Incyte Dermatology

Long-Term Efficacy and Safety of Ruxolitinib Cream in Atopic Dermatitis

Results From TRuE-AD1, TRuE-AD2, and TRuE-AD3

MSL-RCM-US-0234 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.
OPZELURA® (ruxolitinib) cream. Prescribing information. Incyte Corporation; June 2026.

TRuE-AD1 and TRuE-AD2

Two Identically Designed Phase 3 Studies That Evaluated the Efficacy and Safety of Ruxolitinib Cream in Adolescents and Adults With Atopic Dermatitis

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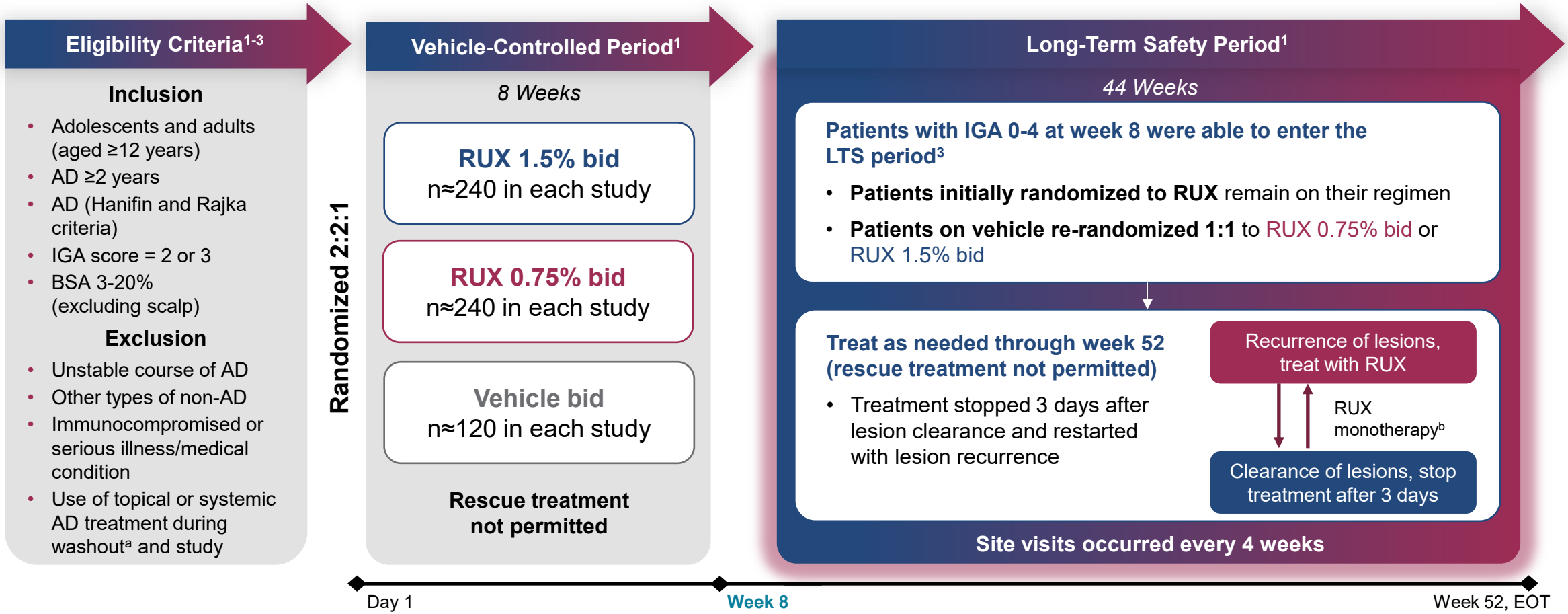
Study Design



Primary Endpoint: *IGA-TS*
Key Secondary Endpoints: *EASI-75, Itch NRS4*

[a] Washout period was 5 half-lives or 12 weeks for biologics, 4 weeks for systemic corticosteroids and other immunomodulating agents, and 1 week for topical agents.[2] [b] 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 if an unscheduled additional visit was needed.[1]

AD, atopic dermatitis; bid, twice daily; BSA, body surface area; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; IGA, Investigator's Global Assessment; IGA-TS, IGA–Treatment Success; Itch NRS4, ≥4-point improvement in Itch Numerical Rating Scale score; LTS, long-term safety; RUX, ruxolitinib cream.

1. Papp K, et al. *J Am Acad Dermatol*. 2023;88:1008-1016. 2. Papp K, et al. *J Am Acad Dermatol*. 2021;85:863-872. 3. Data on file. Incyte Corporation.

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Baseline Demographics and Clinical Characteristics

Characteristics	TRuE-AD1			TRuE-AD2		
	Vehicle bid (n=126)	RUX 0.75% bid (n=252)	RUX 1.5% bid (n=253)	Vehicle bid (n=124)	RUX 0.75% bid (n=248)	RUX 1.5% bid (n=246)
Age, median (IQR), y	31.5 (20.0-49.0)	34.0 (19.0-51.0)	30.0 (19.0-47.0)	37.5 (21.5-53.5)	33.0 (19.0-52.0)	32.0 (21.0-49.0)
Age category, n (%)						
12-17 years, n (%)	23 (18.3)	53 (21.0)	47 (18.6)	22 (17.7)	55 (22.2)	45 (18.3)
≥18 years, n (%)	103 (81.7)	199 (79.0)	206 (81.4)	102 (82.3)	193 (77.8)	201 (81.7)
Female, n (%)	79 (62.7)	154 (61.1)	158 (62.5)	80 (64.5)	150 (60.5)	150 (61.0)
Race, n (%)						
White	85 (67.5)	171 (67.9)	177 (70.0)	85 (68.5)	174 (70.2)	178 (72.4)
Black	29 (23.0)	55 (21.8)	56 (22.1)	32 (25.8)	63 (25.4)	57 (23.2)
Asian	8 (6.3)	10 (4.0)	14 (5.5)	2 (1.6)	6 (2.4)	6 (2.4)
Other	4 (3.2)	16 (6.3)	6 (2.4)	5 (4.0)	5 (2.0)	5 (2.0)
BSA, mean ± SD, %	9.2 ± 5.1	9.9 ± 5.4	9.3 ± 5.2	10.1 ± 5.8	10.1 ± 5.3	9.9 ± 5.4
Baseline EASI, mean ± SD	7.4 ± 4.3	8.2 ± 4.8	7.9 ± 4.6	8.2 ± 5.2	8.1 ± 5.0	7.8 ± 4.9
Head/neck region score >0, n (%)	79 (62.7)	151 (59.9)	153 (60.5)	62 (50.0)	129 (52.0)	122 (49.6)
Baseline IGA, n (%)						
2	31 (24.6)	61 (24.2)	60 (23.7)	33 (26.6)	64 (25.8)	63 (25.6)
3	95 (75.4)	191 (75.8)	193 (76.3)	91 (73.4)	184 (74.2)	183 (74.4)
Itch NRS score, mean ± SD	5.1 ± 2.5	5.1 ± 2.3	5.2 ± 2.5	5.1 ± 2.4	5.2 ± 2.5	4.9 ± 2.5
≥4, n (%)	78 (61.9)	156 (61.9)	161 (63.6)	81 (65.3)	168 (67.7)	154 (62.6)
Duration of disease, median (range), y	17.9 (1.9-79.1)	14.1 (1.0-68.8)	16.0 (0-69.2)	15.9 (0.8-70.7)	15.9 (0.1-68.6)	16.6 (0-68.8)
Number of flares in the past 12 months, mean ± SD	9.4 ± 35.2	5.3 ± 7.5	6.0 ± 23.3	5.1 ± 8.1	5.1 ± 5.8	5.9 ± 8.5

Distribution of baseline demographics and clinical characteristics was similar across treatment groups

bid, twice daily; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; IQR, interquartile range; NRS, Numerical Rating Scale; RUX, ruxolitinib cream.

Papp K, et al. *J Am Acad Dermatol*. 2021;85:863-872.

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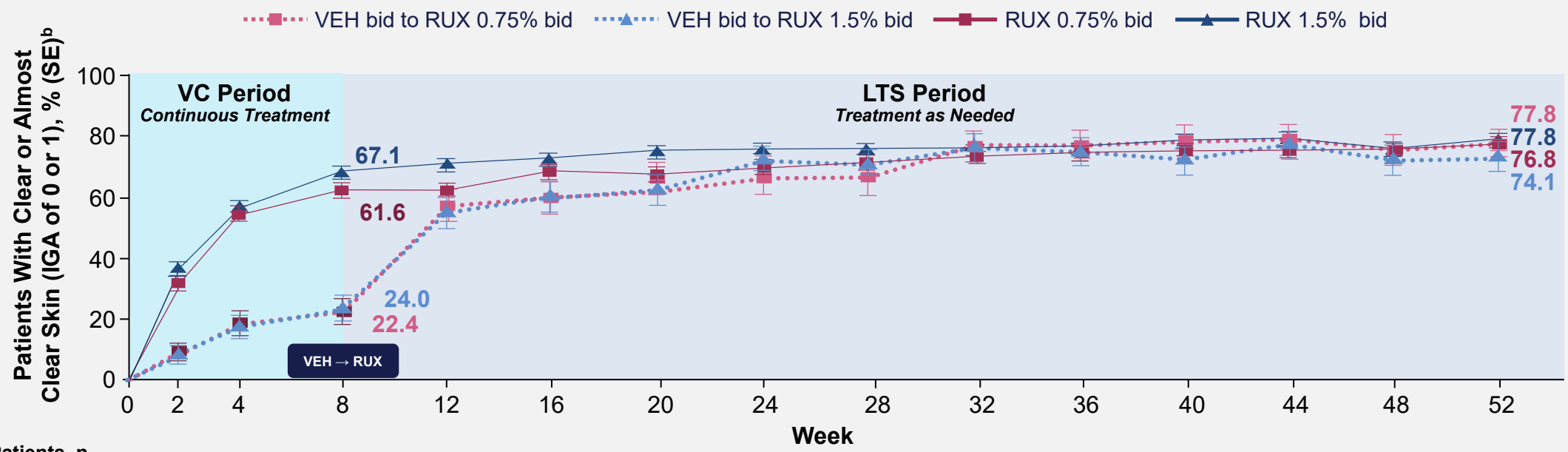
Achievement of Clear or Almost Clear Skin (IGA 0-1) Through Week 52[a]



Patients, n															
VEH bid to RUX 0.75% bid	101	98	98	98	92	90	86	83	74	70	66	67	68	70	72
VEH bid to RUX 1.5% bid	99	96	96	96	94	92	92	88	86	87	82	81	81	81	81
RUX 0.75% bid	426	409	409	409	395	383	370	345	333	316	307	312	320	316	323
RUX 1.5% bid	446	428	428	428	408	399	392	374	354	342	342	332	343	326	342

More patients who applied RUX achieved clear or almost clear skin vs VEH through week 8; improvements were maintained with as-needed RUX through week 52

[a] Among patients who continued into the LTS period. [b] Observed data are shown. Missing values were not imputed.
bid, twice daily; IGA, Investigator's Global Assessment; LTS, long-term safety; RUX, ruxolitinib cream; VC, vehicle-controlled; VEH, vehicle.
Papp K, et al. *J Am Acad Dermatol*. 2023;88:1008-1016.
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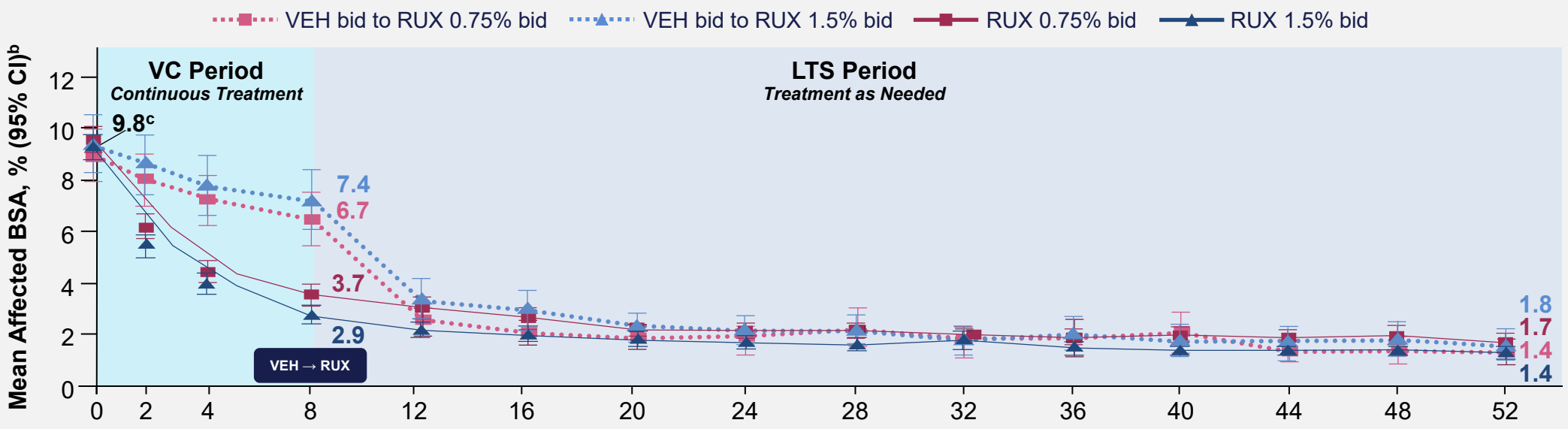
Mean Affected BSA Over 52 Weeks[1,a]



Patients, n															
VEH bid to RUX 0.75% bid	98	97	98	98	91	89	87	83	75	70	68	67	68	70	72
VEH bid to RUX 1.5% bid	96	96	96	96	94	92	92	88	86	87	82	81	81	81	81
RUX 0.75% bid	409	402	408	409	395	383	370	347	334	317	308	312	321	317	323
RUX 1.5% bid	428	424	426	428	408	399	392	374	354	342	342	333	343	327	343

The affected BSA decreased in patients treated with RUX vs VEH through week 8. This reduction was sustained or further improved with as-needed RUX application through week 52

[a] Among patients who continued into the LTS period. [b] Observed data are shown. Missing values were not imputed. [c] Mean baseline BSA for the total pooled population (N=1,249) at the start of the VC period.[2]

bid, twice daily; BSA, body surface area; LTS, long-term safety; RUX, ruxolitinib cream; VC, vehicle-controlled; VEH, vehicle.

1. Papp K, et al. *J Am Acad Dermatol*. 2023;88:1008-1016. 2. Papp K, et al. EADV 2020. Abstract 2012.

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TEAEs During the 52-Week Study Period[a]

n (%)	TEAEs			
	VEH bid to RUX 0.75% bid (n=101)	VEH bid to RUX 1.5% bid (n=99)	RUX 0.75% bid (n=426)	RUX 1.5% bid (n=446)
Patients with TEAE	54 (53.5)	57 (57.6)	287 (67.4)	279 (62.6)
Most common TEAEs[b]				
Upper RTI	6 (5.9)	7 (7.1)	44 (10.3)	51 (11.4)
Nasopharyngitis	8 (7.9)	14 (14.1)	38 (8.9)	44 (9.9)
Headache	2 (2.0)	4 (4.0)	16 (3.8)	20 (4.5)
Bronchitis	3 (3.0)	5 (5.1)	11 (2.6)	15 (3.4)
Rhinitis	3 (3.0)	3 (3.0)	16 (3.8)	9 (2.0)
Influenza	0	7 (7.1)	8 (1.9)	11 (2.5)
AD[c]	1 (1.0)	0	15 (3.5)	11 (2.5)
Hypertension	3 (3.0)	1 (1.0)	13 (3.1)	10 (2.2)
Sinusitis	3 (3.0)	2 (2.0)	14 (3.3)	6 (1.3)
Asthma	2 (2.0)	1 (1.0)	10 (2.3)	11 (2.5)
Patients with application-site reactions	1 (1.0)	1 (1.0)	16 (3.8)	8 (1.8)
Patients who discontinued due to a TEAE	0	0	9 (2.1)	1 (0.2)
Patients with serious TEAE[d]	5 (5.0)	1 (1.0)	12 (2.8)	8 (1.8)

n (%)	Treatment-Related TEAEs			
	VEH bid to RUX 0.75% bid (n=101)	VEH bid to RUX 1.5% bid (n=99)	RUX 0.75% bid (n=426)	RUX 1.5% bid (n=446)
Patients with a treatment-related TEAE	2 (2.0)	6 (6.1)	37 (8.7)	33 (7.4)
Most common treatment-related TEAEs[e]				
Neutropenia	0	3 (3.0)	4 (0.9)	4 (0.9)
Application-site pain[f]	0	0	3 (0.7)	4 (0.9)
Application-site pruritus	1 (1.0)	0	5 (1.2)	0
Oral herpes	0	1 (1.0)	3 (0.7)	0
Application-site folliculitis	0	0	2 (0.5)	1 (0.2)
Skin bacterial infection	0	0	1 (0.2)	2 (0.4)
Alopecia	0	0	2 (0.5)	0
Application-site erythema	0	0	2 (0.5)	0
Dermatitis acneiform	0	0	0	2 (0.4)
Herpes simplex	0	0	0	2 (0.4)
Skin papilloma	0	0	2 (0.5)	0

Reported cases of serious infections, malignancy, MACE, or thromboses were considered unrelated to RUX

[a] Among patients who continued into the LTS period and while in a RUX group; for patients who switched from VEH, that period was 44 weeks. [b] Occurring in >2% of total patients. [c] Includes AD exacerbation, worsening of AD, AD worse from baseline, flare of AD, exacerbation of AD on the neck, itching in AD, worsening of left periorbital AD, atopic skin changes on the thighs, worsening of AD on eyelids, worsening of AD on hands and legs, and AD outbreak. [d] One serious AE (hydatidiform mole [molar pregnancy]) was considered related to treatment. [e] Occurring in >1 patient in any group. [f] Includes application site burning, stinging, and pain after application.
AD, atopic dermatitis; AE, adverse event; bid, twice daily; LTS, long-term safety; MACE, major adverse cardiovascular event; RUX, ruxolitinib cream; TEAE, treatment-emergent adverse event; VEH, vehicle.

Papp K, et al. *J Am Acad Dermatol*. 2023;88:1008-1016.

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AEs of Special Interest in TRuE-AD1 and TRuE-AD2 Relative to the AD Population

Exposure-Adjusted Rates for Selected AEs of Interest Among Patients Who Applied Vehicle or RUX at Any Time During TRuE-AD1 and TRuE-AD2[a]				AD Population in the Literature
Event per 100 person-years	Vehicle bid (n=250) PY=34.99	RUX 0.75% bid (n=601) PY=441.91	RUX 1.5% bid (n=598) PY=466.00	
Herpes zoster	0	0.7 (0.1-2.0)	1.1 (0.3-2.5)	1.4[b]
NMSC[c]	0	0.7 (0.1-2.0)	0.4 (0.1-1.6)	0.7[d]
MI/cerebrovascular accident	0	0.5 (0.1-1.6)	0.2 (0-1.2)	0.6-4[e]
DVT/PE[d]	0	0.2 (0-1.3)	0.2 (0-1.2)	1-3[e]

[a] Across all patients who initiated in the vehicle-controlled period, even if they discontinued before the long-term safety period. Patients applied vehicle for 8 weeks. Data for the RUX groups are for the full time that patients applied RUX; for patients who switched from vehicle, that period was 44 weeks. [b] Data from the placebo group in dupilumab clinical trials. [c] Includes basal cell carcinoma and squamous cell carcinoma. [d] Data from the placebo group in baricitinib clinical trials. [e] Reported rate was IR/PY; rate was multiplied by 100.
AD, atopic dermatitis; AE, adverse event; bid, twice daily; DVT, deep vein thrombosis; IR, incidence rate; MI, myocardial infarction; NA, not applicable; NMSC, nonmelanoma skin cancer; PE, pulmonary embolism; PY, person-year; RUX, ruxolitinib cream.
Papp K, et al. *J Am Acad Dermatol*. 2023;88:1008-1016. Supplemental appendix.

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TRuE-AD3 Study

Phase 3 Study of Ruxolitinib Cream in Children Aged 2 to 11 Years With Atopic Dermatitis

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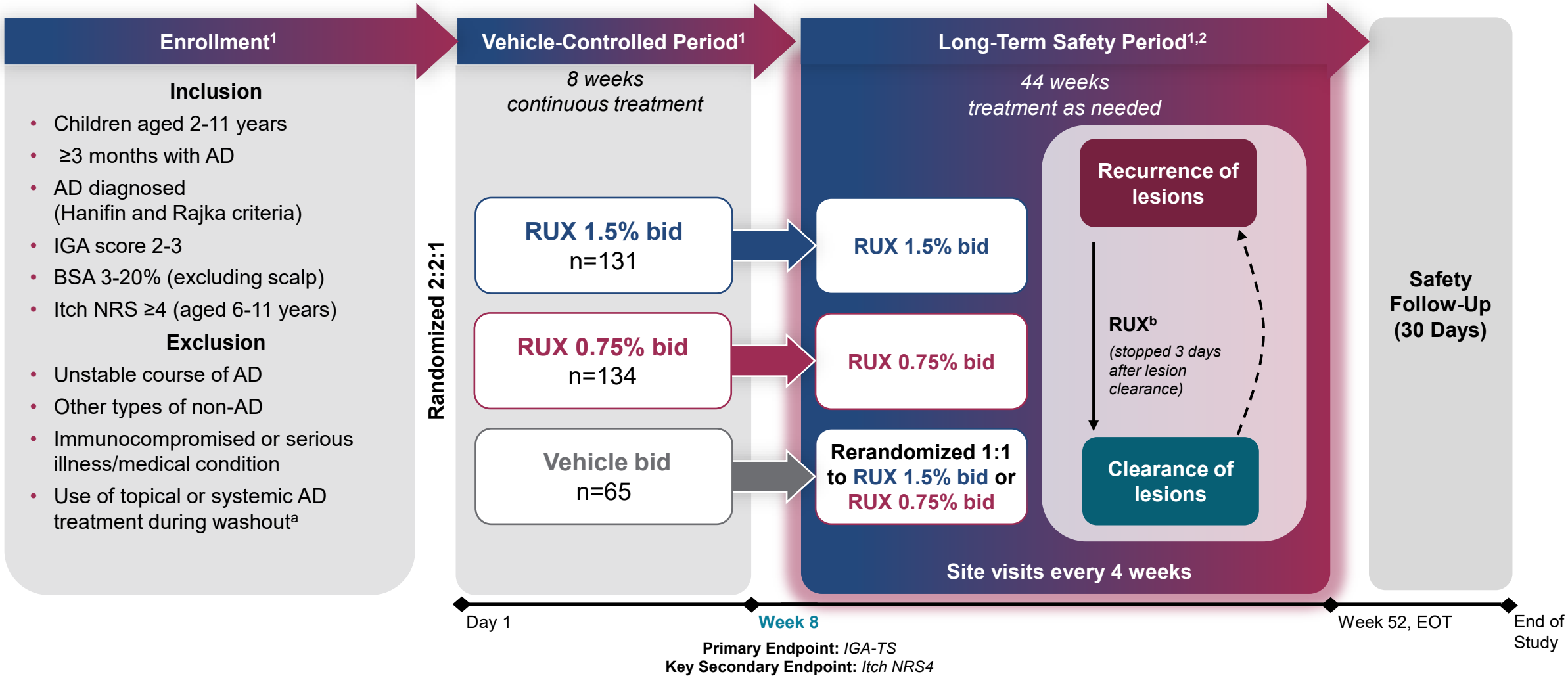
Study Design



[a] Washout period was 5 half-lives or 12 weeks (whichever is longer) for biologics, 4 weeks for systemic corticosteroids and other immunomodulating agents, and 1 week for topical agents. [b] Patients self-evaluated recurrence of lesions between study visits and treated lesions with active AD (≤20% BSA). If new lesions were extensive or appeared in new areas, patients contacted the investigator to determine if an unscheduled additional visit was needed.[2] AD, atopic dermatitis; bid, twice daily; BSA, body surface area; EOT, end of treatment; IGA, Investigator's Global Assessment; IGA-TS, IGA–Treatment Success; Itch NRS4, ≥4-point improvement in Itch Numerical Rating Scale score; RUX, ruxolitinib cream.

1. Eichenfield L, et al. *J Am Acad Dermatol*. 2025;93:689-698. 2. Eichenfield LF, et al. EADV 2024. D2T01.4A.

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Demographics and Baseline Clinical Characteristics Among Patients Aged 2-11 Years

Characteristics	Vehicle bid (n=65)	RUX 0.75% bid (n=134)	RUX 1.5% bid (n=131)
Age, median (range), y	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)
7-11 y, n (%)	32 (49.2)	66 (49.3)	65 (49.6)
Female, n (%)	38 (58.5)	73 (54.5)	68 (51.9)
Race, n (%)			
White	37 (56.9)	75 (56.0)	68 (51.9)
Black	19 (29.2)	45 (33.6)	42 (32.1)
Asian	3 (4.6)	7 (5.2)	11 (8.4)
Other	6 (9.2)	7 (5.2)	10 (7.6)

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

Baseline clinical characteristics were similar across treatment groups

[a] Assessments for baseline Itch NRS scores by visit are shown for patients aged 6-11 y (RUX 1.5%, n=76; RUX 0.75%, n=83; vehicle, n=38; total, n=197). Score is mean of ≥4 of the 7 days immediately prior to the baseline visit. [b] Data were available for 129, 131, and 65 patients in the RUX 1.5%, RUX 0.75%, and vehicle groups, respectively. [c] Includes patients aged ≥4 years; data were available for 94, 101, and 45 patients in the RUX 1.5%, RUX 0.75%, and vehicle groups, respectively. [d] Includes patients aged <4 y; data were available for 29, 24, and 17 patients in the RUX 1.5%, RUX 0.75%, and vehicle 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; NRS, Numerical Rating Scale; POEM, Patient-Oriented Eczema Measure; RUX, ruxolitinib cream.
Eichenfield LF, et al. *J Am Acad Dermatol*. 2025;93:689-698.
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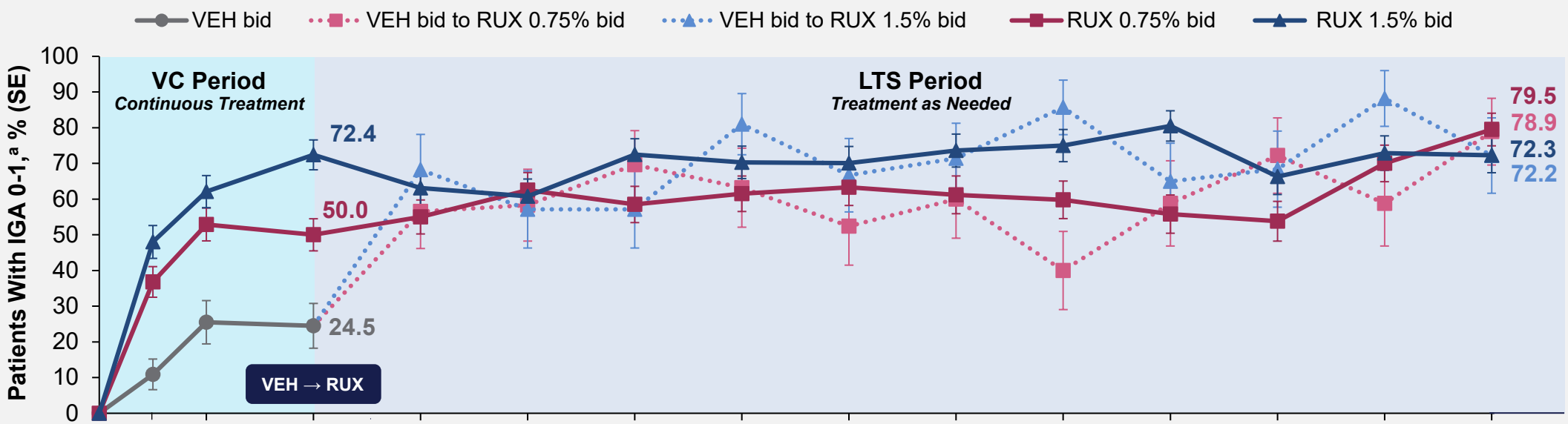
Achievement of Clear or Almost Clear Skin (IGA 0-1) Through Week 52



Patients, n													
VEH bid	65	55	51	49									
VEH bid to RUX 0.75% bid					23	24	23	19	21	20	20	17	18	17	19
VEH bid to RUX 1.5% bid					22	21	21	21	21	21	21	20	19	17	18
RUX 0.75% bid	134	125	121	122	109	96	94	96	90	85	87	86	80	80	78
RUX 1.5% bid	131	125	124	116	103	102	102	101	97	91	92	87	89	85	83

More patients who applied RUX achieved clear or almost clear skin vs VEH through week 8; improvements were maintained or further improved with as-needed RUX through week 52

[a] Week 12-52 data exclude 1 patient each in the RUX 0.75% and 1.5% groups who completed the study but did not receive treatment in the LTS period (maintained IGA and BSA of 0).
bid, twice daily; BSA, body surface area; IGA, Investigator's Global Assessment; LTS, long-term safety; RUX, ruxolitinib cream; VC, vehicle-controlled; VEH, vehicle.
Eichenfield LF, et al. EADV 2024. Abstract 8082. LB Oral Presentation D2T101.4A.

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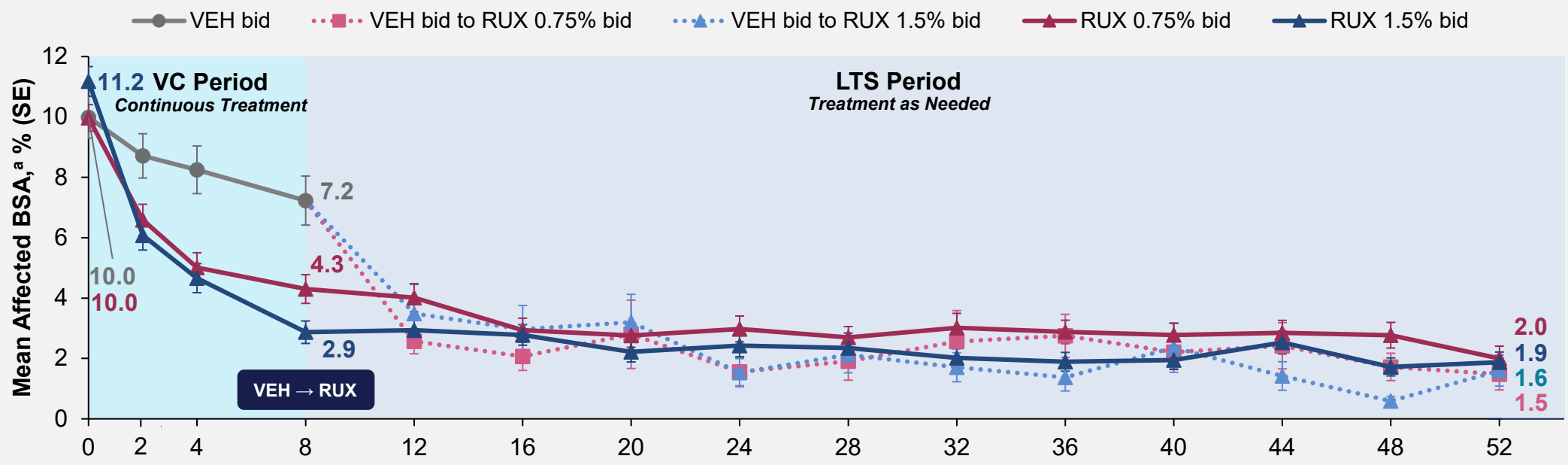
Mean Affected BSA Over 52 Weeks



Patients, n													
VEH bid	65	55	51	49									
VEH bid to RUX 0.75% bid					23	24	23	19	21	20	20	17	18	17	19
VEH bid to RUX 1.5% bid					22	21	21	21	21	21	21	20	19	17	18
RUX 0.75% bid	134	125	121	122	109	96	94	96	90	85	87	86	80	80	78
RUX 1.5% bid	131	125	124	116	103	102	102	101	97	91	92	87	89	85	83

The affected BSA decreased in patients treated with RUX vs VEH through week 8. This reduction was sustained or further improved with as-needed RUX application through week 52

[a] Week 12-52 data exclude 1 patient each in the RUX 0.75% and 1.5% groups who completed the study but did not receive treatment in the LTS period (maintained IGA and BSA of 0).
bid, twice daily; BSA, body surface area; IGA, Investigator's Global Assessment; LTS, long-term safety; RUX, ruxolitinib cream; VC, vehicle-controlled; VEH, vehicle.
Eichenfield LF, et al. EADV 2024. Abstract 8082. LB Oral Presentation D2T101.4A.

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Most Common TEAEs and Select TEAEs in the 52-Week Study[1]

Most common TEAEs[a] n (%)	RUX 0.75% bid (n=134)	RUX 1.5% bid (n=130)
Upper respiratory tract infection	18 (13.4)	21 (16.2)
Nasopharyngitis	7 (5.2)	17 (13.1)
COVID-19	12 (9.0)	9 (6.9)
Pyrexia	10 (7.5)	4 (3.1)
Otitis media	5 (3.7)	7 (5.4)
Asthma	7 (5.2)	4 (3.1)
Gastroenteritis viral	4 (3.0)	7 (5.4)
Pharyngitis streptococcal	8 (6.0)	3 (2.3)
Vomiting	5 (3.7)	6 (4.6)
Influenza	6 (4.5)	4 (3.1)
Application-site pain[b]	5 (3.7)	4 (3.1)
Cough	7 (5.2)	2 (1.5)
Ear infection	5 (3.7)	4 (3.1)

Select TEAEs n (%)	RUX 0.75% bid (n=134)	RUX 1.5% bid (n=130)
Diarrhea	3 (2.2)	5 (3.8)
Contact dermatitis	2 (1.5)	3 (2.3)
Headache	1 (0.7)	3 (2.3)
Nausea	1 (0.7)	0
Serious infections	0	1 (0.8)[c]
Folliculitis	0	0
Herpes zoster	0	0
MACE	0	0
Malignancy	0	0
Thrombosis	0	0

- *No folliculitis or herpes zoster occurred*
- *1 patient with eczema herpeticum was reported[c]*
- *No MACE, malignancies, or thromboses occurred*

[a] TEAE in ≥9 patients (3.4%) across both RUX groups. [b] Reported as burning, stinging, pain, or pain/discomfort at an application site. [c] Eczema herpeticum occurred on day 324 in a 2-year-old with risk factors for the event (moderate AD with early onset and involvement of face and neck). RUX had been stopped 7 days prior for a TEAE of molluscum contagiosum, which was treated with topical 0.1% tretinoin prescribed by primary care physician (onset 28 days before the event of eczema herpeticum).[1,2]

AD, atopic dermatitis; bid, twice daily; MACE, major adverse cardiovascular event; RUX, ruxolitinib cream; TEAE, treatment-emergent adverse event.

1. Eichenfield LF, et al. EADV 2024. Abstract 8082. LB Oral Presentation D2T101.4A. 2. Data on file. Incyte Corporation.

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Integrated Safety Analysis

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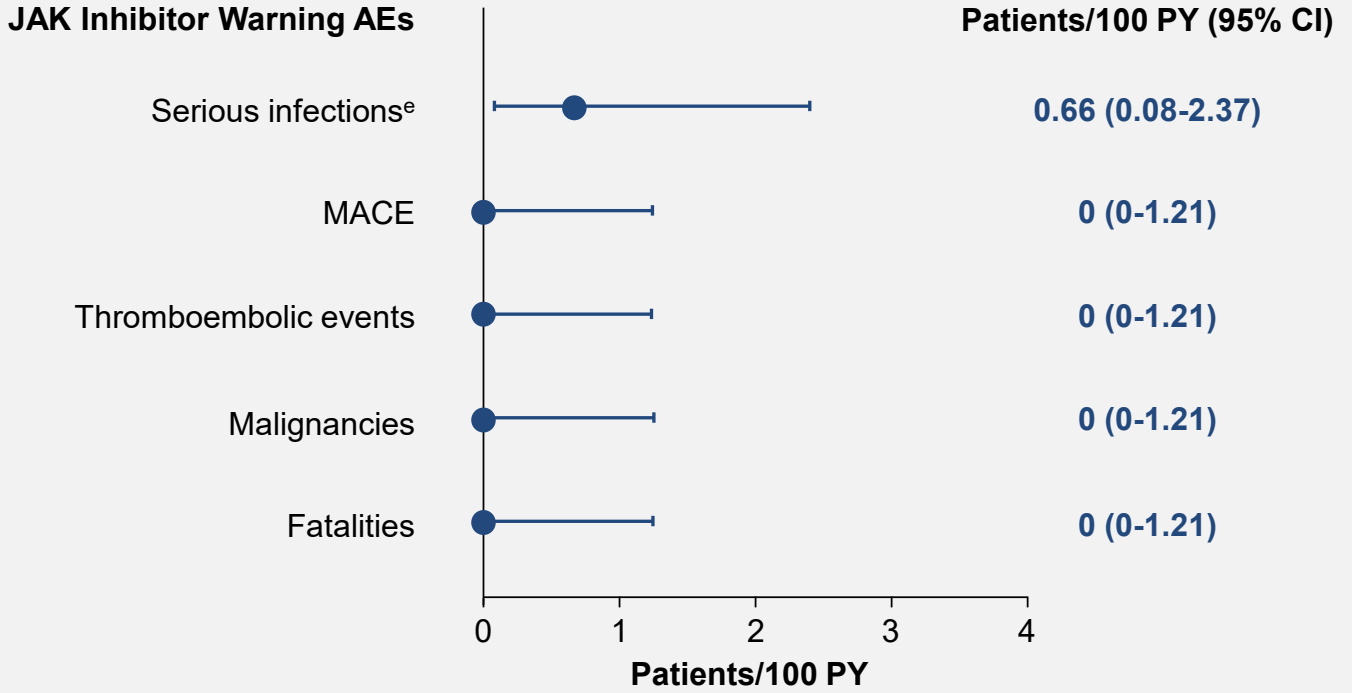
EAIRs of Adverse Events in the JAK Inhibitor Safety Warning Were Low or Absent Among Pediatric Patients With AD Treated With Topical RUX 1.5%

Key study eligibility criteria

TRuE-AD3		Randomized 2:2:1
• Aged 2-11 y • AD ≥3 mo	• IGA 2 or 3 • BSA 3-20%[a]	
TRuE-AD1/2		Randomized 2:2:1
• Aged ≥12 y • AD ≥2 y	• IGA 2 or 3 • BSA 3-20%[a]	
NCT05127421 (phase 2 head/neck)		Randomized 2:1
• Aged 12-70 y • AD ≥6 mo	• IGA 2 or 3[b] • BSA ≤20%[a,c]	
NCT05456529 (phase 3 adolescents)		Open-label
• Aged 12-17 y • AD ≥2 y	• IGA 2 or 3 • BSA 3-20%[a]	
NCT03920852 (maximum use[d])		Open-label
• Aged 12-65 y • AD ≥2 y	• IGA ≥2 • BSA ≥25%[a]	
NCT05034822 (maximum use[d])		Open-label
• Aged 2-11 y • AD ≥3 mo	• IGA ≥2 • BSA ≥35%[a]	
NCT03257644 (safety/PK)		Dose escalation by age
• Aged 2-17 y • AD	• IGA ≥2 • BSA 3-20%[a]	

8 clinical studies; ages 2-17 y, N=461, 304.98 PY



In an integrated safety analysis of JAK inhibitor class-specific AEs across 8 AD clinical trials, no MACE, thromboembolic events, malignancies, or fatalities were reported in patients aged 2-17 years with AD

[a] Excluding scalp. [b] Overall and on the face/neck. [c] With ≥0.5% of total BSA on the face and/or neck. [d] Maximum-use studies are those enrolling patients with elevated levels of affected BSA.
[e] Eczema herpeticum and mycoplasmal pneumonia each occurred in 1 patient; both were considered by the investigator as unrelated to treatment.
AD, atopic dermatitis; AE, adverse event; BSA, body surface area; EAIR, exposure-adjusted incidence rate; JAK, Janus kinase; MACE, major adverse cardiovascular event; PY, patient years; RUX, ruxolitinib cream.

Siri DD, et al. SPD 2025. POS-19.

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Appendix

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TRuE-AD1 and TRuE-AD2: Demographics and Clinical Characteristics of Patients Who Continued Into the LTS Period

Characteristics	VEH bid to RUX 0.75% bid (n=101)	VEH bid to RUX 1.5% bid (n=99)	RUX 0.75% bid (n=426)	RUX 1.5% bid (n=446)
Age, median (range), y	33.0 (12-75)	36.0 (12-82)	35.0 (12-85)	31.0 (12-85)
Female, n (%)	69 (68.3)	57 (57.6)	264 (62.0)	278 (62.3)
Race, n (%)				
White	66 (65.3)	72 (72.7)	308 (72.3)	320 (71.7)
Black	25 (24.8)	22 (22.2)	91 (21.4)	97 (21.7)
Asian	5 (5.0)	3 (3.0)	15 (3.5)	19 (4.3)
Other	5 (5.0)	2 (2.0)	12 (2.8)	10 (2.2)
BSA, median (IQR), %	8.0 (5.0-13.0)	8.0 (5.0-15.0)	9.0 (5.5-15.0)	8.5 (5.0-14.0)
EASI, median (IQR)	6.7 (4.0-10.8)	6.6 (4.0-10.2)	7.3 (4.5-11.4)	7.4 (4.2-10.7)
Baseline IGA, n (%)				
2	25 (24.8)	27 (27.3)	100 (23.5)	100 (22.4)
3	76 (75.2)	72 (72.7)	326 (76.5)	346 (77.6)
Itch NRS score, median (IQR)	5.1 (2.7-7.0)	5.2 (3.0-7.3)	5.2 (3.4-7.0)	5.3 (3.2-7.0)
Duration of disease, median (range), y	18.3 (0.8-72.9)	12.1 (1.9-79.1)	14.9 (0.1-68.6)	16.0 (0-69.2)
Facial involvement, n (%)[a]	43 (42.6)	32 (32.3)	177 (41.5)	185 (41.5)
Flares in the past 12 months, median (IQR)[a]	2.0 (1.0-5.0)	3.0 (2.0-9.0)	3.0 (1.0-6.0)	3.0 (1.0-6.0)

Distribution of baseline demographics and clinical characteristics was similar across treatment groups

[a] Patient reported.

bid, twice daily; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; IQR, interquartile range; LTS, long-term safety; NRS, Numerical Rating Scale; RUX, ruxolitinib cream; VEH, vehicle.

Papp K, et al. *J Am Acad Dermatol*. 2023;88:1008-1016.

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TRuE-AD3: Baseline Demographics and Disease Characteristics in the LTS-Evaluable Population[a]

Characteristics	VEH bid to RUX 0.75% bid (n=25)	VEH bid to RUX 1.5% bid (n=24)	RUX 0.75% bid (n=119)	RUX 1.5% bid (n=114)
Age, median (range), y	8.0 (2-11)	5.5 (2-11)	7.0 (2-11)	6.0 (2-11)
Female, n (%)	15 (60.0)	12 (50.0)	67 (56.3)	55 (48.2)
White, n (%)	14 (56.0)	13 (54.2)	69 (58.0)	61 (53.5)
Affected BSA, mean (SD), %	8.3 (4.5)	12.1 (5.8)	9.9 (5.2)	11.1 (5.6)
Baseline IGA, n (%)				
2	5 (20.0)	7 (29.2)	26 (21.8)	27 (23.7)
3	20 (80.0)	17 (70.8)	93 (78.2)	87 (76.3)
Baseline EASI, mean (SD)	7.4 (3.6)	9.1 (5.3)	8.6 (6.3)	9.0 (4.6)
Itch NRS score,[b] mean (SD)	6.9 (1.7)	6.4 (1.9)	6.5 (1.8)	7.0 (1.5)
Duration of disease, median (range), y	4.2 (0.4-11.2)	4.9 (0.9-10.7)	5.5 (0.3-11.3)	4.6 (0.4-11.2)
Prior therapy in last 12 months, n (%)	16 (64.0)	18 (75.0)	79 (66.4)	75 (65.8)

Baseline clinical characteristics were similar across treatment groups

[a] Patients who applied ≥1 dose of RUX in the LTS period. [b] For patients aged 6-11 years (VEH to RUX 0.75%, n=19; VEH to RUX 1.5%, n=12; RUX 0.75%, n=76; RUX 1.5%, n=66). Score is mean of ≥4 of the 7 days immediately prior to the baseline visit.

bid, twice daily; BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; LTS, long-term safety; NRS, Numerical Rating Scale; RUX, ruxolitinib cream; VEH, vehicle.

Eichenfield LF, et al. EADV 2024. Abstract 8082. LB Oral Presentation D2T101.4A.

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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.

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

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