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As-Needed Ruxolitinib Cream Sustained Itch and Quality of Life Improvements in Children With Atopic Dermatitis

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Objective

- To evaluate PROs in children with AD who applied 1.5% ruxolitinib cream during the long-term, as-needed treatment period of TRuE-AD3 (NCT04921969)

Conclusions

- **In children aged 2–11 years with mild to moderate AD, improvements in itch, sleep, and quality of life achieved at Week 8 with 1.5% ruxolitinib cream BID were generally sustained through Week 52 with as-needed use**
- **Patients who crossed over from vehicle to ruxolitinib cream during the LTS period quickly reached similar levels of improvement in PRO assessments as patients initially randomized to ruxolitinib cream**
- **These findings, along with previously reported efficacy and safety data,[4,5] support ruxolitinib cream as a treatment option that provides effective disease control and improvements in quality of life for children with AD**

Abbreviations

AD, atopic dermatitis; BID, twice daily; BL, baseline; BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; DFI, Dermatitis Family Impact; IDQoL, Infants' Dermatitis Quality of Life Index; IGA, Investigator's Global Assessment; JAK, Janus kinase; LTS, long-term safety; POEM, Patient-Oriented Eczema Measure; PRO, patient-reported outcome; RUX, ruxolitinib; VC, vehicle-controlled.

Disclosures

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Introduction

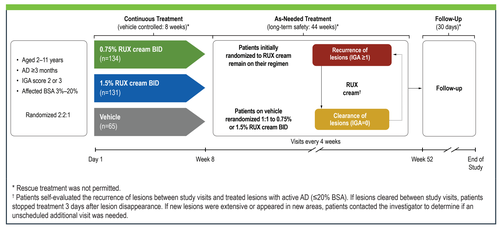
- AD is a chronic, pruritic, inflammatory skin disease, with onset usually occurring in childhood[1]
- Topical therapy is the mainstay of AD treatment in patients with mild to moderate disease[2]
- Ruxolitinib cream, a selective JAK1/JAK2 inhibitor,[3] demonstrated efficacy, improved PROs, and was well tolerated in children aged 2–11 years with mild to moderate AD in the 8-week VC period of the phase 3 TRuE-AD3 study[4]
- Long-term use with as-needed ruxolitinib cream maintained disease control and was well tolerated to Week 52 in TRuE-AD3[5]

Methods

Study Design and Assessments

- Eligible patients were randomized 2:2:1 to apply ruxolitinib cream BID (0.75% or 1.5%) or vehicle BID for 8 weeks of continuous treatment and then remained on ruxolitinib cream or were rerandomized to either of the 2 ruxolitinib cream regimens for a 44-week, as-needed treatment period (**Figure 1**)
- PRO assessments included the POEM, CDLQI (patients aged ≥4 y), IDQoL (patients aged <4 y), and DFI questionnaire; data are reported as observed

Figure 1. Study Design



* 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

- In the overall LTS-evaluable population (N=282), the median (range) age was 7.0 (2–11) years, 52.8% of patients were female, and 55.7% were White
- At baseline, the mean (SD) affected BSA was 10.4% (5.4%), and 77.0% of patients had an IGA of 3
- Of the 138 patients who applied 1.5% ruxolitinib cream during the LTS period, 114 patients were initially randomized to 1.5% ruxolitinib cream, and 24 patients crossed over from vehicle at Week 8 (beginning of the LTS)

Results

Patient-Reported Outcomes

- Improvements in total mean POEM score achieved with 1.5% ruxolitinib cream during the 8-week VC period were maintained throughout the LTS period with as-needed use (**Figure 2**)
  - During the LTS period, patients who crossed over from vehicle to 1.5% ruxolitinib cream reported mean POEM scores comparable to patients initially randomized to ruxolitinib cream
- The proportion of patients reporting no days of itch (POEM question 1; **Figure 3**) and no nights of disturbed sleep (POEM question 2; **Figure 4**) was substantially higher in the 1.5% ruxolitinib cream group vs vehicle at Week 8, with response levels maintained throughout the LTS period
  - Patients who crossed over from vehicle reached similar response levels during the LTS period
- Patients initially randomized to 1.5% ruxolitinib cream reported improvements vs vehicle in CDLQI (**Figure 5**), IDQoL (**Figure 6**), and DFI (**Figure 7**) through Week 8, and improvements were generally maintained throughout the LTS period
  - Patients who crossed over from vehicle to ruxolitinib cream experienced rapid improvements in CDLQI, IDQoL, and DFI during the LTS period
  - The proportion of patients who achieved a score of 0–1 (no effect on quality of life) was sustained or increased during the LTS period

Safety

- Ruxolitinib cream was generally well tolerated during the LTS period, with only 1 application site reaction among patients who applied 1.5% ruxolitinib cream, which resolved after 1 day
- No new safety signals emerged with long-term treatment
- No serious treatment-emergent adverse events were considered related to treatment

Figure 2. POEM Total Scores

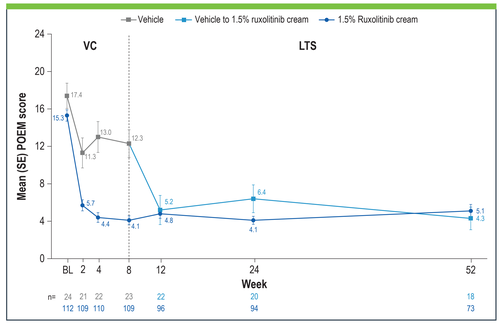


Figure 3. POEM Itch Scores (Question 1)

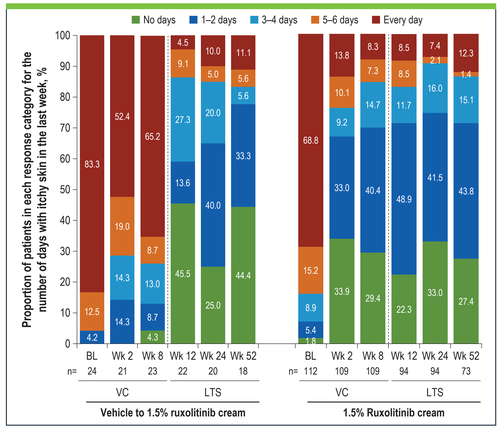


Figure 4. POEM Sleep Scores (Question 2)

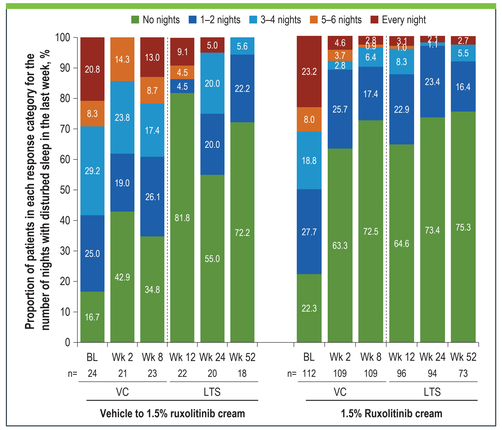
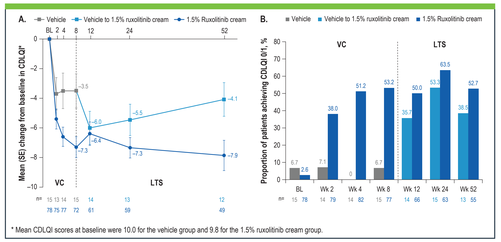
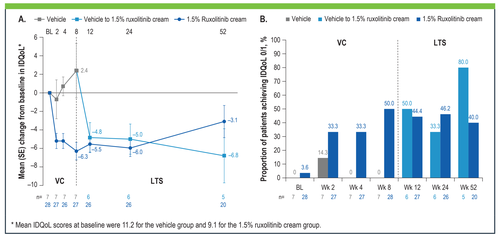


Figure 5. CDLQI (A) Change From Baseline and (B) Proportion of Patients Achieving Score of 0–1 (No Effect of AD on Child's Quality of Life)



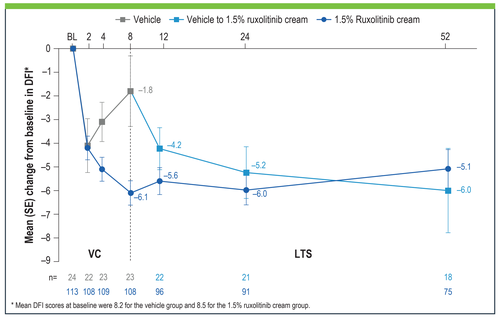
* Mean CDLQI scores at baseline were 10.0 for the vehicle group and 9.8 for the 1.5% ruxolitinib cream group.

Figure 6. IDQoL (A) Change From Baseline and (B) Proportion of Patients Achieving Score of 0–1 (No Effect of AD on Infant's Quality of Life)



* Mean IDQoL scores at baseline were 11.2 for the vehicle group and 9.1 for the 1.5% ruxolitinib cream group.

Figure 7. Change From Baseline in DFI



* Mean DFI scores at baseline were 8.2 for the vehicle group and 8.5 for the 1.5% ruxolitinib cream group.