Efficacy and Safety of Ruxolitinib Cream by Anatomic Region in Children Aged 2 to 11 Years With Atopic Dermatitis: Results From TRuE-AD3

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Objective

- To evaluate the efficacy and safety of ruxolitinib cream by anatomic region in the randomized, double-blind, phase 3 TRuE-AD3 study (NCT04921969)

Conclusions

- **Significant improvements in EASI region subscores were observed with ruxolitinib cream as early as Week 2 across all anatomic regions in children with AD**
- **Improvements in AD signs in each body region continued through Week 8**
- **Ruxolitinib cream was well tolerated, with infrequent application site reactions regardless of lesion location, including among patients with head/neck involvement**

Abbreviations

AD, atopic dermatitis; BID, twice daily; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; JAK, Janus kinase; LSM, least squares mean; RUX, ruxolitinib.

Disclosures

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Introduction

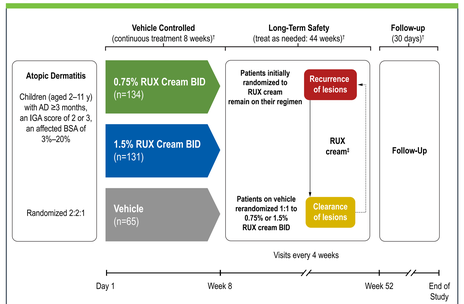
- AD is a chronic, highly pruritic, inflammatory skin disease[1]
- Head/neck involvement is common in children with AD[2] and is associated with reduced quality of life compared with other, less visible body regions, such as the back and pelvis[3,4]
- Ruxolitinib (JAK1/JAK2 inhibitor[5]) cream has demonstrated efficacy and safety in patients aged ≥2 years with AD[6-10]
- In adolescents (aged ≥12 y) and adults with AD, application of ruxolitinib cream resulted in significant improvements across all anatomic regions vs vehicle[11]

Methods

Study Design and Analyses

- Eligible patients were randomized 2:2:1 to apply 0.75% ruxolitinib cream, 1.5% ruxolitinib cream, or vehicle cream BID for 8 weeks (**Figure 1**)
- Efficacy was evaluated using the EASI subscores for head/neck, trunk, upper limbs, and lower limbs[12]
- Application site reactions were also assessed

Figure 1. Study Design



RUX, ruxolitinib.
† Rescue treatment was not permitted.
‡ Patients self-evaluated the recurrence of lesions between study visits and treated lesions with active AD (≤20% BSA). If lesions cleared between study visits, patients stopped treatment 3 days after lesion disappearance. If new lesions were extensive or appeared in new areas, patients contacted the investigator to determine if an unscheduled additional visit was needed.

Results

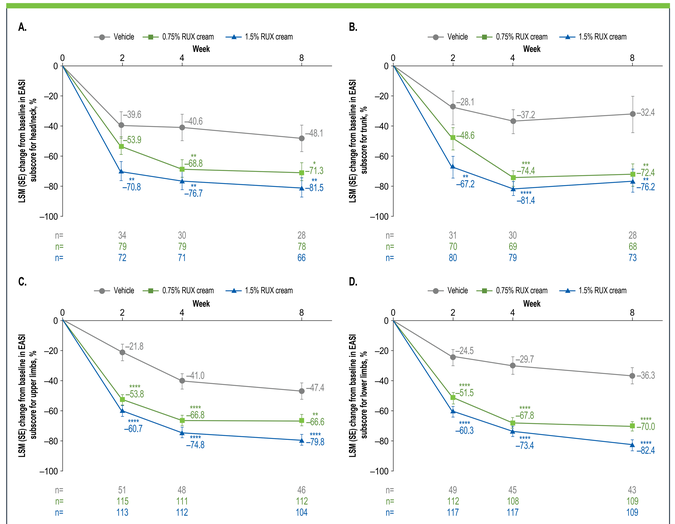
Patients

- Of the 330 patients in TRuE-AD3, the mean (SD) age was 6.5 (2.9) years, and 179 patients (54.2%) were female
- The mean (SD) baseline EASI score was 8.6 (5.4) and was similar across treatment groups (vehicle, 8.6 [5.5]; 0.75% ruxolitinib cream, 8.4 [6.1]; 1.5% ruxolitinib cream, 8.9 [4.6])

Efficacy

- Improvements in EASI score were demonstrated with 0.75% and 1.5% ruxolitinib cream vs vehicle at first observation (Week 2), with statistically significant differences (at 0.05 alpha level) in the head and neck, trunk, upper limbs, and lower limbs at Week 8 (**Figure 2**)

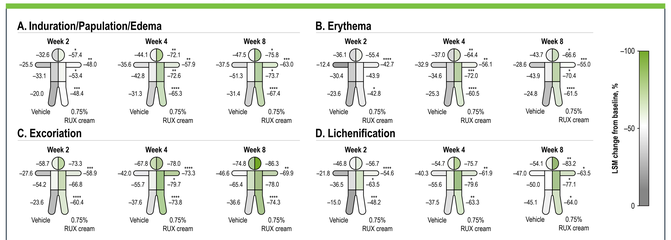
Figure 2. LSM Percentage Change From Baseline in Total EASI Anatomic Regions Subscores for A) Head and Neck, B) Trunk, C) Upper Limbs, and D) Lower Limbs



LSM, least squares mean; RUX, ruxolitinib.
* *P*<0.05 vs vehicle; ** *P*<0.01 vs vehicle; *** *P*<0.001 vs vehicle; **** *P*<0.0001 vs vehicle. All *P* values are nominal.

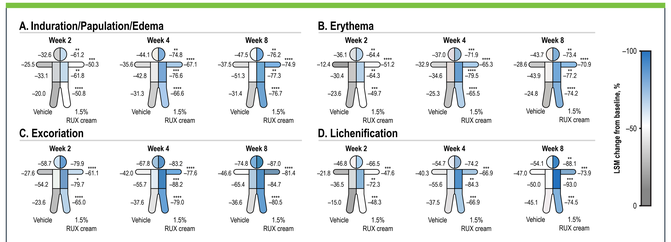
- Improvements in induration/papulation/edema, erythema, excoriation, and lichenification were observed for 0.75% (**Figure 3**) and 1.5% (**Figure 4**) ruxolitinib cream vs vehicle in all regions as early as Week 2, with statistical significance (at 0.05 alpha level) in nearly all AD signs and regions at Week 8

Figure 3. LSM Percentage Change From Baseline in EASI Anatomic Region Subscores for A) Induration/Papulation/Edema, (B) Erythema, C) Excoriation, and D) Lichenification in Patients Applying 0.75% RUX Cream vs Vehicle



* *P*<0.05 vs vehicle; ** *P*<0.01 vs vehicle; *** *P*<0.001 vs vehicle; **** *P*<0.0001 vs vehicle. All *P* values are nominal.

Figure 4. LSM Percentage Change From Baseline in EASI Anatomic Region Subscores for A) Induration/Papulation/Edema, (B) Erythema, C) Excoriation, and D) Lichenification in Patients Applying 1.5% RUX Cream vs Vehicle



* *P*<0.05 vs vehicle; ** *P*<0.01 vs vehicle; *** *P*<0.001 vs vehicle; **** *P*<0.0001 vs vehicle. All *P* values are nominal.

Safety

- Both strengths of ruxolitinib cream were well tolerated; application site reactions (all grade 1 or 2) were similar among patients with head/neck involvement vs the overall population (**Table 1**)

Table 1. Summary of Application Site Reactions at Week 8 Among Patients With Head/Neck Involvement at Baseline and the Overall Population

	Patients with head/neck involvement		Overall population	
n (%)	Vehicle (n=40)	RUX cream (n=161)†	Vehicle (n=65)	RUX cream (n=264)†
Application site reaction	2 (5.0)	7 (4.3)	2 (3.1)	12 (4.5)
Pain‡	0	4 (2.5)	0	8 (3.0)
Erythema	0	0	0	2 (0.8)
Irritation	0	2 (1.2)	0	2 (0.8)
Discomfort	0	1 (0.6)	0	1 (0.4)
Infection	1 (2.5)	0	1 (1.5)	0
Pruritus	1 (2.5)	0	1 (1.5)	0

† Includes patients who applied 0.75% or 1.5% RUX cream.
‡ Includes burning, intermittent skin pain, and stinging.