Efficacy and safety of ruxolitinib cream in children aged 2 to 11 years with moderate and/or more extensive atopic dermatitis: subgroup analysis from the TRuE-AD3 study

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Introduction/Background: Atopic dermatitis (AD) is a chronic, inflammatory skin disease with onset usually occurring in childhood. Topical therapy is the mainstay of AD treatment and is typically used prior to systemic therapy in patients with moderate disease. Ruxolitinib (Janus kinase [JAK] 1/JAK2 inhibitor) cream is approved by the US Food and Drug Administration for patients aged ≥12 years with mild to moderate AD, and has demonstrated efficacy and was well
tolerated in children (aged 2–11 y) with AD in TRuE-AD3 (NCT04921969), a phase 3, double-blind, randomized, vehicle-controlled study.

**Objectives:** Here we investigated the effects of ruxolitinib cream in a subset of patients from TRuE-AD3 with moderate and/or more extensive disease at baseline.

**Methods:** TRuE-AD3 included children aged 2–11 years with AD for ≥3 months, an Investigator’s Global Assessment (IGA) score of 2 or 3, and an affected body surface area (BSA) of 3%–20%. Patients were randomized 2:2:1 to apply 1.5% ruxolitinib cream, 0.75% ruxolitinib cream, or vehicle cream twice daily for 8 weeks. Rescue treatment was not permitted. Patients from TRuE-AD3 with moderate and/or more extensive disease at baseline (defined as an IGA score of 3, ≥10% affected BSA, or a combined IGA score of 3 and ≥10% BSA) were included in this analysis. Efficacy was assessed as the proportion of patients in each treatment group who achieved IGA treatment success (IGA-TS; a score of 0 or 1 with a ≥2-grade improvement from baseline), ≥75% improvement from baseline in the Eczema Area and Severity Index (EASI-75), and ≥90% improvement from baseline in the Eczema Area and Severity Index (EASI-90) at Weeks 2, 4, and 8. Statistical significance was assessed at Week 8 using exact logistic regression. Patients with missing post-baseline data were imputed as nonresponders.

**Results:** Patients in TRuE-AD3 (N=330) had a median (range) age of 6 (2–11) years, 54.2% were girls, and 54.5% were White. The mean (SD) BSA was 10.5% (5.4%), the mean (SD) EASI was 8.6 (5.4), and 252 patients (76.4%) had a baseline IGA of 3. Among patients with an IGA of 3 at baseline, more patients who applied 1.5% ruxolitinib cream or 0.75% ruxolitinib cream versus vehicle achieved IGA-TS (40.0% and 29.1%, respectively, vs 6.1%), EASI-75 (43.0% and 38.8% vs 8.2%), and EASI-90 (17.0% and 21.4% vs 0%) at Week 2. Improvements were also observed at Week 8 (IGA-TS, 59.0% [P<0.0001] and 37.9% [P=0.004] vs 14.3%; EASI-75,
64.0% \( [P<0.0001] \) and 48.5% \( [P<0.0001] \) vs 14.3%; EASI-90, 40.0% \( [P<0.0001] \) and 33.0% \( [P=0.001] \) vs 8.2%), with 1.5% ruxolitinib cream consistently resulting in numerically better improvements than 0.75% ruxolitinib cream. Similar improvements were observed with ruxolitinib cream versus vehicle among patients with \( \geq 10\% \) affected BSA at baseline and a combined baseline IGA of 3 and \( \geq 10\% \) BSA. Both strengths of ruxolitinib cream were well tolerated among patients with an IGA of 3 at baseline; no serious treatment-emergent adverse events (TEAEs) were reported.

**Conclusions:** Children with moderate and/or more extensive AD in this study had substantially higher rates of clinical responses with ruxolitinib cream monotherapy versus vehicle as early as Week 2 (first assessment), with further improvement throughout the 8-week treatment period. Ruxolitinib cream was well tolerated with no serious TEAEs.

**Keywords:** ruxolitinib cream, atopic dermatitis (AD), moderate disease severity, eczema, pediatric

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