LTS) periods of two phase 3 studies.

Methods: In two phase 3 studies (TRuE-AD1/TRuE-AD2), 1249 patients with AD (≥12 years, Investigator's Global Assessment [IGA] 2/3, 3%–20% affected body surface area) were randomized to twice-daily 0.75% RUX/1.5% RUX/vehicle for an 8-week, double-blinded, vehicle-controlled period followed by a 44-week double-blinded long-term safety (LTS) period. In the LTS period, patients applied RUX as needed to treat active lesions and stopped after clearance, resuming treatment upon recurrence. IGA, itch (Patient-Oriented Eczema Measure [POEM] question 1) and sleep disturbance (POEM question 2) were evaluated in the LTS period from patients initially randomized to 0.75% (n=409) or 1.5% RUX (n=428).

Results: The percentages of of patients who applied 0.75%/1.5% RUX and achieved IGA 0/1 at Weeks 8 and 52 were 61.6%/67.1% and 60.6%/62.1%, respectively. With each consecutive visit, the majority of patients maintained IGA 0/1. Itch for 0 days in the past week was reported at Week 8 in 27.4%/32.2% and for 1-2 days in the past week in 32.8%/34.6% of patients, and at Week 52 in 21.5%/28.3% and 29.1%/25.9% of patients, respectively. Sleep disturbance for 0 or 1–2 days in the past week was reported at Week 8 in 64.3%/70.8% and 23.0%/19.4% of patients, and at Week 52 in 57.2%/57.9% and 12.2%/13.3% of patients.

Conclusions: In summary, RUX monotherapy use demonstrated maintenance of disease and symptom control with as needed use over a 44-week period in adults and adolescents with AD.

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