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Long-Term Disease Control and Safety With Ruxolitinib Cream in Adults With Moderate Atopic Dermatitis Following Failure of Prior Topical Therapies: Results From the TRuE-AD4 Phase 3b Study

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Introduction
Patients with moderate atopic dermatitis (AD) often receive systemic therapy. In TRuE-AD4, ruxolitinib cream demonstrated efficacy and safety at Week 8 in adults with moderate AD having inadequate response/intolerance/contraindication to topical corticosteroids and topical calcineurin inhibitors (post-TCS and -TCI). Here, we report 24-week disease control and safety in these patients.

Materials and Methods
Adults with Investigator's Global Assessment (IGA) of 3, Eczema Area and Severity Index (EASI) >7, itch numerical rating scale (NRS) ≥4, and 10%–20% affected body surface area (BSA) post-TCS and -TCI were randomized to twice-daily 1.5% ruxolitinib cream or vehicle for 8 weeks. Patients who achieved ≥50% improvement from baseline in EASI (EASI-50) continued double-blind, twice-daily treatment as needed for 16 weeks. Patients not maintaining EASI-50 at 2 consecutive visits could enter an open-label ruxolitinib cream as-needed escape arm.

Results
A total of 121 patients continued with double-blind treatment as needed after Week 8. Most patients (84.3%) completed double-blind treatment, with 84.5% having achieved EASI-75 and 70.9% having achieved IGA 0/1 with ≥2-point improvement from baseline at Week 24. Mean affected BSA (2.5%) and itch NRS 7-day scores (2.4) were low. Few patients switched to the escape arm (11.6%), and none discontinued due to lack of efficacy. Ruxolitinib cream was well tolerated in the as-needed period; 2 patients interrupted treatment and none discontinued due to treatment-emergent adverse events.

Conclusions
In summary, in patients with moderate AD in which TCS and TCI have failed, ruxolitinib cream may be an effective therapy option to delay/prevent progression to systemic therapy.