Incyte Dermatology

Phase 2, Double-Blind, Dose-Ranging Study

Ruxolitinib Cream 1.5%, Triamcinolone Cream 0.1%, and Vehicle

MSL-RCM-US-0236 08/26

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Notice

- Some information contained in this presentation may not be included in the approved Prescribing Information for OPZELURA® (ruxolitinib) cream. 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. Please consult the full Prescribing Information, including boxed warnings, before using or prescribing OPZELURA

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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 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable

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.

FDA, US Food and Drug Administration.
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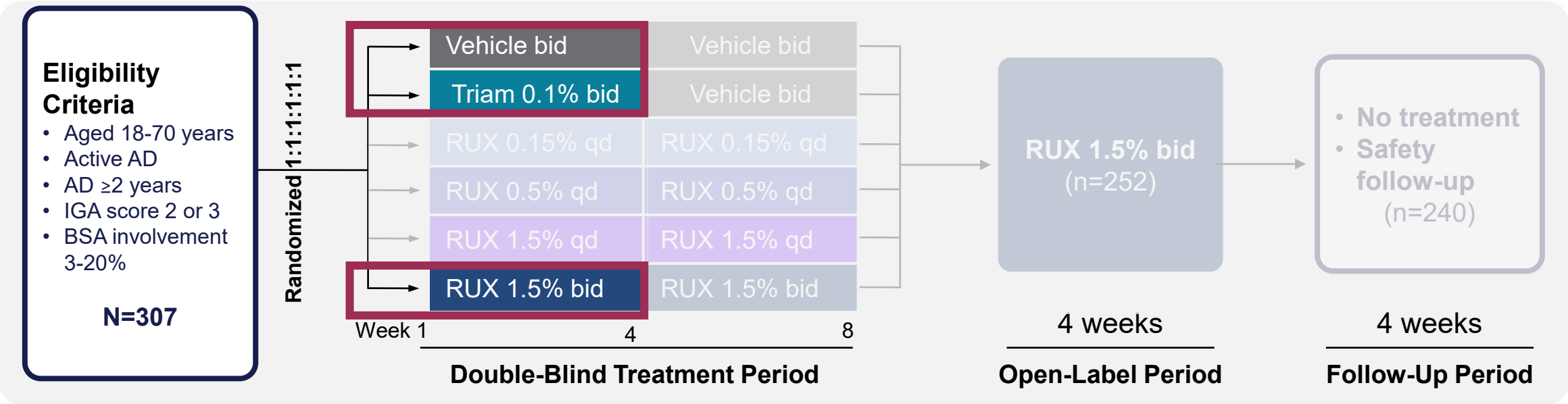
Study Design

A phase 2, randomized, double-blind, dose-ranging, vehicle- and active-controlled study in adult patients with AD conducted in the United States and Canada at 52 study sites[1-3]



- **Primary endpoint: mean percentage change from baseline in EASI score with RUX 1.5% bid vs vehicle bid at week 4**
- **Secondary endpoints: mean percentage change from baseline in EASI score at week 4 in patients treated with RUX qd or bid vs triamcinolone cream 0.1% bid or vehicle bid**; percentage of patients achieving IGA-TS,[a] EASI-75/90, or NRS4;[b] mean change in Itch NRS from baseline; and safety

[a] IGA score of 0-1 with an improvement of ≥2 points from baseline. [b] Improvement of ≥4 points from baseline in Itch NRS.
AD, atopic dermatitis; bid, twice daily; EASI, Eczema Area and Severity Index; EASI-75/90, ≥75%/90% improvement from baseline in EASI; IGA, Investigator's Global Assessment; IGA-TS, IGA–Treatment Success; NRS, Numerical Rating Scale; qd, once daily; RUX, ruxolitinib cream; Triam, triamcinolone acetonide cream.

1. Kim BS, et al. *J Allergy Clin Immunol*. 2020;145:572-582. 2. Kim BS, et al. *J Am Acad Dermatol*. 2020;82:1305-1313. 3. Kircik L, et al. *J Drugs Dermatol.* 2025;24:1036-1039.

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Patient Eligibility

Key inclusion criteria[1,2]

- Patients aged 18-70 years with active AD
- History of AD ≥2 years
- IGA score of 2 or 3
- BSA involvement of 3-20%

Key exclusion criteria[2]

- Clinically meaningful, active infections
- Use of other topical AD treatments within 2 weeks of baseline
- Systemic drug use within 4 weeks or 5 half-lives of baseline

Treatment of facial dermatitis was not permitted because of the restrictions on the use of triamcinolone on the face[2]

AD, atopic dermatitis; BSA, body surface area; IGA, Investigator's Global Assessment.

1. Kircik L, et al. *J Drugs Dermatol.* 2025;24:1036-1039. *2.* Kim BS, et al. *J Allergy Clin Immunol*. 2020;145:572-582.

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Baseline Demographics and Clinical Characteristics[1]

Demographics	Vehicle bid (n=52)	Triam 0.1% bid (n=51)	RUX 1.5% bid (n=50)
Age, median (range), y	31.5 (18-69)	35.0 (18-69)	35.5 (18-70)
Female, n (%)	32 (61.5)	28 (54.9)	24 (48.0)
Race, n (%)			
White	27 (51.9)	28 (54.9)	33 (66.0)
Black	15 (28.8)	13 (25.5)	13 (26.0)
Asian	8 (15.4)	8 (15.7)	2 (4.0)
Other	2 (3.8)	2 (3.9)	2 (4.0)

Clinical Characteristics	Vehicle bid (n=52)	Triam 0.1% bid (n=51)	RUX 1.5% bid (n=50)
BSA, mean (SD), %	9.5 (5.0)	9.9 (5.5)	10.5 (5.2)
Facial lesions, n (%)	21 (40.4)	21 (41.2)	18 (36.0)
Baseline EASI, mean (SD)	8.6 (5.1)	8.4 (4.7)	8.4 (4.7)
≤7, n (%)	24 (46.2)	24 (47.1)	25 (50.0)
>7, n (%)	28 (53.8)	27 (52.9)	25 (50.0)
Baseline IGA,[a] n (%)			
2	15 (28.8)	18 (35.3)	14 (28.0)
3	36 (69.2)	33 (64.7)	36 (72.0)
Itch NRS score,[b] mean (SD)	6.0 (2.1)	5.2 (2.2)	5.9 (2.3)
Duration of disease, median (range), y	19.5 (2.2-65.3)	24.8 (2.3-62.2)	21.2 (0.1-64.8)
Number of flares in last 12 months, mean (SD)	10.6 (20.2)	4.7 (6.0)	12.8 (51.7)

Demographics and baseline clinical characteristics were evenly distributed across all treatment groups[2]

[a] Excludes 1 patient with an IGA of 4 at baseline. [b] Range of NRS, 0-10 (0, no itch; 10, worst imaginable itch).
BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; NRS, Numerical Rating Scale; Triam, triamcinolone acetonide cream.
1. Kim BS, et al. *J Allergy Clin Immunol*. 2020;145:572-582. 2. Kircik L, et al. *J Drugs Dermatol.* 2025;24:1036-1039.

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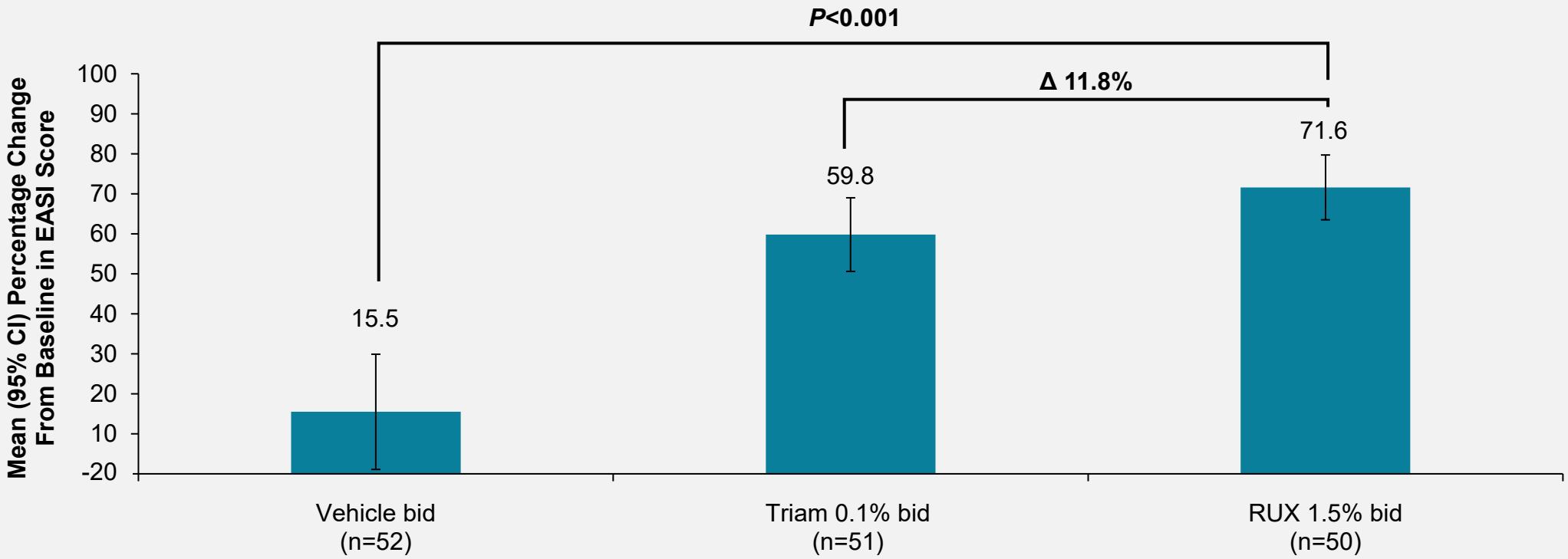
Mean Percentage Change From Baseline in EASI Score at Week 4



At week 4, RUX 1.5% bid demonstrated statistically significant improvement in EASI scores vs vehicle and numerically greater rates of improvement in EASI scores vs triamcinolone cream 0.1% bid

Descriptive analysis only; no statistical comparisons between RUX and triamcinolone are shown. No conclusions of efficacy or safety should be made based on these results.

bid, twice daily; EASI, Eczema Area and Severity Index; RUX, ruxolitinib cream; Triam, triamcinolone acetonide cream.

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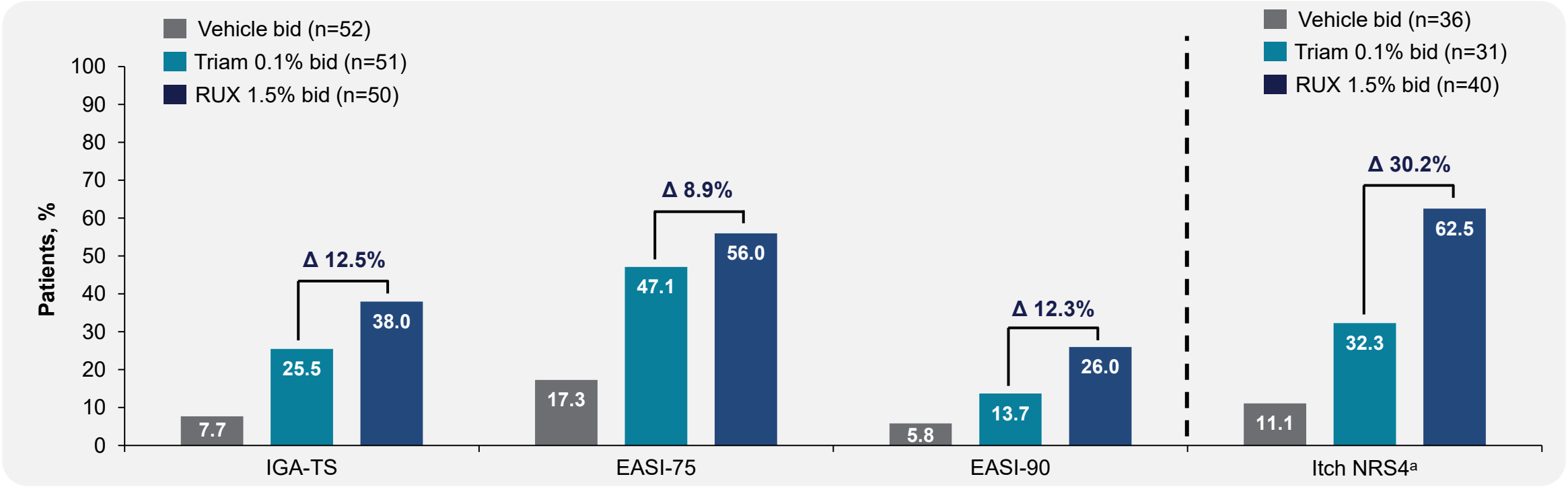
Efficacy Results at Week 4



- ***More patients who applied RUX 1.5% bid achieved IGA-TS and EASI-75/90 at week 4 than those who applied triamcinolone cream 0.1% bid***
- ***More patients who applied RUX 1.5% bid achieved Itch NRS4 at week 4 than those who applied triamcinolone cream 0.1% bid (OR [95% CI], 3.5 [1.3-9.5]; P=0.0128)***

Descriptive analysis only; no statistical comparisons between RUX and triamcinolone are shown. No conclusions of efficacy or safety should be made based on these results.

Patients who discontinued treatment were included as nonresponders. [a] Patients included in this analysis had an Itch NRS ≥4 at baseline.

bid, twice daily; EASI, Eczema Area and Severity Index; EASI-75/90, ≥75%/90% improvement from baseline in EASI score; IGA-TS, Investigator's Global Assessment–Treatment Success; Itch NRS2, ≥2-point improvement in Itch Numerical Rating Scale score from baseline; Itch NRS4, ≥4-point improvement in Itch NRS score from baseline; OR, odds ratio; RUX, ruxolitinib cream; Triam, triamcinolone acetonide cream. Kircik L, et al. J *Drugs Dermatol.* 2025;24:1036-1039.

Reproduced with permission from Kircik L, Sturm D, Kallender H, Xue Z, Nasir A. Ruxolitinib Cream Versus Triamcinolone Cream in Adults With Mild to Moderate Atopic Dermatitis. *J Drugs Dermatol*. 2025 Oct 1;24(10):1036-1039. doi: 10.36849/JDD.8920.

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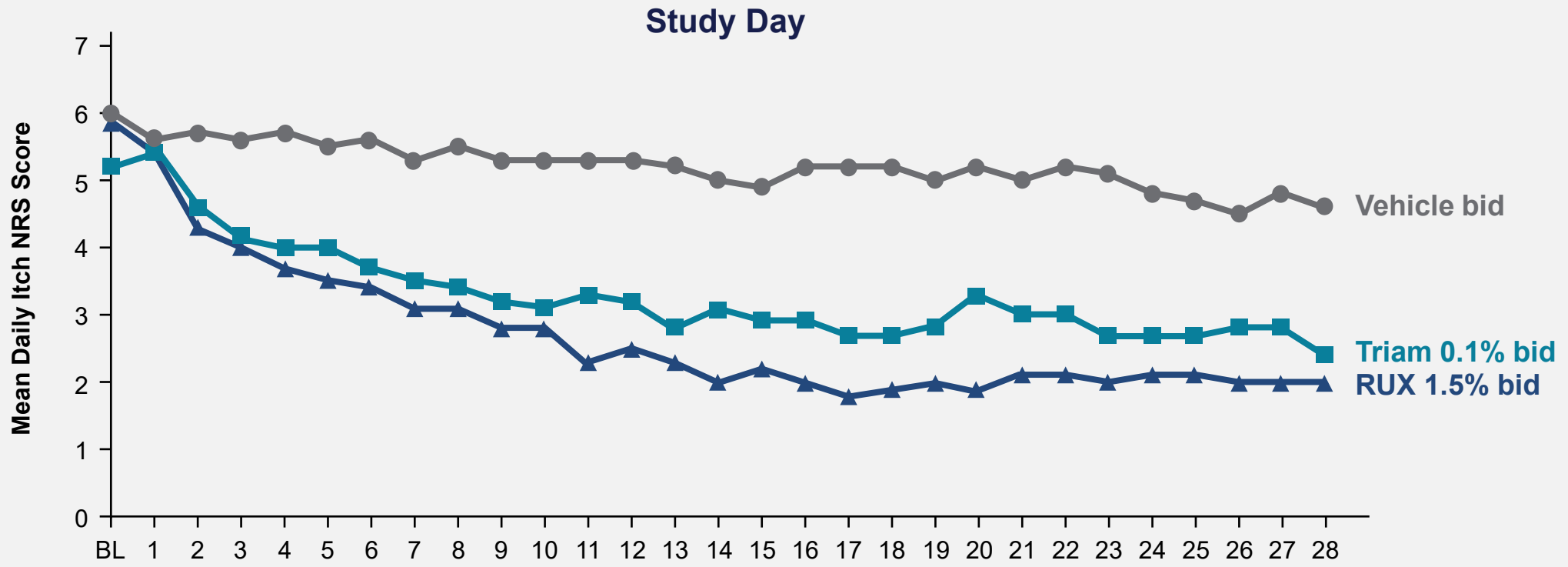
Mean Daily Itch NRS Scores From Baseline Through Week 4



Patients, n	BL	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Vehicle bid	48	44	45	45	46	44	46	48	49	47	48	46	48	46	43	45	40	39	42	41	40	41	41	43	38	38	35	40	42
Triam 0.1% bid	44	45	47	44	45	45	44	44	45	42	46	43	43	43	45	43	46	42	44	41	44	47	41	41	39	42	43	39	41
RUX 1.5% bid	47	46	43	42	44	42	47	44	45	48	46	49	47	44	47	45	46	42	43	42	42	46	42	46	46	43	43	47	44

Mean daily itch scores were numerically lower for RUX 1.5% bid vs triamcinolone cream 0.1% bid from day 2 through day 28, despite a higher itch score at baseline for RUX 1.5% bid

Descriptive analysis only; no statistical comparisons between RUX and triamcinolone are shown. No conclusions of efficacy or safety should be made based on these results.

bid, twice daily; BL, baseline; NRS, Numerical Rating Scale; RUX, ruxolitinib cream; Triam, triamcinolone acetonide cream.Kircik L, et al. *J Drugs Dermatol.* 2025;24:1036-1039.

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TEAEs at 4 Weeks

n (%)	Vehicle bid (n=52)	Triam 0.1% bid (n=51)	RUX 1.5% bid (n=50)
Patients with TEAE	12 (23.1)	11 (21.6)	10 (20.0)
Most common TEAEs[a]			
Nasopharyngitis	3 (5.8)	0	2 (4.0)
AD	3 (5.8)	0	0
Application-site pain	2 (3.8)	0	1 (2.0)
Headache	1 (1.9)	0	2 (4.0)
Application-site pruritus	2 (3.8)	0	0
Upper respiratory tract infection	2 (3.8)	0	0
Patients with treatment-related TEAE	5 (9.6)[b]	1 (2.0)[c]	3 (6.0)[d]
Patients with grade ≥3 TEAE	0	1 (2.0)[e]	0
Patients with serious TEAE	0	1 (2.0)[e]	0
Patients who discontinued due to a TEAE	1 (1.9)	0	0

Descriptive analysis only; no statistical comparisons between RUX and triamcinolone are shown. No conclusions of efficacy or safety should be made based on these results.

[a] Occurred in ≥2 patients in any treatment group. [b] Included application-site pain (n=2), application-site pruritus (n=2), application-site reaction (n=1), application-site erythema (n=1), increased blood lactate dehydrogenase (n=1), and pruritus (n=1). [c] Included folliculitis (n=1). [d] Included application-site erythema, application-site pain, application-site papules, and skin exfoliation (all n=1). [e] Grade 3 myocardial infarction considered unrelated to treatment.

AD, atopic dermatitis; AE, adverse event; bid, twice daily; RUX, ruxolitinib cream; Triam, triamcinolone acetonide cream; TEAE, treatment-emergent adverse event.

Kircik L, et al. *J Drugs Dermatol.* 2025;24:1036-1039.

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Important Safety Information

SERIOUS INFECTIONS
Patients treated with oral Janus kinase (JAK) inhibitors for inflammatory conditions are at risk for serious infections that may lead to hospitalization or death. These include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis.**
- **Other bacterial or viral infections, including herpes zoster, due to opportunistic pathogens.**

Avoid use in patients with an active, serious infection. If a serious infection develops, stop OPZELURA until the infection is controlled. Carefully consider the benefits and risks of treatment prior to use in patients with chronic or recurrent infection. Closely monitor patients for the development of signs of infection during and after treatment with OPZELURA.

Serious lower respiratory tract infections were reported in the clinical development program with topical ruxolitinib.

No cases of active tuberculosis (TB) were reported in clinical trials with OPZELURA; however, cases were reported in clinical trials of oral JAK inhibitors to treat inflammatory conditions. Consider evaluating patients for latent and active TB infection prior to treatment. Monitor patients for the development of signs and symptoms of TB.

Viral reactivation, including cases of herpes virus reactivation were reported in clinical trials with JAK inhibitors used to treat inflammatory conditions including OPZELURA. If a patient develops herpes zoster, consider interrupting OPZELURA treatment until the episode resolves.

Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking oral ruxolitinib. OPZELURA is not recommended in patients with active hepatitis B or hepatitis C.

POST-MARKETING SAFETY
In a large randomized postmarketing safety study of rheumatoid arthritis (RA) patients 50 years and older with at least one cardiovascular risk factor, the following were higher with an oral JAK inhibitor than with a tumor necrosis factor (TNF) blocker: all-cause mortality, major adverse cardiovascular events (defined as cardiovascular death, myocardial infarction, and stroke), thrombosis, malignancies (excluding non-melanoma skin cancer [NMSC]). Consider the benefits and risks prior to initiating or continuing therapy with OPZELURA. **Discontinue OPZELURA in patients who have experienced a myocardial infarction or stroke.**

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. Patients who are current or past smokers are at increased risk. Inform patients about the symptoms of serious cardiovascular events and the steps to take if they occur.

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

Non-melanoma skin cancers, including basal cell and squamous cell carcinoma, have occurred in patients treated with OPZELURA. Perform periodic skin examinations during OPZELURA treatment. Limit exposure to sunlight and UV light with protective clothing and broad-spectrum sunscreen.

OPZELURA® (ruxolitinib) cream. Prescribing information. Incyte Corporation; June 2026.

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Important Safety Information (cont)

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. Avoid OPZELURA in patients at risk. If symptoms of thrombosis occur, discontinue OPZELURA and treat appropriately.

CYTOPENIAS

Thrombocytopenia, anemia, neutropenia, lymphopenia, and leukopenia were reported in the clinical trials with OPZELURA. Consider the benefits and risks for patients who have a known history of these events prior to initiating therapy. Perform CBC monitoring as clinically indicated. Discontinue OPZELURA if symptoms associated with clinically significant decreases in laboratory values occur.

POTENTIAL RISKS RELATED TO JAK INHIBITION

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

ADVERSE REACTIONS

In atopic dermatitis, the most common adverse reactions (≥1%) are nasopharyngitis, bronchitis, ear infection, eosinophil count increased, urticaria, diarrhea, folliculitis, tonsillitis, rhinorrhea, upper respiratory tract infection, COVID-19, application site reaction, pyrexia, and white blood cell decreased.

In nonsegmental vitiligo, the most common adverse reactions (≥1%) are application site acne, application site pruritus, nasopharyngitis, headache, urinary tract infection, application site erythema, and pyrexia.

PREGNANCY REGISTRY

There is a registry that monitors pregnancy outcomes in persons exposed to OPZELURA during pregnancy. Pregnant persons exposed to OPZELURA and healthcare providers should report OPZELURA exposure by calling 1-855-463-3463 or visiting www.opzelura.pregnancy.incyte.com.

LACTATION

Advise women not to breastfeed during treatment with OPZELURA and for approximately four weeks after the last dose (approximately 5-6 elimination half-lives).

Please see Full Prescribing Information, including Boxed Warning, and Medication Guide for OPZELURA.

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