Ruxolitinib cream 1.5% twice daily for the treatment of extensive atopic dermatitis in children aged 2–11 years: 52 week results from a maximum-use trial

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Background: Eight-week safety and tolerability, efficacy, and limited systemic absorption of ruxolitinib cream 1.5% in an open-label, single-arm, maximum-use trial (MUsT) of children with moderate to severe atopic dermatitis (AD; NCT05034822) were previously described. This is the first report of longer-term data from the same study.

Objectives: Data on tolerability, safety, systemic exposure, and clinical and patient-reported outcomes are presented from the entire 52-week treatment period to assess whether clinical benefits and tolerability observed through Week 8 are sustained during the as-needed treatment long-term safety period through Week 52.

Methods: In this open-label, single-arm MUsT, patients 2-11 years old with AD ≥3 months, ≥35% affected body surface area (BSA), and Investigator’s Global Assessment (IGA) ≥3 applied twice-daily ruxolitinib cream 1.5% for 4 weeks to baseline lesions, then as-needed to active lesions for 4 weeks; patients could continue into the as-needed 44-week long-term safety period.
**Results:** This MUsT included 29 patients with moderate to severe AD. Treatment-emergent adverse events through Week 52 occurred in 31.0% of patients. One patient (3.4%) had 2 treatment-related application site reactions (paresthesia and folliculitis); no adverse events resulted in treatment interruption/discontinuation; none were serious or suggested systemic Janus kinase (JAK) inhibition. Through the 4-week continuous-use twice-daily treatment period, the mean (SD) application quantity was 8.5 (6.29) g/day, which was associated with a mean steady-state ruxolitinib plasma concentration of 98.2 nM, well below half-maximal concentration of JAK–mediated myelosuppression in adults (281 nM). From Week 8 to Week 52 (as-needed use), mean (SD) application quantity was 3.2 (2.79) g/day, consistent with lower, as-needed use in this long-term safety period. At Weeks 4 and 52 (assessed in n=26 and n=13 patients, respectively), 53.8%/53.8% achieved IGA–Treatment Success (IGA 0/1 with ≥2-grade improvement from baseline). Mean BSA decreased from 58.0% (range, 35.0%–92.0%) at baseline (n=29) to 11.4% at Week 4 and continued to decrease to 2.2% through Week 52 (n=26 and n=14, respectively). Patient-reported outcomes, such as the Patient-Oriented Eczema Measure, Children's Dermatology Life Quality Index, and Infants’ Dermatitis Quality of Life Index, were collected through Week 52.

**Conclusions:** Ruxolitinib cream 1.5% demonstrated consistently good tolerability and safety over 52 weeks in children aged 2 to 11 years with extensive moderate to severe AD. Rapid lesion clearance over 4 weeks with twice-daily therapy, which was sustained with longer-term as-needed use associated with low quantities of ruxolitinib cream being applied, may address application burden concerns.

**Key words:** atopic dermatitis, pediatric, ruxolitinib cream
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