ATOPIC ECZEMA/DERMATITIS

12-WEEK EFFICACY AND SAFETY DATA OF RUXOLITINIB CREAM IN ADULT PATIENTS WITH ATOPIC DERMATITIS: RESULTS FROM A PHASE 2 STUDY

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Background: Janus kinases (JAKs) mediate skin inflammation in atopic dermatitis (AD). Results of 8-week applications of ruxolitinib cream (RUX), a JAK1/JAK2 inhibitor, in adult patients with AD were previously reported.

Objective: To report efficacy and safety data in patients with AD after treatment with 1.5% RUX twice daily (BID) for 12 continuous weeks or after switching to it following 8 weeks of other treatments (below).

Materials and Methods: Patients with AD ages 18–70 years with an Investigator's Global Assessment (IGA) score of 2 or 3 and an affected body surface area of 3%–20% were equally randomized to RUX (1.5% BID or once daily [QD], 0.5% QD, or 0.15% QD), vehicle, or 0.1% triamcinolone cream BID (4 weeks followed by 4 weeks of vehicle) for 8 weeks (blinded period), followed by 4 weeks of open-label treatment (OLT) with 1.5% RUX BID. Assessments included IGA response (0–1 score with ≥2-point improvement from baseline), Eczema Area and Severity Index (EASI), and safety.

Results: 252/307 randomized patients entered OLT (mean age, 38.7 years). In patients initially on 1.5% RUX BID who continued to OLT (n=43), mean percentage change from baseline at Week (W) 12 in EASI score was 84.9% (n=41). EASI-50, -75, and -90 at W12 were achieved by 39 (95.1%), 30 (73.2%), and 23 (56.1%) patients, respectively. Twenty-four patients (58.5%) were IGA responders at W12. Transitioning patients from their randomized groups, including patients who first received triamcinolone and vehicle, to 1.5% RUX BID (OLT) was associated with substantial improvement in EASI scores and IGA response. RUX was well tolerated and not associated with any notable safety concerns.

Conclusions: RUX was effective and well tolerated during this 12-week study, with

sustained responses to 1.5% RUX BID from the blinded period and further improvements for patients who crossed over in the OLT.