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Long-Term Disease Control and Safety With Ruxolitinib Cream in Adults With Moderate Atopic Dermatitis Following Failure of Prior Topical Therapies: Results From the TRuE-AD4 Phase 3b Study

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Objective

- To evaluate long-term (24-week) disease control and safety with as-needed BID use of ruxolitinib cream in adults with moderate AD post-TCS and post-TCI in the TRuE-AD4 study (NCT06238817)

Introduction

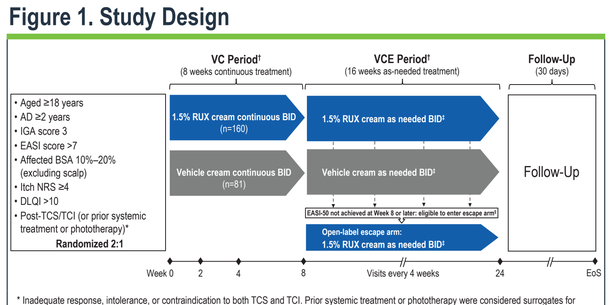
- Ruxolitinib (selective JAK1/JAK2 inhibitor) cream was effective and well tolerated in patients aged ≥2 years with mild to moderate AD,[1-4] regardless of prior AD therapies[5,6]
- In the TRuE-AD4 phase 3b study in adults with moderate AD in which standard topical therapies (TCS and TCI) had failed and who might otherwise be eligible for systemic therapy, 1.5% ruxolitinib cream was well tolerated and reduced clinical signs and symptoms of AD with 8 weeks of continuous BID use[7]
  - Early improvements in IGA score, EASI score, and affected BSA were observed at Week 2, with itch reduction demonstrated 15 minutes after first application

Methods

Patients and Study Design

- Eligible patients were randomized 2:1 to apply 1.5% ruxolitinib cream or vehicle cream BID for 8 weeks (VC period)
- At Week 8, patients who achieved EASI-50 continued double-blind, BID treatment for an additional 16 weeks but only applied ruxolitinib cream as needed (VCE period; **Figure 1**)
  - Patients for whom EASI-50 was not achieved at 2 consecutive visits ≥1 week apart (1 visit could be unscheduled) were eligible to enter the escape arm at Week 8 or later, in which open-label ruxolitinib cream was applied as needed

Figure 1. Study Design



* Inadequate response, intolerance, or contraindication to both TCS and TCI. Prior systemic treatment or phototherapy were considered surrogates for post-TCS/TCI.
† Rescue therapy was not permitted.
‡ Patients self-evaluated 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 whether an unscheduled additional visit was needed. Patients were discontinued from study treatment if affected BSA exceeded 20%.
§ To be eligible for the escape arm, EASI-50 must not have been achieved at 2 consecutive visits ≥1 week apart (1 visit could be unscheduled).

Results

Patients

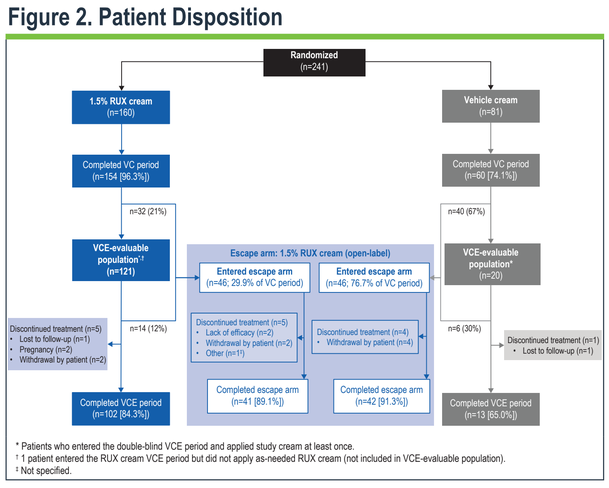
- Of 241 patients randomized in the VC period, 141 achieved EASI-50 at Week 8 and applied study cream at least once in the double-blind as-needed period (VCE primary population)
  - Demographics and baseline disease characteristics were similar among treatment groups (**Table 1**)
- A much lower proportion of ruxolitinib cream–treated patients (29.9%) switched to the escape arm than vehicle-treated patients (76.7%); of these patients, approximately 90% completed ruxolitinib cream treatment in the escape arm (**Figure 2**)
- A high proportion of ruxolitinib cream–treated patients (84.3%) completed the VCE period, with no patients withdrawing due to lack of efficacy

Table 1. Patient Demographics and Baseline Disease Characteristics (VCE Primary Population)

Characteristic	Vehicle (n=20)	1.5% RUX cream (n=121)
Age, median (range), y	43.5 (19–73)	35.0 (19–88)
<65 y, n (%)	18 (90.0)	114 (94.2)
Female, n (%)	14 (70.0)	75 (62.0)
Race, n (%)		
White	19 (95.0)	93 (76.9)
Asian	1 (5.0)	18 (14.9)
Black	0	4 (3.3)
Other	0	1 (0.8)
Missing/not reported	0	5 (4.1)
Europe region, n (%)*	11 (55.0)	84 (69.4)
Affected BSA, mean (SD), %	14.2 (3.0)	15.1 (3.0)
EASI, mean (SD)	12.5 (4.5)	12.2 (3.8)
<16, n (%)	16 (80.0)	102 (84.3)
≥16, n (%)	4 (20.0)	19 (15.7)
IGA 3, n (%)	20 (100)	120 (99.2)†
Itch NRS score, mean (SD)‡	7.5 (1.7)	7.3 (1.6)
Prior facial/neck involvement, n (%)	10 (50.0)	97 (80.2)
Duration of disease, median (range), y	14.5 (2.5–52.9)	21.0 (2.2–58.1)
Prior therapy in last 12 mo, n (%)§		
TCS	19 (95.0)	117 (96.7)
TCI	17 (85.0)	98 (81.0)
Systemic therapy	5 (25.0)	39 (32.2)
Phototherapy	2 (10.0)	12 (9.9)

* The remaining patients were enrolled in the US, Canada, and Australia.
† 1 patient had IGA 3 at screening that progressed to IGA 4 by the baseline visit.
‡ By-visit analysis from a mean of ≥4 of the 7 days immediately prior to the baseline visit.
§ Patients could be included in ≥1 category of prior therapy.

Figure 2. Patient Disposition



* Patients who entered the double-blind VCE period and applied study cream at least once.
† 1 patient entered the RUX cream VCE period but did not apply as-needed RUX cream (not included in VCE-evaluable population).
‡ Not specified.

Efficacy

- Among patients in the VCE primary population (EASI-50 at Week 8) who applied ruxolitinib cream, IGA-TS (**Figure 3**) and EASI-75 (**Figure 4**) achievements at Week 8 were maintained with as-needed treatment to Week 24
  - Among vehicle-treated patients who entered the escape arm at Week 8 (did not achieve EASI-50), IGA-TS and EASI-75 were rapidly achieved by 39.5% and 50.0% of patients at Week 12, respectively, with further improvement to Week 24 (62.2% and 70.3%, respectively)
  - Among ruxolitinib cream–treated patients who entered the escape arm at Week 8, IGA-TS and EASI-75 were each achieved by 34.5% and 37.9% of patients, respectively, at Week 12, and 46.4% and 60.7% at Week 24
- EASI score was substantially improved at Week 24 relative to baseline in nearly all patients who applied ruxolitinib cream (VCE primary population; **Figure 5**)

Figure 3. IGA-TS Achievement Relative to Baseline Among Patients Who Applied Ruxolitinib Cream (VCE Primary Population)

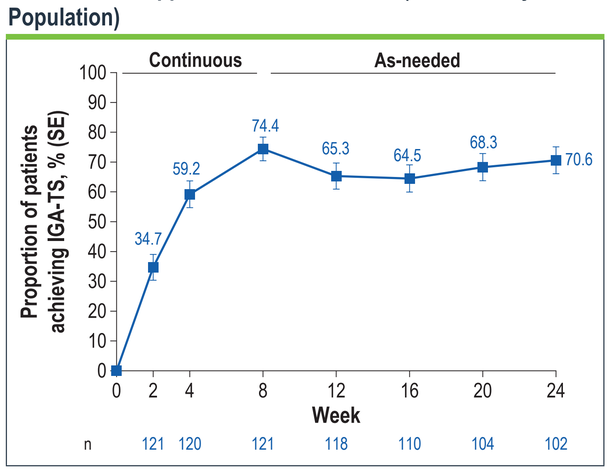


Figure 4. EASI-75 Achievement Relative to Baseline Among Patients Who Applied Ruxolitinib Cream (VCE Primary Population)

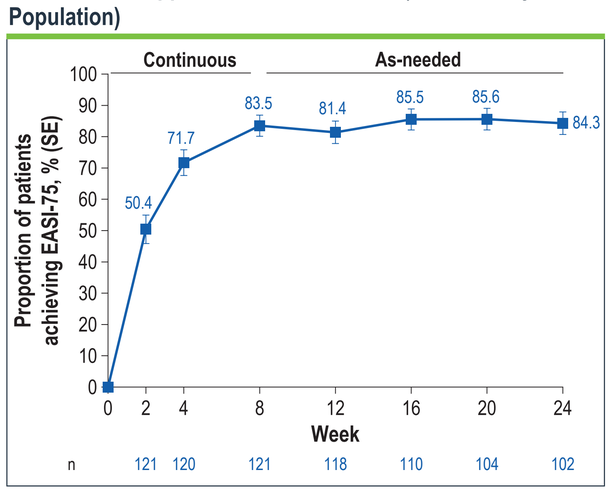
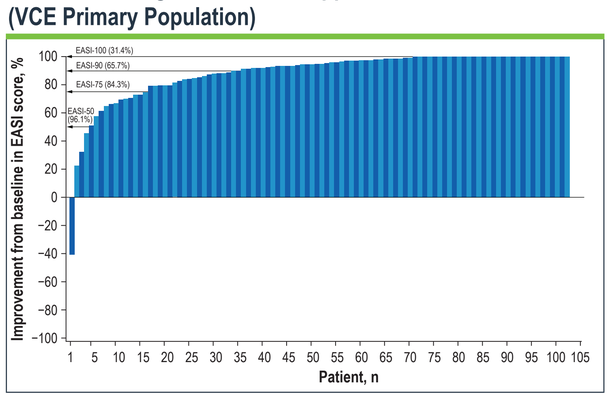
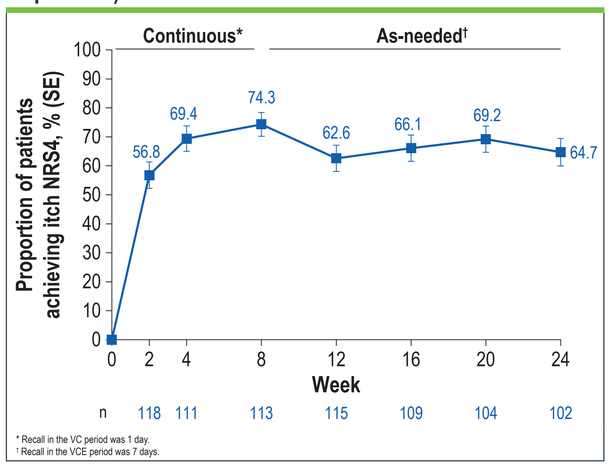


Figure 5. EASI Improvement at Week 24 Relative to Baseline Among Patients Who Applied Ruxolitinib Cream (VCE Primary Population)



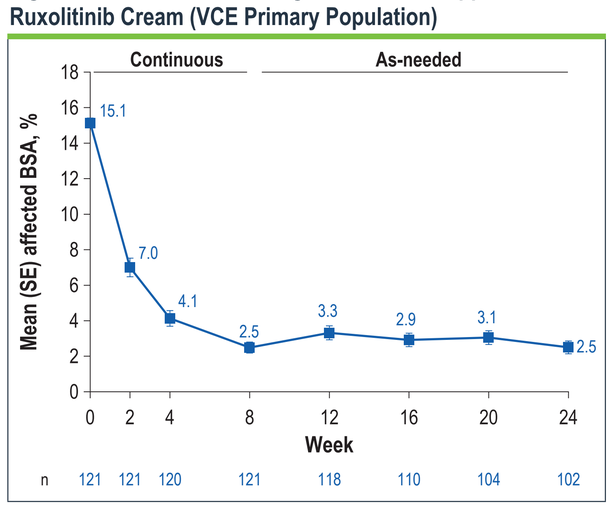
- Among patients in the VCE primary population who applied ruxolitinib cream, itch NRS4 achievement (**Figure 6**) and affected BSA reduction (**Figure 7**) at Week 8 were maintained with as-needed treatment through to Week 24
  - Among vehicle-treated patients who entered the escape arm at Week 8 (did not achieve EASI-50), 68.4% and 63.9% of patients achieved itch NRS4 at Weeks 12 and 24, respectively, and mean affected BSA was 7.1% and 4.6%
  - Among ruxolitinib cream–treated patients who entered the escape arm at Week 8, itch NRS4 was achieved by 51.7% and 74.1% at Weeks 12 and 24, respectively, and mean affected BSA was 8.8% and 5.8%

Figure 6. Itch NRS4 Achievement Relative to Baseline Among Patients Who Applied Ruxolitinib Cream (VCE Primary Population)



* Recall in the VC period was 1 day.
† Recall in the VCE period was 7 days.

Figure 7. Affected BSA Among Patients Who Applied Ruxolitinib Cream (VCE Primary Population)



Safety

- As-needed ruxolitinib cream was well tolerated in the VCE period (**Table 2**)
  - Few application site reactions occurred (1.7% of patients)
  - No new safety signals emerged with as-needed treatment up to 24 weeks
- Median ruxolitinib plasma concentrations at Week 24 remained low (18.0 nM)
  - This is approximately 11-fold lower than the 281 nM threshold associated with JAK-mediated myelosuppression (using in vitro assays in whole blood in adults)[8]
- Among all patients initially randomized to ruxolitinib cream in the 24-week study (safety population), the most common TEAEs were upper respiratory tract infection (10.6%) and nasopharyngitis (6.3%; **Table 3**)
  - No MACE, malignancies, serious infections, or thromboses were observed
  - TEAEs associated with AD and other AD treatments were infrequent (<4%) or absent

Table 2. TEAEs in the VCE Period (VCE Primary Population)

n (%)	Vehicle (n=20)	1.5% RUX cream (n=121)
Patients with TEAE	5 (25.0)	43 (35.5)
Most common TEAEs*		
Upper respiratory tract infection	1 (5.0)	9 (7.4)
Nasopharyngitis	0	7 (5.8)
Patients with treatment-related TEAE	0	4 (3.3)†
Patients with grade ≥3 TEAE	0	1 (0.8)‡
Patients with serious TEAE	0	1 (0.8)‡
Patients with fatal TEAE	0	0
Patients with TEAE leading to interruption of study drug	0	2 (1.7)
Patients with TEAE leading to discontinuation of study drug	0	0

* TEAE in >2 patients (1.7%) in the RUX cream group.
† Application site acne, application site folliculitis, herpes simplex, oral herpes, tinea pedis, and viral upper respiratory tract infection each occurred in 1 patient.
‡ Spontaneous abortion (judged by the investigator as unrelated to treatment).

Table 3. Most Common TEAEs and Select TEAEs in the 24-Week Study

n (%)	1.5% RUX cream (n=160)
Most common TEAEs*	
Upper respiratory tract infection	17 (10.6)
Nasopharyngitis	10 (6.3)
Application site acne	7 (4.4)
Headache	6 (3.8)
Influenza	5 (3.1)
Acne	3 (1.9)
Bronchitis	3 (1.9)
Hypertension	3 (1.9)
JAK inhibitor class-specific TEAEs	
MACE	0
Malignancy	0
Serious infection	0
Thrombosis	0
TEAEs associated with AD and other AD treatments	
Headache	6 (3.8)
Diarrhea	1 (0.6)
Folliculitis†	1 (0.6)
Herpes zoster‡	1 (0.6)
Nausea	1 (0.6)
Contact dermatitis	0

* Events occurring in >2 (1.3%) patients treated with RUX cream.
† Application site folliculitis.
‡ A case of herpes zoster occurred on the right side of the face (not in a treatment area) that resolved with systemic antiviral therapy (acyclovir); there was no change in RUX cream application, and the event was considered not related to the study drug by the investigator.

Conclusions

- **In adults with moderate AD in whom standard topical therapies have failed (ie, patients otherwise suitable for systemic therapy), 16 weeks of as-needed use of 1.5% ruxolitinib cream maintained improvements in clinical signs (ie, IGA, EASI, BSA) and itch observed after 8 weeks of continuous use**
- **Ruxolitinib cream was well tolerated in the VCE period, with no new safety signals emerging with long-term, as-needed treatment**
- **Ruxolitinib cream may therefore be an effective topical therapy option to delay or prevent progression to systemic therapy in patients with moderate AD**

Abbreviations

AD, atopic dermatitis; BID, twice daily; BSA, body surface area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI-50/75/90/100, ≥50%/≥75%/≥90%/100% improvement in EASI score from baseline; EoS, end of study; IGA, Investigator's Global Assessment; IGA-TS, IGA treatment success (IGA score of 0 or 1 with a ≥2-point improvement from baseline); JAK, Janus kinase; MACE, major cardiovascular event; NRS, numerical rating scale; NRS4, ≥4-point improvement in numerical rating scale score from baseline; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids; TEAE, treatment-emergent adverse event; RUX, ruxolitinib; VC, vehicle-controlled; VCE, vehicle-controlled extension.

Disclosures

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References

1. Papp K, et al. *J Am Acad Dermatol*. 2021;85(4):863-872. **2.** Papp K, et al. *J Am Acad Dermatol*. 2023;88(5):1008-1016. **3.** Eichenfield LF, et al. *J Am Acad Dermatol*. 2025;93(3):689-698. **4.** Eichenfield LF, et al. 52-week safety and disease control with ruxolitinib cream in children aged 2–11 years with atopic dermatitis: results from the phase 3 TRuE-AD3 study. Presented at: 33rd European Academy of Dermatology and Venereology (EADV) Congress; September 25–28, 2024; Amsterdam, The Netherlands. **5.** Blauvelt A, et al. *Dermatol Ther (Heidelb)*. 2024;14(11):3161-3174. **6.** Eichenfield LF, et al. Efficacy of ruxolitinib cream for the treatment of atopic dermatitis in children aged 2-11 years by previous medication history: subgroup analysis from the randomized, phase 3 TRuE-AD3 study. Presented at: American Academy of Dermatology; March 8-12, 2024; San Diego, CA, USA. **7.** Carrascosa JM, et al. Efficacy and safety of ruxolitinib cream in adults with moderate atopic dermatitis: results from TRuE-AD4, a phase 3b, randomized, double-blind, vehicle-controlled study. Presented at: 15th Georg RAJKA International Symposium on Atopic Dermatitis; October 24–26, 2025; Melbourne, Australia. **8.** Quintás-Cardama A, et al. *Blood*. 2010;115(15):3109-3117.

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