Incyte Dermatology

Ruxolitinib Cream for Atopic Dermatitis in Patients Aged 2 to 11 Years

TRuE-AD3 Study Design and Results

This presentation was developed by Incyte Corporation, in a manner consistent with the FDA Guidance for Industry: Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses (SIUU) of Approved/Cleared Medical Products.

MSL-RCM-US-0184 06/25

Notice

- Ruxolitinib cream has not been approved by the FDA for use in patients aged 2 to 11 years with atopic dermatitis, and the safety and effectiveness of ruxolitinib cream for atopic dermatitis in patients aged 2 to 11 years has not been established. This presentation is not intended to offer recommendations for any administration, indication, dosage, or other use for OPZELURA in a manner inconsistent with the approved Prescribing Information

- **FOR MEDICAL INFORMATION PURPOSES ONLY. NOT FOR PROMOTIONAL USE. DO NOT COPY, DISTRIBUTE OR OTHERWISE REPRODUCE**

Indication and Usage

- OPZELURA is a Janus kinase (JAK) inhibitor indicated for:
  - the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
  - the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older

Limitations of Use

- Use of OPZELURA in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended

Contraindications

- None

Please see the Full Prescribing Information, including Warnings & Precautions and Medication Guide for OPZELURA

Scan QR code to view
OPZELURA® (ruxolitinib) cream
Prescribing Information

FDA, US Food and Drug Administration.
Opzelura® (ruxolitinib) cream. Prescribing Information. Incyte Corporation; August 2024.

Efficacy and Safety of Ruxolitinib Cream in Children Aged 2 to 11 Years With Atopic Dermatitis: Results From TRuE-AD3, a Phase 3, Randomized, Double-Blind Study

Lawrence F. Eichenfield, MD; Linda F. Stein Gold, MD; Eric L. Simpson, MD, MCR; Andrea L. Zaenglein, MD; April W. Armstrong, MD, MPH; Megha M. Tollefson, MD; Weily Soong, MD, Lara Wine Lee, MD, PhD; Alim R. Devani, MD; Seth B. Forman, MD; Dareen D. Siri, MD; Howard Kallender, PhD;[a] Brett Angel, MD;[a] Qian Li, PhD;[a] Xuejun Chen, PhD;[a] Amy S. Paller, MD

[a] Employee of Incyte Corporation.

Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Scan QR code to view TRuE-AD3 publication

Financial Disclosures

- Lawrence F. Eichenfield, Linda F. Stein Gold, Eric L. Simpson, April W. Armstrong, Weily Soong, Alim R. Devani, Seth B. Forman, Dareen D. Siri, and Amy S. Paller have been paid consultants for Incyte Corporation

- Lawrence F. Eichenfield, Linda F. Stein Gold, Andrea L. Zaenglein, April W. Armstrong, Megha M. Tollefson, Weily Soong, Lara Wine Lee, Alim R. Devani, Seth B. Forman, Dareen D. Siri, and Amy S. Paller have been investigators for Incyte Corporation

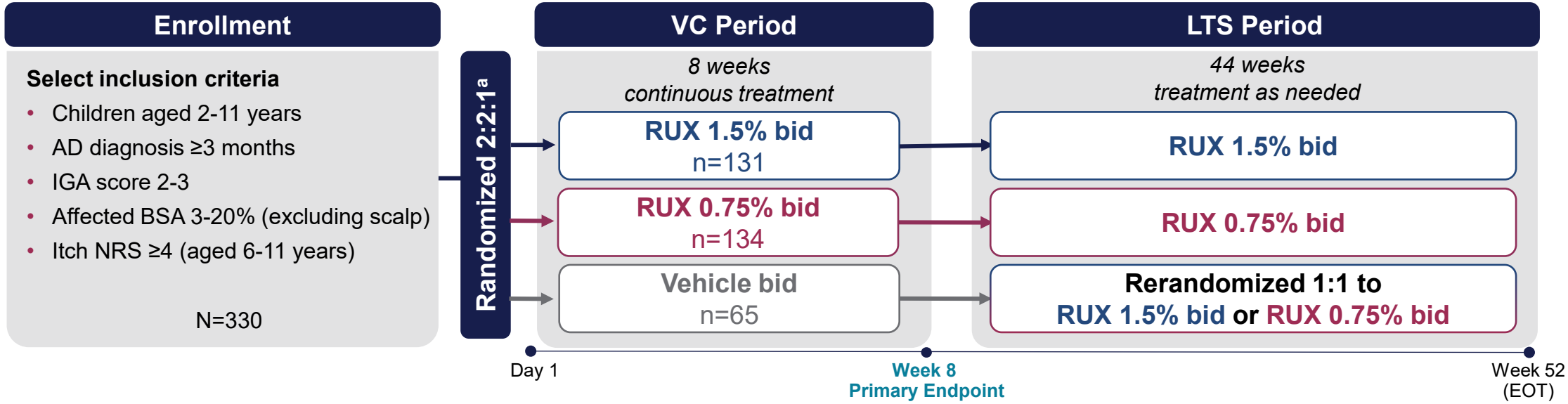
- Howard Kallender, Brett Angel, Qian Li, and Xuejun Chen are employees and shareholders of Incyte Corporation

Note: The authors did not receive any compensation for participating in the authorship of the manuscript. Medical writing support was provided by Citrus Health Group, which has been funded by Incyte Corporation.
Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

TRuE-AD3 Study Design

TRuE-AD3: Study Design

Study Design: Phase 3, multicenter, randomized, double-blind study of the efficacy and safety of ruxolitinib cream in children aged 2-11 years with mild-to-moderate AD



Study limitations: 8-week VC time period and enrollment limited to North America

[a] Randomization was stratified by IGA score (2 or 3) and age (2-6 years or 7-11 years).
AD, atopic dermatitis; bid, twice daily; BSA, body surface area; EOT, end of treatment; IGA, Investigator's Global Assessment; LTS, long-term safety; NRS, numerical rating scale; RUX, ruxolitinib cream; VC, vehicle-controlled.
Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Study Endpoints

Primary Endpoint:[a]

- Proportion of patients achieving IGA-TS[b] at week 8

Key Secondary Endpoint:[a]

- Proportion of patients achieving itch NRS4[c,d] at week 8

Other Secondary Endpoints:[e]

- Proportion of patients achieving EASI-75 at week 8
- Time to achieve itch NRS4
- Safety and tolerability

Exploratory Endpoint:[e]

- Proportion of patients achieving EASI-90 at week 8

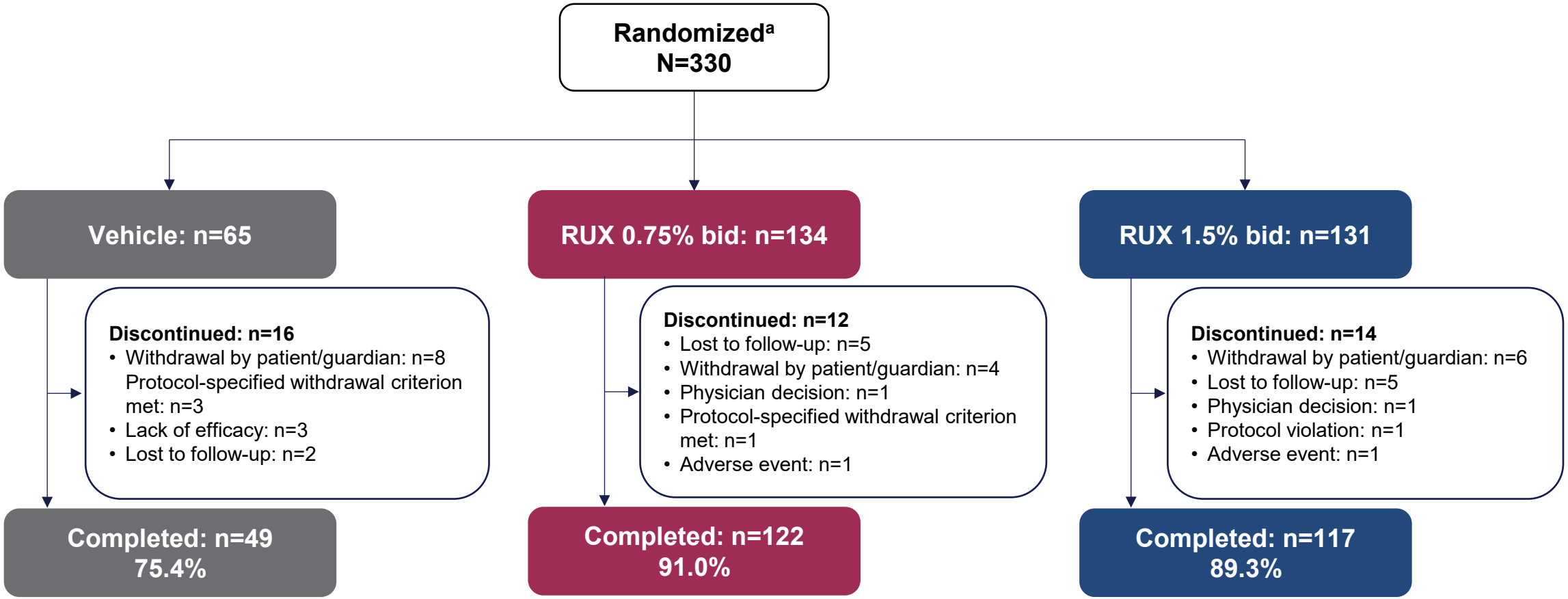
[a] Primary and key secondary endpoints analyzed by exact logistic regression. Bonferroni method was used to control the overall type 1 error rate for pairwise comparison between either strength of ruxolitinib cream versus vehicle. Each endpoint was tested in a fixed sequence at a 2-sided alpha level of 0.025; each key secondary endpoint was tested only if the null hypothesis of the associated primary endpoint was rejected. [b] Defined as IGA score of 0 (clear) or 1 (almost clear) with ≥2-point improvement from baseline). [c] Defined as a ≥4-point reduction from baseline in itch NRS score (worst itch level in past 24 hours recorded in diary). [d] Itch NRS data were only collected in patients aged 6-11 years. [e] Not an exhaustive list.

EASI-75/90, ≥75%/90% improvement from baseline in Eczema Area Severity Index; IGA, Investigator's Global Assessment; IGA-TS, IGA–Treatment Success (IGA score of 0/1 with a ≥2-point improvement from baseline); NRS, numerical rating scale.

Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Patient Disposition and Characteristics

Patient Disposition



[a] All randomized patients were included in the efficacy analyses. One patient in the RUX 1.5% treatment group did not apply any treatment and was excluded from the safety analyses.
bid, twice daily; RUX, ruxolitinib cream.

Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. Supplementary appendix. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Baseline Patient Demographics

Demographic characteristics	Vehicle (n=65)	RUX 0.75% bid (n=134)	RUX 1.5% bid (n=131)	Total (N=330)
Age, median (range), y	6.0 (2-11)	6.0 (2-11)	6.0 (2-11)	6.0 (2-11)
2-6 y, n (%)	33 (50.8)	68 (50.7)	66 (50.4)	167 (50.6)
7-11 y, n (%)	32 (49.2)	66 (49.3)	65 (49.6)	163 (49.4)
Female, n (%)	38 (58.5)	73 (54.5)	68 (51.9)	179 (54.2)
Race, n (%)				
White	37 (56.9)	75 (56.0)	68 (51.9)	180 (54.5)
Black	19 (29.2)	45 (33.6)	42 (32.1)	106 (32.1)
Asian	3 (4.6)	7 (5.2)	11 (8.4)	21 (6.4)
Other	6 (9.2)	7 (5.2)	10 (7.6)	23 (7.0)

bid, twice daily; RUX, ruxolitinib cream.

Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Baseline Clinical Characteristics

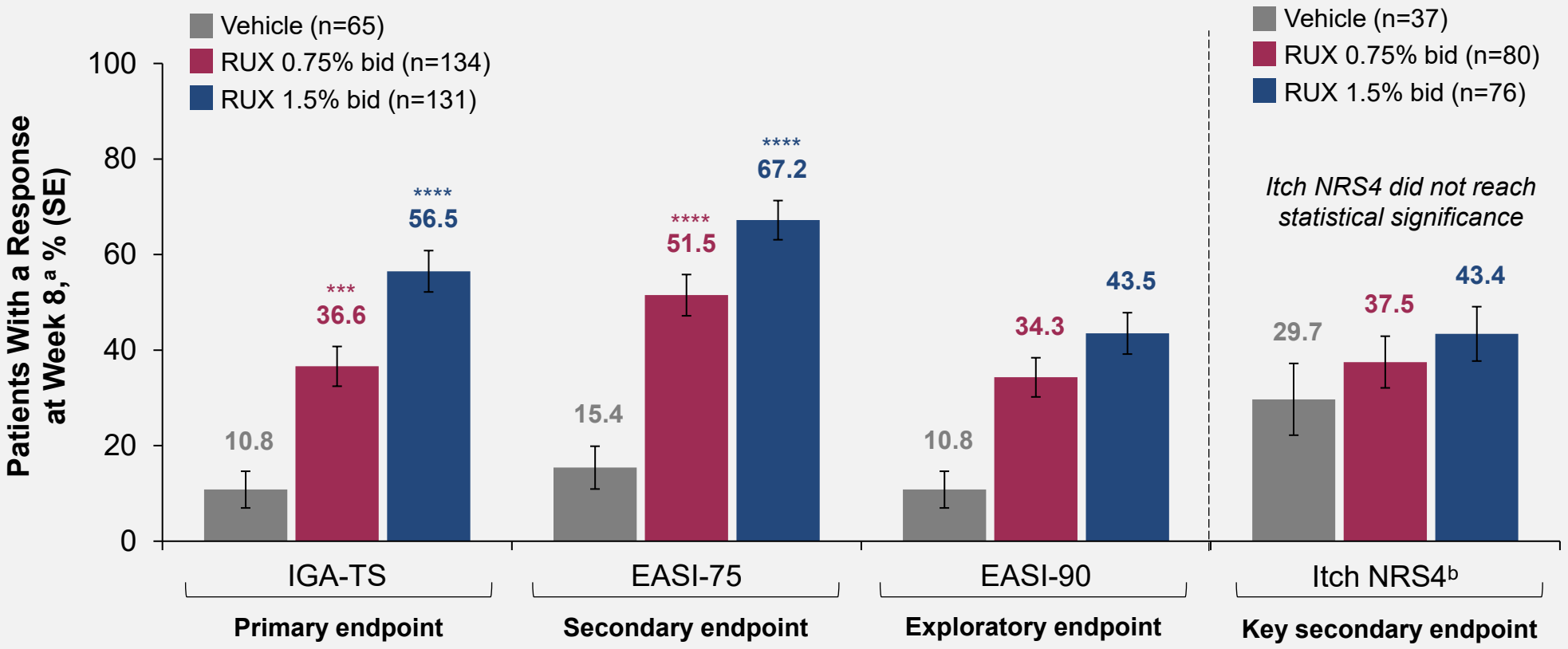
Clinical characteristics	Vehicle (n=65)	RUX 0.75% bid (n=134)	RUX 1.5% bid (n=131)	Total (N=330)
Affected BSA, mean (SD), %	10.0 (5.5)	10.0 (5.1)	11.2 (5.6)	10.5 (5.4)
EASI, mean (SD)	8.6 (5.5)	8.4 (6.1)	8.9 (4.6)	8.6 (5.4)
>7, n (%)	36 (55.4)	62 (46.3)	79 (60.3)	177 (53.6)
IGA, n (%)				
2	16 (24.6)	31 (23.1)	31 (23.7)	78 (23.6)
3	49 (75.4)	103 (76.9)	100 (76.3)	252 (76.4)
Itch NRS score, mean (SD)[a]	6.5 (1.8)	6.6 (1.8)	6.9 (1.6)	6.7 (1.7)
POEM score, mean (SD)[b]	16.7 (6.8)	15.4 (6.3)	15.3 (6.3)	NA
CDLQI score, mean (SD)[c]	10.0 (7.0)	10.2 (6.6)	9.8 (6.2)	NA
IDQOL score, mean (SD)[d]	11.2 (6.4)	9.6 (6.9)	9.1 (4.4)	NA
Facial/neck involvement, n (%)	41 (63.1)	87 (64.9)	83 (63.4)	211 (63.9)
Duration of disease, median (range), y	4.4 (0.4-11.2)	5.2 (0.3-11.3)	4.7 (0.4-11.2)	4.8 (0.3-11.3)
Number of flares in the past 12 months, mean (SD)	7.3 (8.1)	18.4 (54.2)	12.4 (33.0)	13.9 (40.6)
Prior AD therapy in the past 12 months, n (%)	46 (70.8)	86 (64.2)	90 (68.7)	222 (67.3)

[a] Assessments for baseline itch NRS scores by visit are shown for patients aged 6-11 y (vehicle, n=38; RUX 0.75%, n=83; RUX 1.5%, n=76; total, n=197). Score is mean of ≥4 of the 7 days immediately prior to the baseline visit. [b] Data were available for 65, 131, and 129 patients in the vehicle, RUX 0.75%, and RUX 1.5% groups, respectively. [c] Includes patients aged ≥4 years; data were available for 45, 101, and 94 patients in the vehicle, RUX 0.75%, and RUX 1.5% groups, respectively. [d] Includes patients aged <4 y; data were available for 17, 24, and 29 patients in the vehicle, RUX 0.75%, and RUX 1.5% groups, respectively.
AD, atopic dermatitis; bid, twice daily; BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; EASI, Eczema Area Severity Index; IDQOL, Infants' Dermatitis Quality of Life Index; IGA, Investigator's Global Assessment; NA, not available; NRS, numerical rating scale; POEM, Patient-Oriented Eczema Measure; RUX, ruxolitinib cream; SD, standard deviation.

Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Efficacy Results

Efficacy at Week 8 of the VC Period



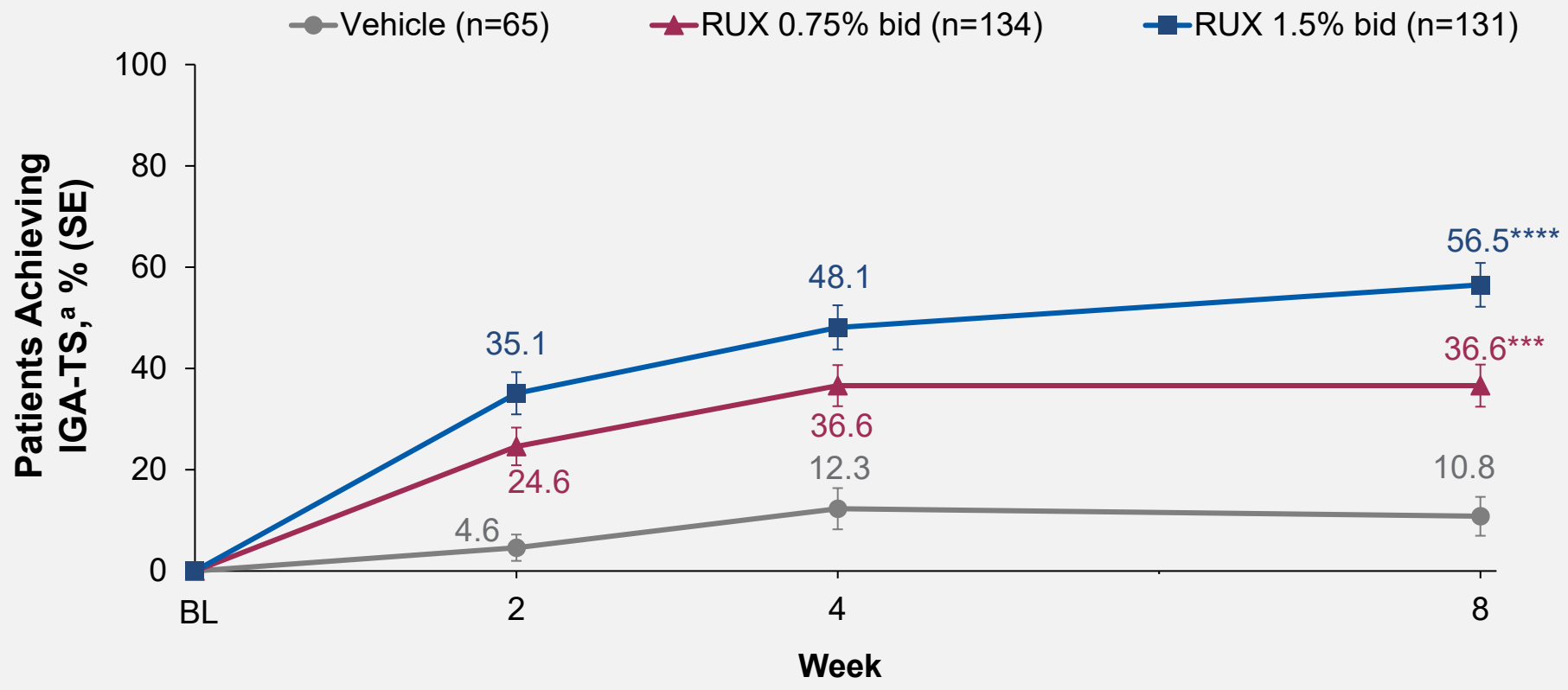
*** *P*<0.001 vs vehicle; **** *P*<0.0001 vs vehicle. [a] Patients with missing data were imputed as nonresponders at weeks 2, 4 and 8. [b] Patients aged 6-11 y with baseline itch NRS ≥4 were included in this analysis.

bid, twice daily; EASI-75/90, ≥75%/90% improvement in Eczema Area Severity Index from baseline; IGA-TS, Investigator's Global Assessment–Treatment Success (IGA score of 0/1 with a ≥2-point improvement from baseline); NRS, numerical rating scale; NRS4, ≥4-point reduction in numerical rating scale score; RUX, ruxolitinib cream; VC, vehicle-controlled.

Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Proportion of Patients Achieving IGA-TS Through Week 8

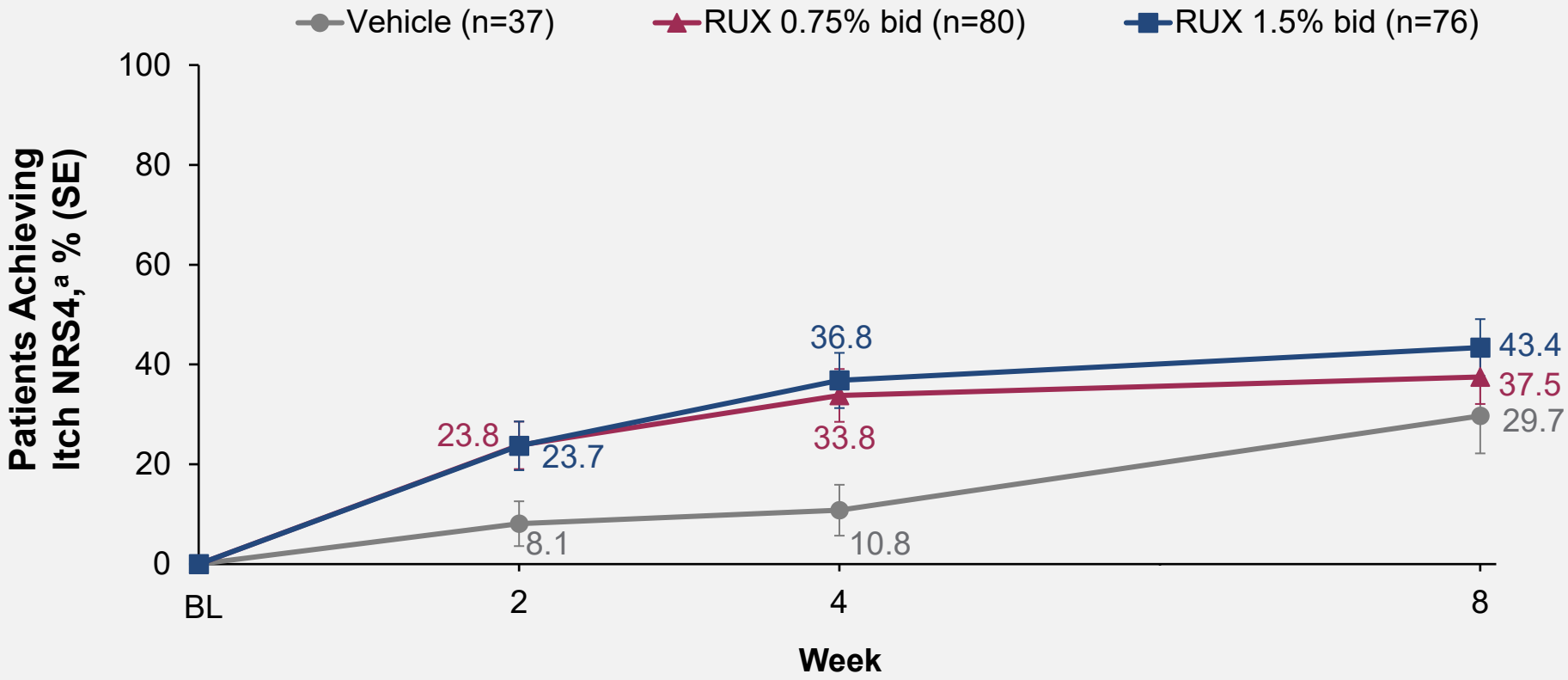
Primary Endpoint



*** *P*<0.001 vs vehicle. **** *P*<0.0001 vs vehicle. [a] Patients with missing data were imputed as nonresponders at weeks 2, 4, and 8.
bid, twice daily; BL, baseline; IGA-TS, Investigator's Global Assessment–Treatment Success (IGA score of 0/1 with a ≥2-point improvement from baseline); RUX, ruxolitinib cream.
Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. Supplementary appendix. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Proportion of Patients Aged 6-11 Years Achieving Itch NRS4

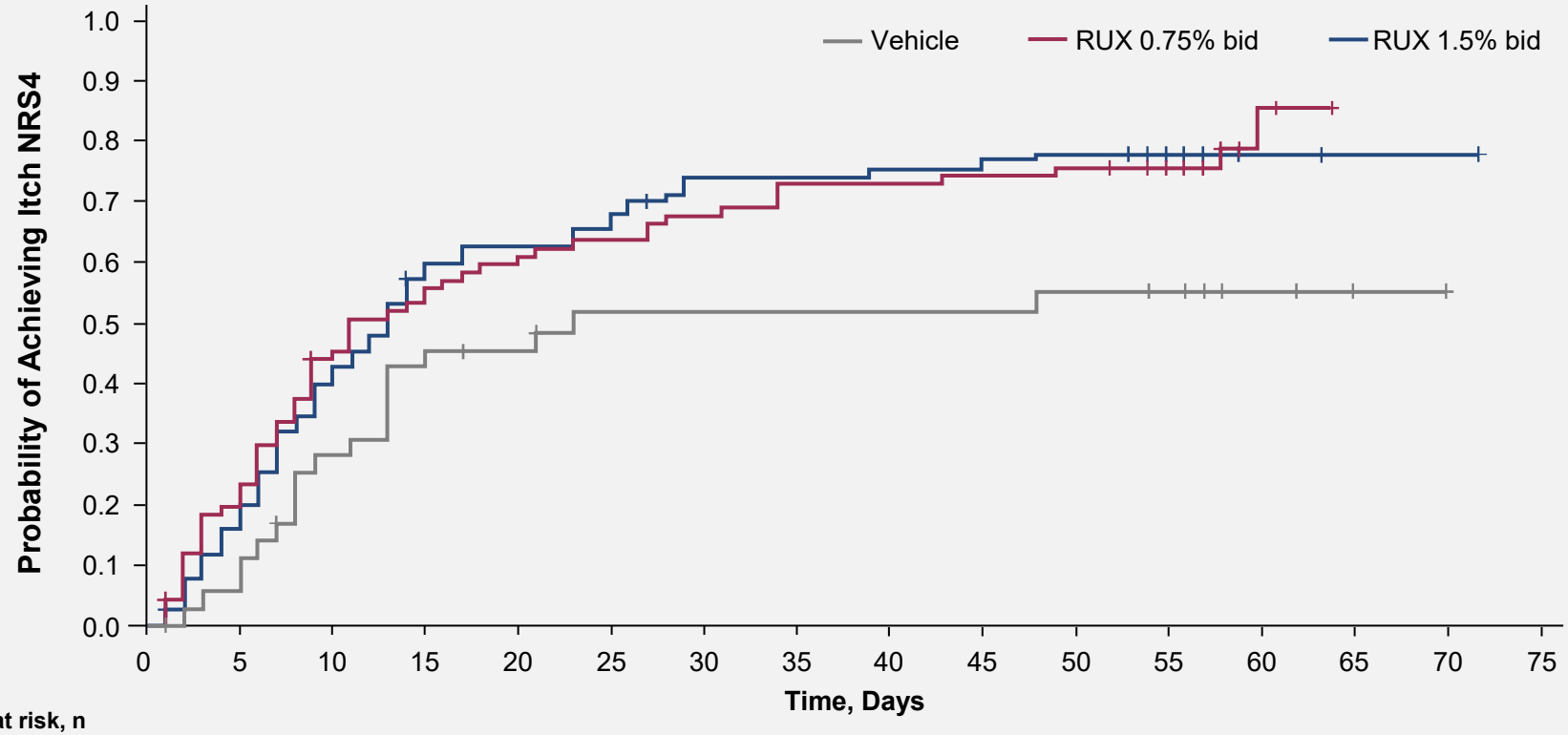
Key Secondary Endpoint



[a] Patients aged 6-11 y with itch NRS score ≥4 at baseline were included in this analysis. Patients with missing data were imputed as nonresponders at weeks 2, 4, and 8.
bid, twice daily; BL, baseline; NRS4, ≥4-point reduction in numerical rating scale score; RUX, ruxolitinib cream.
Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Time to Achieve Itch NRS4 in Patients Aged 6-11 Years

Secondary Endpoint



Patients at risk, n																
Vehicle	37	34	25	20	18	14	14	14	14	14	13	12	3	2	1	0
RUX 0.75% bid	79	62	42	35	30	27	24	20	20	19	18	15	3	0		
RUX 1.5% bid	76	63	45	31	27	25	18	18	17	17	15	13	2	1	1	0

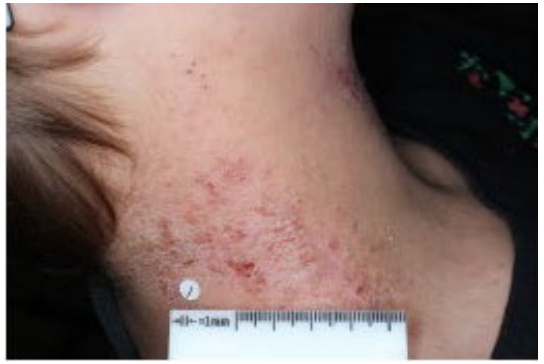
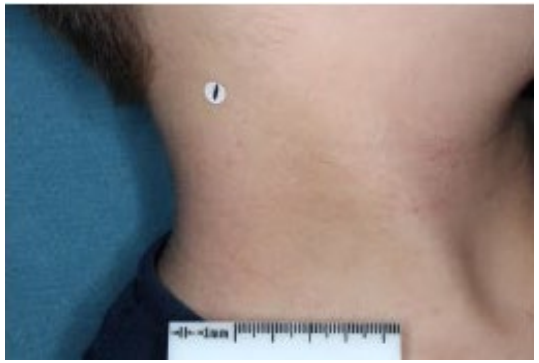
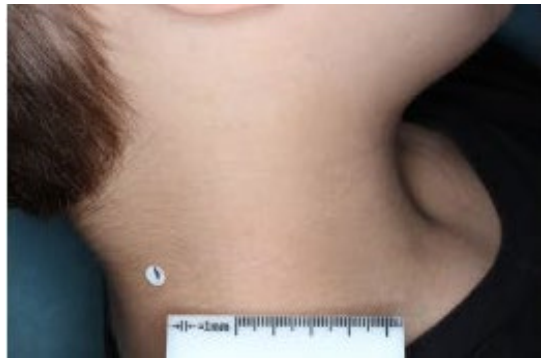
* *P*<0.05 vs vehicle.
bid, twice daily; NRS4, ≥4-point reduction in numerical rating scale score; RUX, ruxolitinib.
Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Clinical Images of a Patient With Improvement in AD at Week 8

RUX 0.75% Twice Daily

11-year-old White male with AD on the neck (right side)

RUX 0.75% bid

Baseline	Week 2	Week 8
		
BSA=16% **IGA=3** **Total EASI=18.6**	**BSA=16%** **IGA=2** **Total EASI=7.6**	**BSA=6%** **IGA=1** **Total EASI=4.0**

AD, atopic dermatitis; bid, twice daily; BSA, body surface area; EASI, Eczema Area Severity Index; IGA, Investigator's Global Assessment; RUX, ruxolitinib cream.

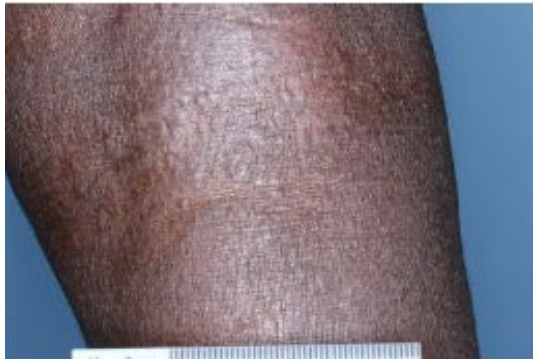
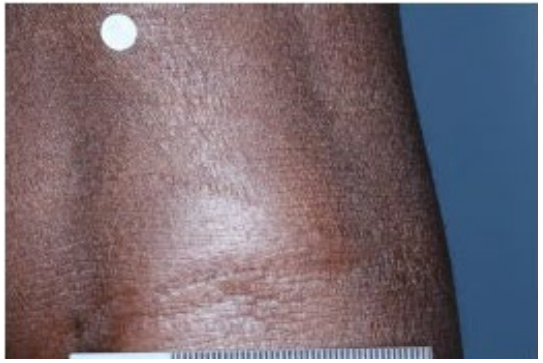
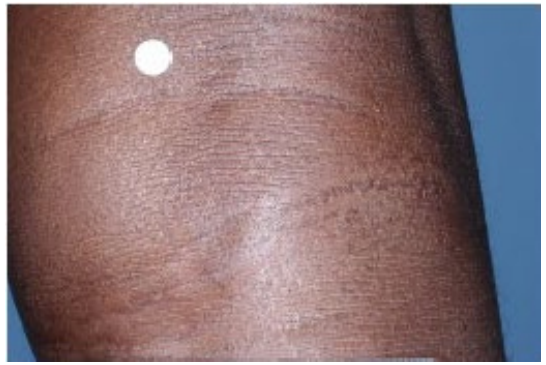
Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. Supplementary appendix. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Clinical Images of a Patient With Improvement in AD at Week 8

RUX 0.75% Twice Daily

9-year-old Black female with AD on the back of the leg (right)

RUX 0.75% bid

Baseline	Week 2	Week 8
		
BSA=7% **IGA=3** **Total EASI=17.6**	**BSA=0%** **IGA=0** **Total EASI=0**	**BSA=0%** **IGA=0** **Total EASI=0**

AD, atopic dermatitis; bid, twice daily; BSA, body surface area; EASI, Eczema Area Severity Index; IGA, Investigator's Global Assessment; RUX, ruxolitinib cream.

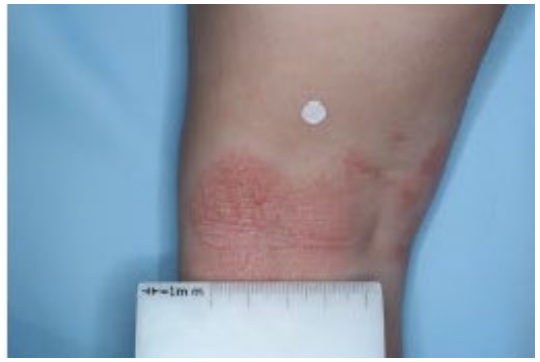
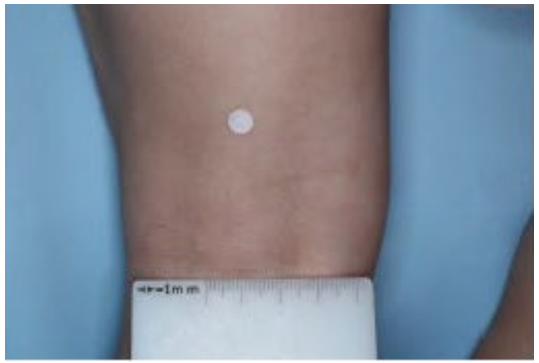
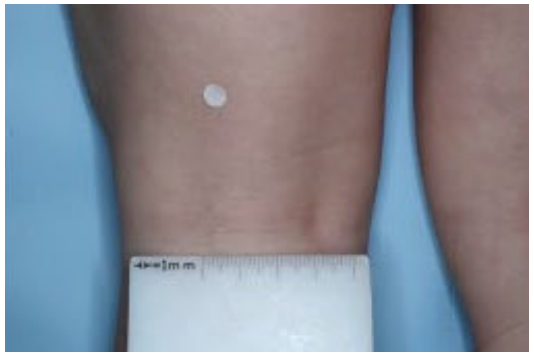
Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. Supplementary appendix. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Clinical Images of a Patient With Improvement in AD at Week 8

RUX 1.5% Twice Daily

2-year-old White male with AD on the posterior knee (left)

RUX 1.5% bid

Baseline	Week 2	Week 8
		
BSA=16% **IGA=3** **Total EASI=7.8**	**BSA=0%** **IGA=3** **Total EASI=0**	**BSA=0%** **IGA=0** **Total EASI=0**

AD, atopic dermatitis; bid, twice daily; BSA, body surface area; EASI, Eczema Area Severity Index; IGA, Investigator's Global Assessment; RUX, ruxolitinib cream.

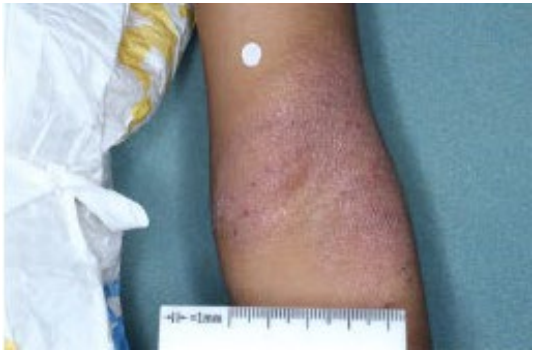
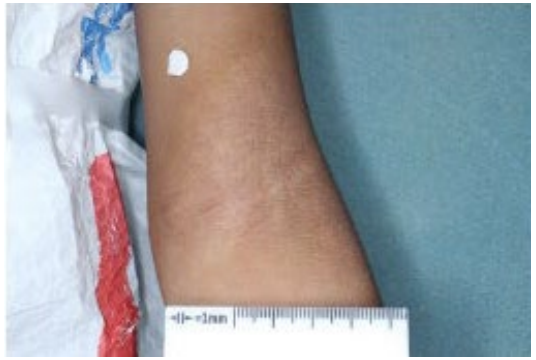
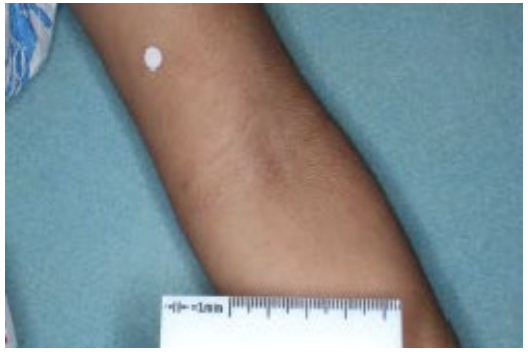
Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. Supplementary appendix. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Clinical Images of a Patient With Improvement in AD at Week 8

RUX 1.5% Twice Daily

5-year-old Asian male with AD on the front side of the elbow (left)

RUX 1.5% bid

Baseline	Week 2	Week 8
		
BSA=15% **IGA=3** **Total EASI=12.8**	**BSA=3%** **IGA=1** **Total EASI=0.5**	**BSA=1%** **IGA=1** **Total EASI=0.3**

AD, atopic dermatitis; bid, twice daily; BSA, body surface area; EASI, Eczema Area Severity Index; IGA, Investigator's Global Assessment; RUX, ruxolitinib cream.

Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. Supplementary appendix. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Safety Results

Safety During VC Period

n (%)	Vehicle (n=65)	RUX 0.75% bid (n=134)	RUX 1.5% bid (n=130)
Patients with TEAE	18 (27.7)	35 (26.1)	48 (36.9)
Most common TEAEs[a]			
Upper respiratory tract infection	2 (3.1)	7 (5.2)	11 (8.5)
Nasopharyngitis	1 (1.5)	2 (1.5)	8 (6.2)
COVID-19	1 (1.5)	4 (3.0)	5 (3.8)
Application-site pain	0	5 (3.7)	3 (2.3)
Pyrexia	0	4 (3.0)	3 (2.3)
Vomiting	1 (1.5)	2 (1.5)	3 (2.3)
Cough	2 (3.1)	3 (2.2)	1 (0.8)
Abdominal pain	2 (3.1)	0	0

n (%)	Vehicle (n=65)	RUX 0.75% bid (n=134)	RUX 1.5% bid (n=130)
Patients with any treatment-related TEAE	3 (4.6)	8 (6.0)	7 (5.4)
Most common treatment-related TEAEs[b]			
Application-site pain	0	5 (3.7)	3 (2.3)
Application-site erythema	0	0	2 (1.5)
Discontinuation due to a TEAE[c]	0	1 (0.7)	1 (0.8)
Patients with dose interruption due to a TEAE[d]	4 (6.2)	4 (3.0)	1 (0.8)
Patients with grade ≥3 TEAE[e]	0	0	2 (1.5)
Patients with serious TEAE	0	0	0

[a] Occurring in >2% of patients in any treatment group. [b] Occurring in ≥2 patients in any treatment group. [c] Discontinuations due to grade 2 application-site pain, possibly related to study drug (RUX 0.75%); grade 3 worsening of AD, unlikely related to study drug (RUX 1.5%). [d] TEAEs resulting in dose interruptions included contact dermatitis, application-site infection, blood lactate dehydrogenase increased, blood alkaline phosphatase increased, and application-site pruritus for vehicle; application-site irritation, upper respiratory tract infection, application-site pain, upper abdominal pain, maculopapular rash for RUX 0.75%; and lymphopenia for RUX 1.5%. [e] None were related to treatment. One patient had grade 3 sleep apnea, grade 3 adenoidal hypertrophy, and grade 3 tonsillar hypertrophy. One patient had grade 3 worsening of AD, unlikely related to study drug.

AD, atopic dermatitis; bid, twice daily; RUX, ruxolitinib cream; TEAE, treatment-emergent adverse event; VC, vehicle-controlled.

Eichenfield L, et al. *J Am Acad Dermatol*. 2025:S0190-9622(25)02124-3. doi: 10.1016/j.jaad.2025.05.1385. Online ahead of print.

Ruxolitinib Cream Warnings and Precautions

Ruxolitinib Cream: Boxed Warning

Serious Infections

- Patients treated with oral Janus kinase inhibitors for inflammatory conditions are at risk for developing serious infections that may lead to hospitalization or death
- Reported infections include:
  - Active tuberculosis, which may present with pulmonary or extrapulmonary disease
  - Invasive fungal infections, including cryptococcosis, and pneumocystosis
  - Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens
- Avoid use of OPZELURA in patients with an active, serious infection, including localized infections. If a serious infection develops, interrupt OPZELURA until the infection is controlled
- The risks and benefits of treatment with OPZELURA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection
- Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with OPZELURA

Opzelura® (ruxolitinib) cream. Prescribing information. Incyte Corporation; August 2024.

Ruxolitinib Cream: Boxed Warning (cont)

Mortality

- In a large, randomized, postmarketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing an oral JAK inhibitor to tumor necrosis factor (TNF) blocker treatment, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor

Malignancies

- Malignancies were reported in patients treated with OPZELURA. Lymphoma and other malignancies have been observed in patients receiving JAK inhibitors used to treat inflammatory conditions. In RA patients treated with an oral JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk

JAK, Janus kinase.

Opzelura® (ruxolitinib) cream. Prescribing information. Incyte Corporation; August 2024.

Ruxolitinib Cream: Boxed Warning (cont)

Major Adverse Cardiovascular Events (MACE)

- In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with an oral JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke), was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue OPZELURA in patients who have experienced a myocardial infarction or stroke

Thrombosis

- Thromboembolic events were observed in trials with OPZELURA. Thrombosis, including pulmonary embolism (PE), deep venous thrombosis (DVT), and arterial thrombosis have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with an oral JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid OPZELURA in patients at risk. If symptoms of thrombosis occur, discontinue OPZELURA and treat appropriately

JAK, Janus kinase; RA, rheumatoid arthritis; TNF, tumor necrosis factor.

Opzelura® (ruxolitinib) cream. Prescribing information. Incyte Corporation; August 2024.

Ruxolitinib Cream: Warnings & Precautions

Serious Infections

- Avoid use of OPZELURA in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating OPZELURA in patients:
  - with chronic or recurrent infection
  - with a history of a serious or an opportunistic infection
  - who have been exposed to tuberculosis
  - who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or
  - with underlying conditions that may predispose them to infection

- Closely monitor patients for the development of signs and symptoms of infection during and after treatment with OPZELURA. Interrupt OPZELURA if a patient develops a serious infection, an opportunistic infection, or sepsis. Do not resume OPZELURA until the infection is controlled

Opzelura® (ruxolitinib) cream. Prescribing information. Incyte Corporation; August 2024.

Ruxolitinib Cream: Warnings & Precautions (cont)

Serious Infections

Tuberculosis

- Consider evaluating patients for latent and active TB infection prior to administration of OPZELURA
- During OPZELURA use, monitor patients for the development of signs and symptoms of TB

Viral Reactivation

- If a patient develops herpes zoster, consider interrupting OPZELURA treatment until the episode resolves

Hepatitis B and C

- OPZELURA initiation is not recommended in patients with active hepatitis B or hepatitis C

TB, tuberculosis.

Opzelura® (ruxolitinib) cream. Prescribing information. Incyte Corporation; August 2024.

Ruxolitinib Cream: Warnings & Precautions (cont)

Mortality

- In a large, randomized, postmarketing safety study of an oral JAK inhibitor in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed in patients treated with the JAK inhibitor compared with TNF blockers
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA

JAK, Janus kinase; TNF, tumor necrosis factor.

Opzelura® (ruxolitinib) cream. Prescribing information. Incyte Corporation; August 2024.

Ruxolitinib Cream: Warnings & Precautions (cont)

Malignancy and Lymphoproliferative Disorders

- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA, particularly in patients with a known malignancy (other than successfully treated non-melanoma skin cancers), patients who develop a malignancy when on treatment, and patients who are current or past smokers

Non-melanoma Skin Cancers

- Perform periodic skin examinations during OPZELURA treatment and following treatment as appropriate. Exposure to sunlight and UV light should be limited by wearing protective clothing and using broad-spectrum sunscreen

UV, ultraviolet.

Opzelura® (ruxolitinib) cream. Prescribing information. Incyte Corporation; August 2024.

Ruxolitinib Cream: Warnings & Precautions (cont)

Major Adverse Cardiovascular Events and Thrombosis

Major Adverse Cardiovascular Events (MACE)

- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OPZELURA, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. Discontinue OPZELURA in patients that have experienced a myocardial infarction or stroke

Thrombosis

- Avoid OPZELURA in patients who may be at increased risk of thrombosis. If symptoms of thrombosis occur, discontinue OPZELURA and evaluate and treat patients appropriately

Opzelura® (ruxolitinib) cream. Prescribing information. Incyte Corporation; August 2024.

Ruxolitinib Cream: Warnings & Precautions (cont)

Thrombocytopenia, Anemia and Neutropenia, and Lipid Elevations

Thrombocytopenia, Anemia, and Neutropenia

- Thrombocytopenia, anemia, and neutropenia were reported in the clinical trials with OPZELURA. Consider the benefits and risks for individual patients who have a known history of these events prior to initiating therapy with OPZELURA. Perform CBC monitoring as clinically indicated. If signs and/or symptoms of clinically significant thrombocytopenia, anemia, and neutropenia occur, patients should discontinue OPZELURA

Lipid Elevations

- Treatment with oral ruxolitinib has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides

CBC, complete blood count.

Opzelura® (ruxolitinib) cream. Prescribing information. Incyte Corporation; August 2024.

Incyte Dermatology

FOR MEDICAL INFORMATION PURPOSES ONLY