**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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**Objective**

- To evaluate the efficacy and safety of ruxolitinib cream in a subset of patients from TRuE-AD3 with moderate and/or more extensive disease at baseline

**Conclusions**

- Similar to the overall TRuE-AD3 population, ruxolitinib cream monotherapy demonstrated similar efficacy, safety, and tolerability in this subset of patients with moderate and/or more extensive disease
- Substantially higher rates of clinical responses were observed with ruxolitinib cream monotherapy versus vehicle at all time points
- Given these results, ruxolitinib cream may serve to simplify topical regimens and delay or prevent the progression to systemic therapy

**Methods**

**Patients and Study Design**

- Eligible patients were randomized 2:2:1 to apply 0.75% ruxolitinib cream, 1.5% ruxolitinib cream, or vehicle cream twice daily for 8 weeks (Figure 1)

**Introduction**

- Atopic dermatitis (AD) is a chronic, inflammatory skin disease with onset usually occurring in childhood.
- Traditional 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 in the US for patients aged ≥2 years with mild to moderate AD
- Ruxolitinib cream 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

**Results**

- Patients in TRuE-AD3 (N=330) had a median (range) age of 6 (2–11) years; 54.2% of patients were girls, and 54.5% were White
- The mean (SD) BSA was 10.5% (5.4%), and the mean (SD) Eczema Area and Severity Index (EASI) was 8.6 (5.4)
- 252 patients (76.4%) had a baseline IGA score of 3, 162 (49.1%) had a baseline affected BSA >10%, and 139 (42.1%) had both a baseline IGA score of 3 and >10% affected BSA

**Efficacy**

- Among patients with an IGA score of 3, substantially more patients who applied 1.5% ruxolitinib cream or 0.75% ruxolitinib cream versus vehicle achieved IGA treatment success (IGA-TS), 37% improvement from baseline in EASI (EASI-75), and ≥20% improvement from baseline in EASI (EASI-20) as early as Week 2 (Figure 2)
- Improvements with ruxolitinib cream versus vehicle were also observed among patients with ≥10% affected BSA at baseline and among patients with combined IGA score of 3 and ≥10% affected BSA at baseline (Figure 3)

**Safety**

- Both strengths of ruxolitinib cream were well tolerated among patients with an IGA score of 3 at baseline (Table 1)

**Acknowledgments**

- Supported by grant 1U01AI143878 from the National Institute of Allergy and Infectious Diseases, National Institutes of Health

**References**