INTEGUMENT-INFANT: Once-Daily Roflumilast Cream 0.05% in Infants Aged 3 to <24 Months With Atopic Dermatitis

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on behalf of the INTEGUMENT-INFANT investigators

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Disclosure of Relevant Relationship with Industry

Lawrence F. Eichenfield, MD

S023 Late-Breaking Research: Session 1

DISCLOSURES

Consultant, investigator, and/or member of board of directors for AbbVie, Acrotech, Almirall, Amgen, Apogee Therapeutics, Arcutis, Attovia, BMS, Castle Biosciences, CorEvitas, Dermavant, Dermira, Forte Biosciences, Galderma, Incyte, Janssen, Johnson & Johnson, Kymera, LEO Pharma, Lilly, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi-Genzyme, Target RWE, TRex Bio, and UCB

Background

Burden of AD

- Infants with AD, and their families, experience substantial disease burden and there are limited evidence-based treatment options for this population[1]
- Current topical therapies for infants with AD (ie, TCS, crisaborole [topical PDE4 inhibitor]) have limitations due to higher absorption on thin skin, restrictions on duration of use, and/or potential application-site reactions[2–6]

Topical Roflumilast

- Topical roflumilast is a PDE4 inhibitor–based advanced targeted topical therapy
- This topical therapy for AD does not contain potentially skin-irritating excipients such as ethanol, isopropyl alcohol, propylene glycol, polyethylene glycol, formaldehyde-releasing agents, or fragrances[7]
- Roflumilast cream 0.05% and 0.15% are approved for the treatment of mild-to-moderate AD in patients aged 2–5 years and ≥6 years, respectively[8]

INTEGUMENT-INFANT

The safety and efficacy of roflumilast cream 0.05% in infants aged 3 to <24 months with mild-to-moderate AD were investigated in the 4-week phase 2 INTEGUMENT-INFANT (NCT06998056) trial.

AD, atopic dermatitis; PDE4, phosphodiesterase 4; TCI, topical calcineurin inhibitor; TCS, topical corticosteroids.

1. Weidinger S, et al. *Br J Dermatol.* 2024;190:846–857. 2. Eichenfield LF, et al. *J Am Acad Dermatol*. 2014;71:116–132. 3. Davari DR, et al. *J Asthma Allergy*. 2020;13:563–573. 4. Puar N, et al. *Ann Allergy Asthma Immunol*. 2021;126:21–31. 5. Lin CP-L, et al. *J Am Acad Dermatol.* 2019;80(5):1451–1453. 6. Burshtein J, et al. *Dermatol Online J*. 2025;31(1). 7. Draelos ZD, et al. *J Drugs Dermatol*.2024;23(10):834–84. doi:10.5070/D331164978. 8. ZORYVE (roflumilast) cream 0.3%, 0.15%, 0.05% [Prescribing information]. Arcutis Biotherapeutics, Inc. October 2025.

INTEGUMENT-INFANT Study Design

Phase 2, open-label, 4-week study of roflumilast cream 0.05% in infants aged 3 to <24 months

Eligibility

- Mild-to-moderate AD (vIGA-AD 2 or 3)
- Aged 3 to <24 months
- BSA ≥3% (scalp and nonscalp)
- AD duration of ≥1 month

Roflumilast cream 0.05% QD

4 weeks

Nonmedicated emollients or moisturizers could be applied to treatment and non-treatment areas

Endpoints

Primary

- TEAEs
- SAEs
- Application-site tolerability

Exploratory

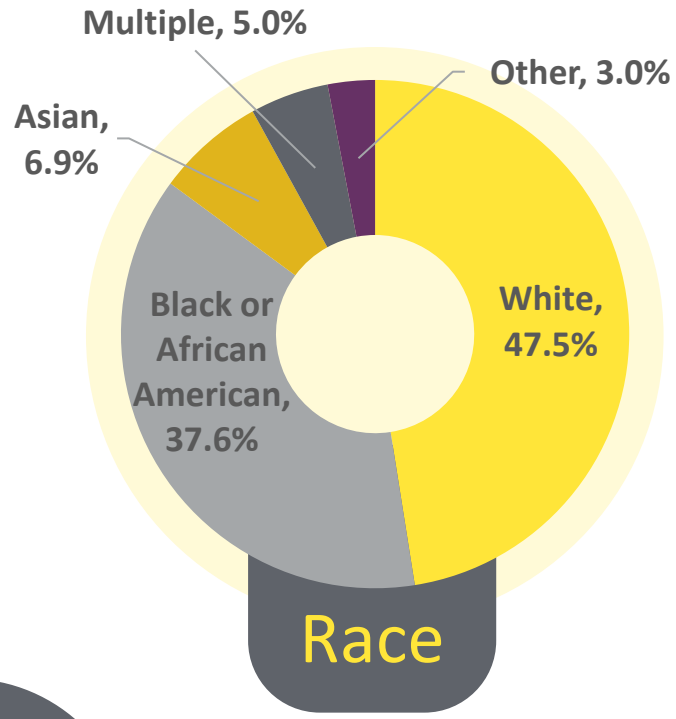
- vIGA-AD and IGA-Scalp success[a]
- vIGA-AD 0/1
- EASI-75
- BSA
- WSI-NRS success[b]
- Dynamic Pruritus Score-25[c]

- This study was conducted across 22 clinical sites in the United States, Canada, and Dominican Republic
- Caregivers applied roflumilast cream 0.05% monotherapy QD and completed the WSI-NRS and Dynamic Pruritus Score assessments
  - Dynamic Pruritus Score was assessed 10 minutes, 1 hour, and 4 hours after the first application

[a]vIGA-AD clear/almost clear (0/1) plus ≥2-point improvement from baseline. [b]Worst scratch/itch in the previous 24 hours (caregiver-reported) in patients with baseline WSI-NRS ≥4. [c]≥25% improvement in pruritus from baseline in patients with WSI-NRS >0.
AD, atopic dermatitis; BSA, body surface area affected; EASI-75, ≥75% improvement in Eczema Area and Severity Index from baseline; QD, once daily; SAE, serious adverse event; TEAE, treatment-emergent adverse event; vIGA-AD, Validated Investigator Global Assessment for AD; WSI-NRS, Worst Scratch/Itch-Numeric Rating Scale.

Baseline Demographics and Clinical Characteristics

65.3%
of patients were male



Mean age
61.3
weeks

Median: 61.0
Range: 12–102

Characteristic		Roflumilast cream 0.05% (n=101)
Hispanic or Latino, n (%)		35 (34.7)
Fitzpatrick skin type, n (%)	Type I–III	54 (53.5)
	Type IV–VI	47 (46.5)
vIGA-AD, n (%)	2 (mild)	20 (19.8)
	3 (moderate)	81 (80.2)
IGA-Scalp ≥2, n (%)		41 (40.6)
Mean (median) [range]	IGA-Scalp	1.0 (0) [0–3]
	EASI	14.6 (13.0) [1.6–40.4]
	BSA, %	30.1 (22.5) [3.7–87.0]
	WSI-NRS[a]	6.5 (7.5) [0–10]
Body region with AD involvement, n (%)	Face	77 (76.2)
	Scalp	44 (43.6)
	Perioral area	36 (35.6)
	Diaper area	32 (31.7)
	Eyelids	30 (29.7)
Prior inadequate response, intolerance, and/or contraindication to TCS, n (%)		58 (57.4)

Safety population. [a]Daily WSI-NRS based on worst itch in the previous 24 hours.
AD, atopic dermatitis; BSA, body surface area affected; EASI; Eczema Area and Severity Index; TCS, topical corticosteroids; vIGA-AD, Validated Investigator Global Assessment for AD; WSI-NRS, Worst Scratch/Itch-Numeric Rating Scale.

Safety of Roflumilast Cream 0.05% in Infants

Safety summary

n (%)	Roflumilast cream 0.05% (n=101)
Patients with ≥1 TEAE	44 (43.6)
Mild	36 (35.6)
Moderate	8 (7.9)
Severe	0
Patients with ≥1 treatment-related AE	16 (15.8)
Patients with ≥1 SAE	0
Patients with ≥1 TEAE leading to study drug/study discontinuation	4 (4.0)/1 (1.0)

Most common (≥2% of patients) TEAEs

Patients, n (%)	Roflumilast cream 0.05% (n=101)
Diarrhea	13 (12.9)
Nasopharyngitis	9 (8.9)
Upper respiratory tract infection	6 (5.9)
Vomiting	6 (5.9)
Application-site pruritus	2 (2.0)
Hand-foot-and-mouth disease	2 (2.0)
Sleep disorder	2 (2.0)
Teething	2 (2.0)
Viral infection	2 (2.0)

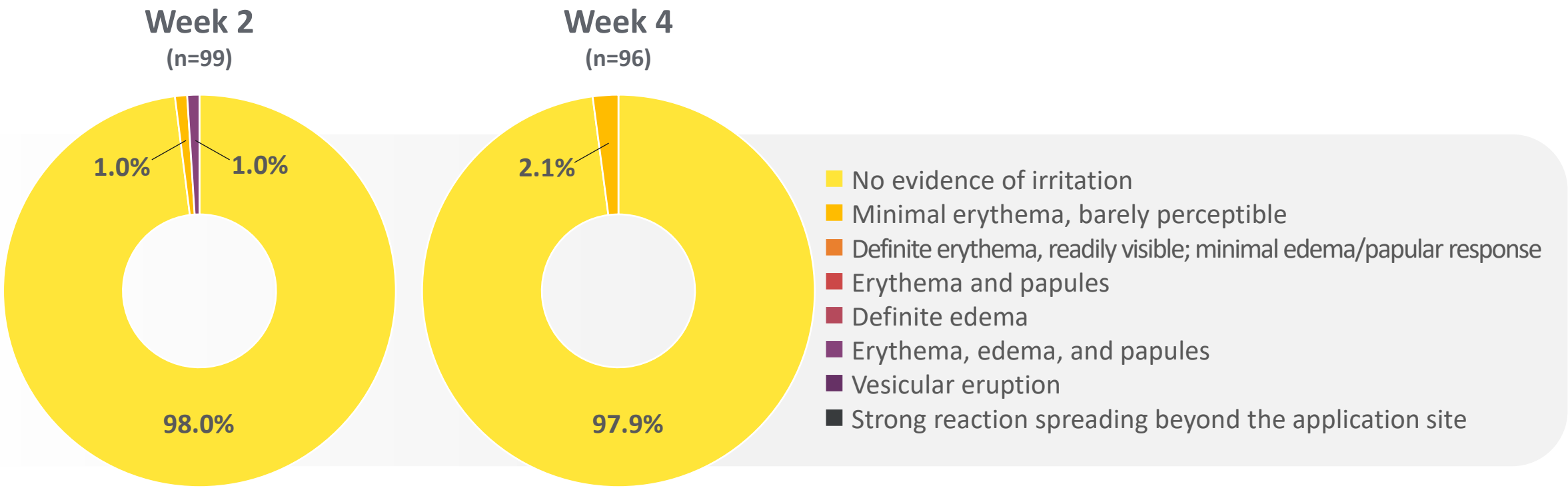
Roflumilast cream 0.05% was well tolerated in infants aged 3 to <24 months

- Safety outcomes were consistent across sex and age subgroups (12–52 weeks of age; 53–78 weeks of age; 79 to <104 weeks of age)

Safety population. AE, adverse event; SAE, serious AE, TEAE, treatment-emergent AE.

Investigator-Rated Application-Site Tolerability

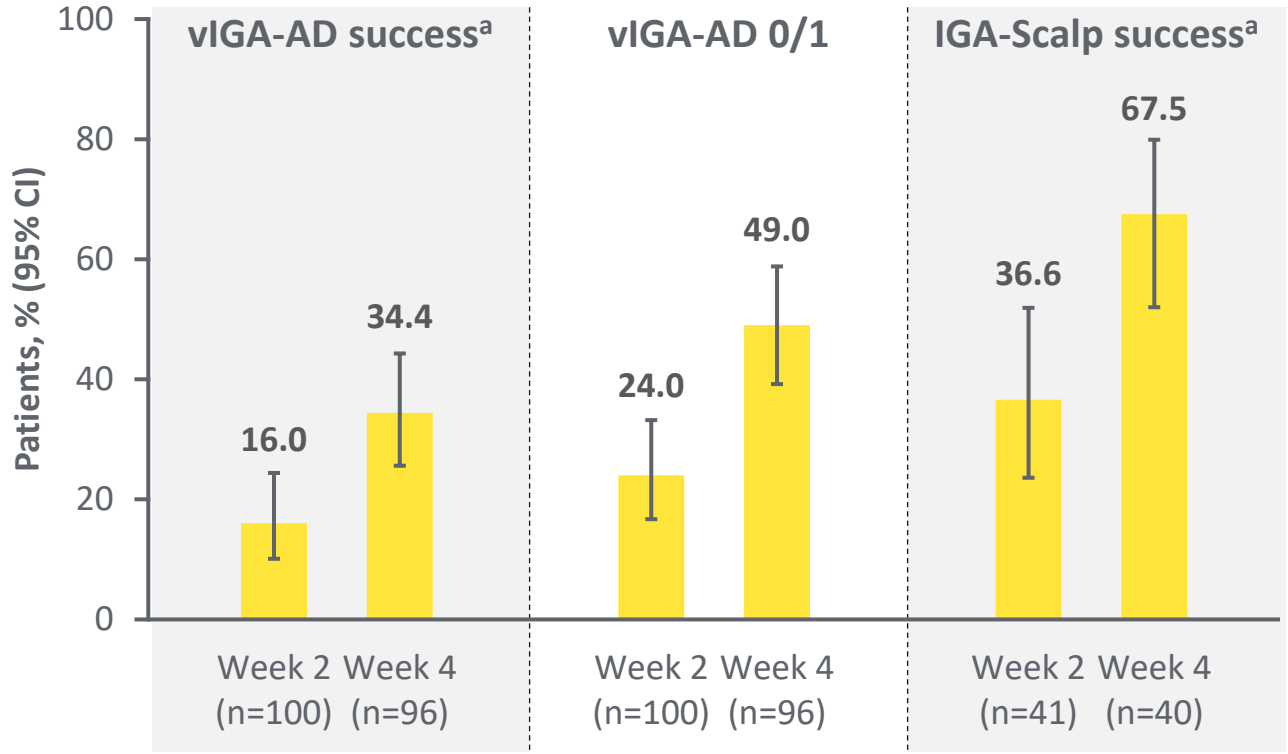
There was no evidence of irritation at the application site in ≥97.9% of patients throughout 4 weeks of roflumilast cream 0.05% application

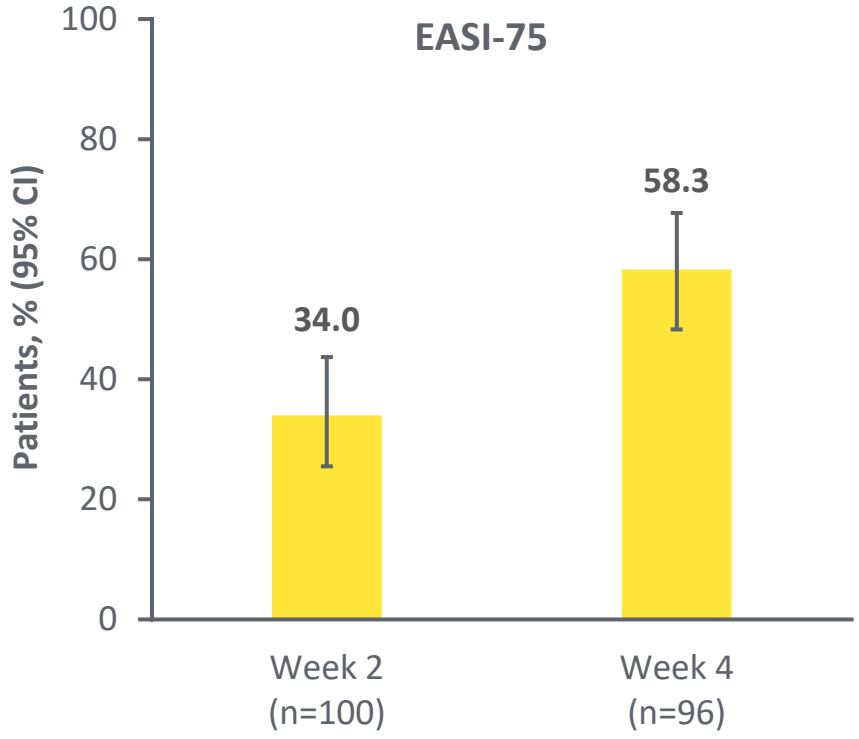


Safety population.

Improvements in Signs of AD With Roflumilast Cream 0.05%

Roflumilast cream 0.05% improved signs of AD and AD severity through 4 weeks of application

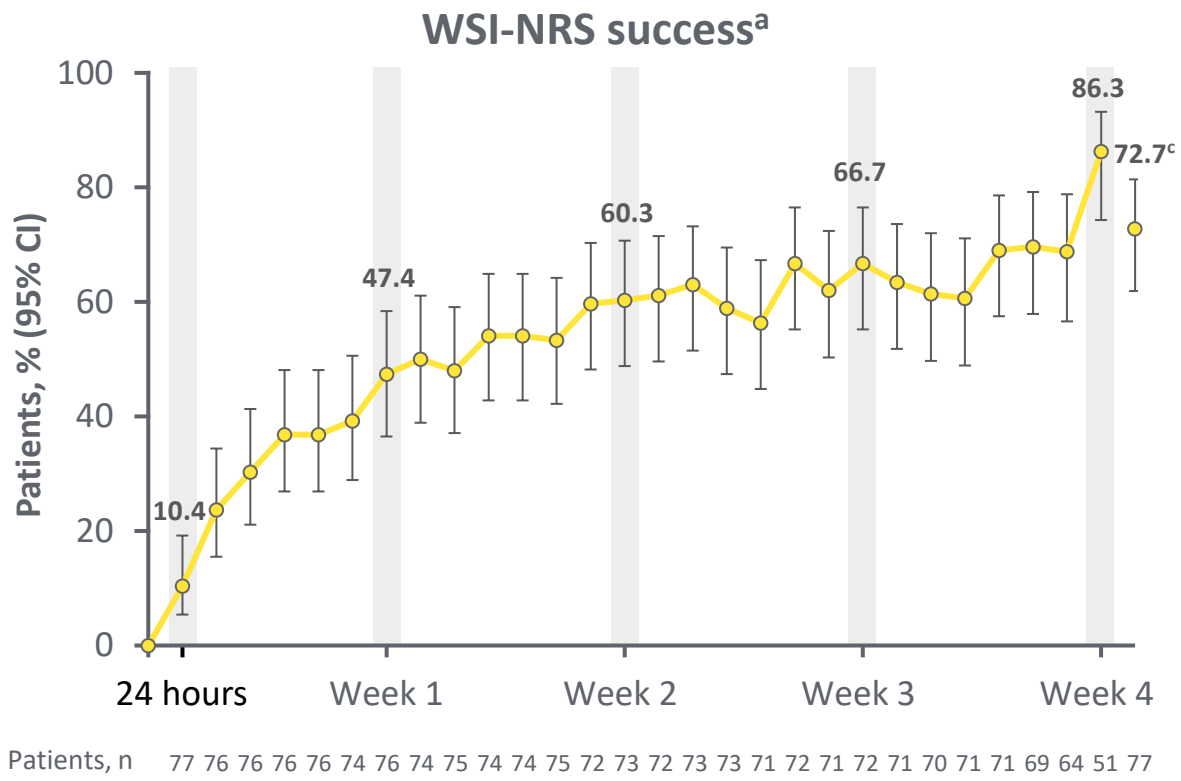


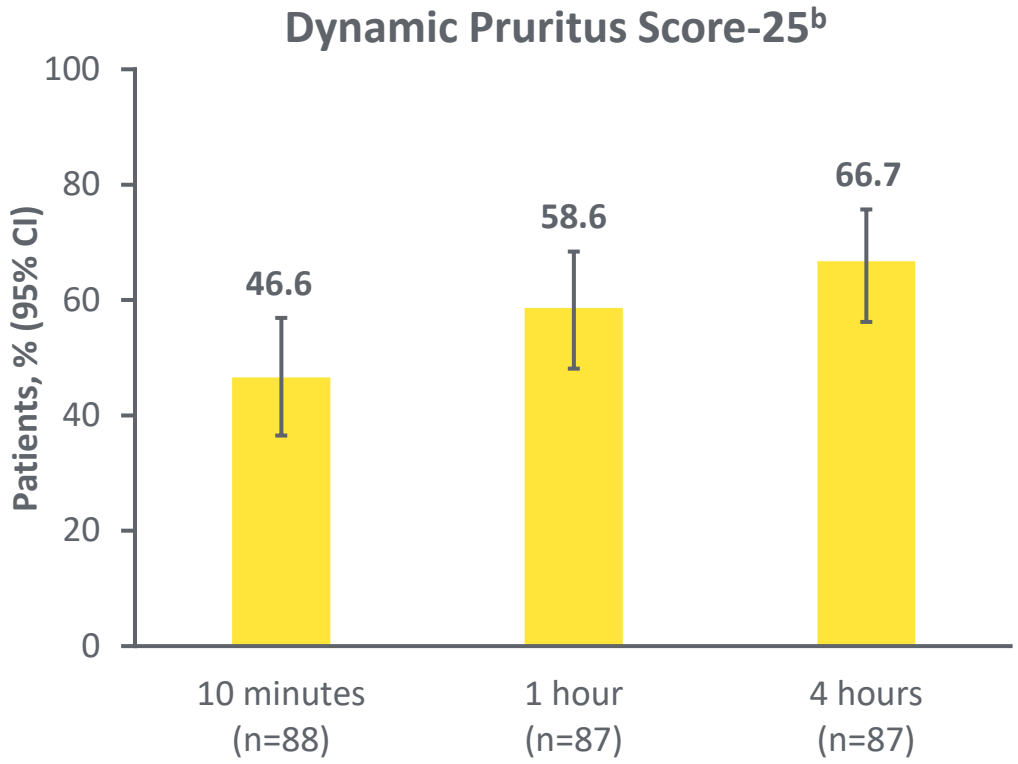


Safety population; observed data. [a]vIGA-AD or IGA-Scalp clear/almost clear (0/1) plus ≥2-point improvement from baseline (among patients with baseline score ≥2 for IGA-Scalp).
EASI-75, ≥75% improvement in Eczema Area and Severity Index from baseline; vIGA-AD, Validated Investigator Global Assessment for AD.

Improvement in Caregiver-Reported Patient Itch With Roflumilast Cream 0.05%

Caregivers reported a rapid improvement in itch symptoms with roflumilast cream 0.05%



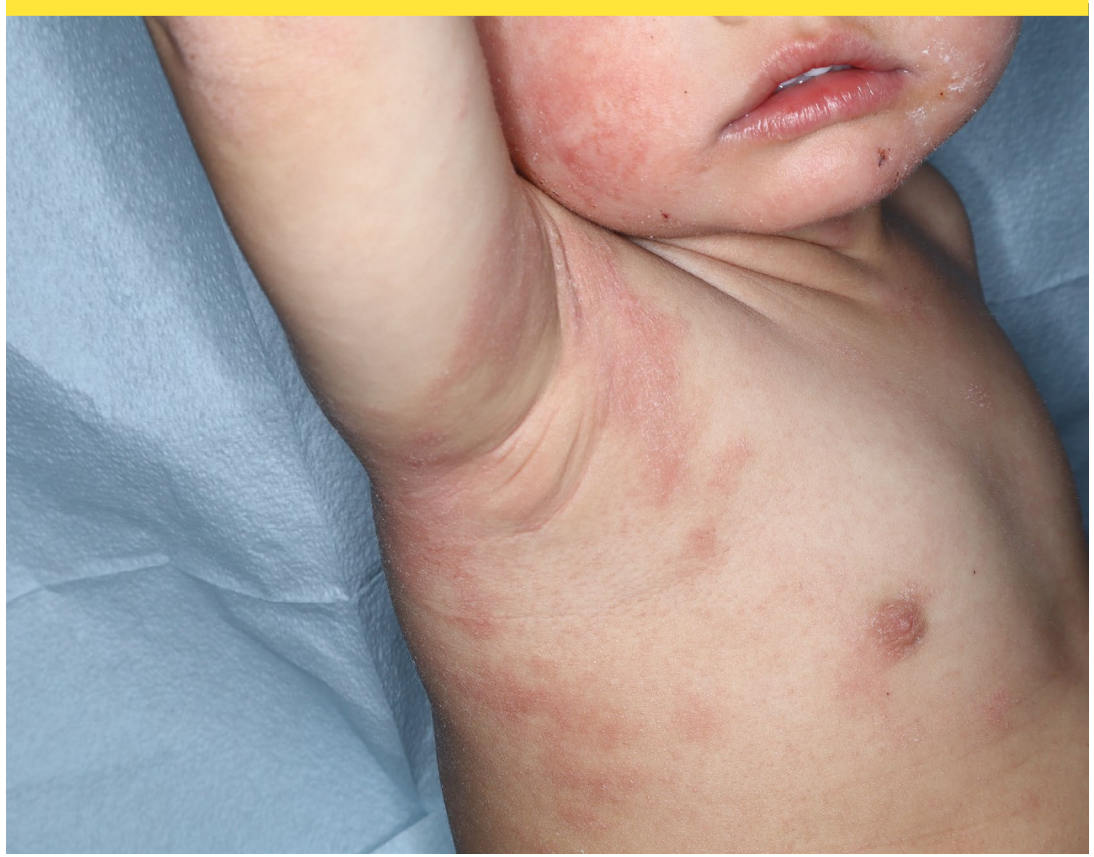


Safety population; observed data. [a]WSI-NRS success defined as ≥4-point improvement from baseline WSI-NRS ≥4. [b]Dynamic Pruritus Score-25 defined as ≥25% improvement in pruritus from baseline in patients with WSI-NRS >0.
[c]Last observed.
WSI-NRS, Worst Scratch/Itch-Numeric Rating Scale.

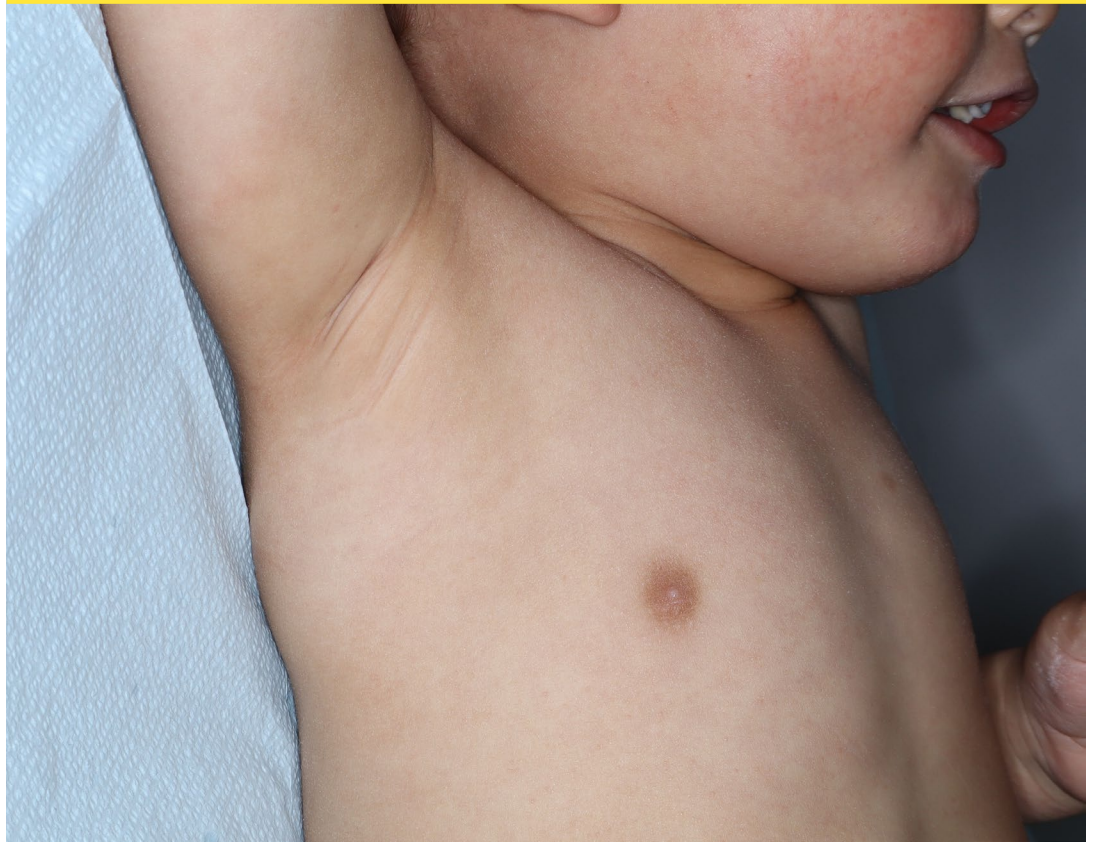
Improvements in AD Over Time

23–month-old White, Asian boy with a history of prior inadequate response, intolerance, or contraindication to TCS

Baseline (vIGA-AD 3)



Week 4 (vIGA-AD 1)

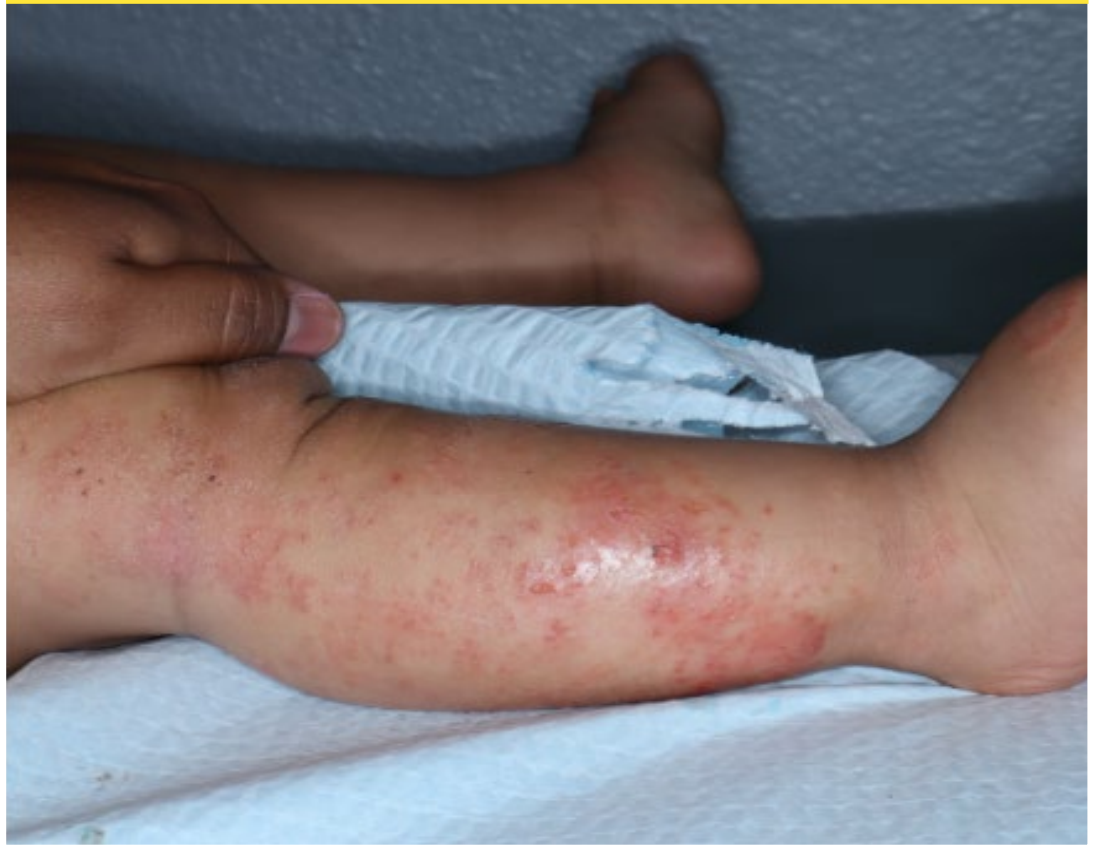


AD, atopic dermatitis; TCS, topical corticosteroids; vIGA-AD, Validated Investigator Global Assessment for AD.

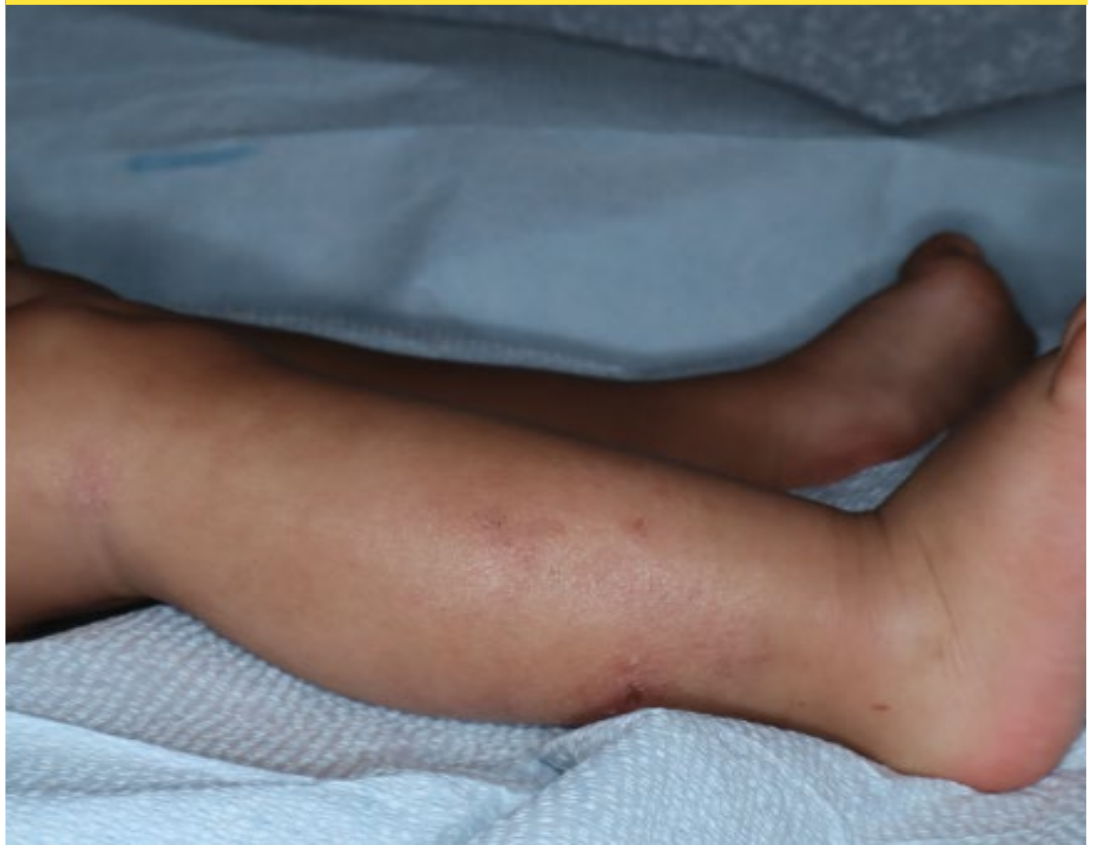
Improvements in AD Over Time

10–month-old White, Hispanic/Latino boy with a history of prior inadequate response, intolerance, or contraindication to TCS

Baseline (vIGA-AD 3)



Week 4 (vIGA-AD 1)

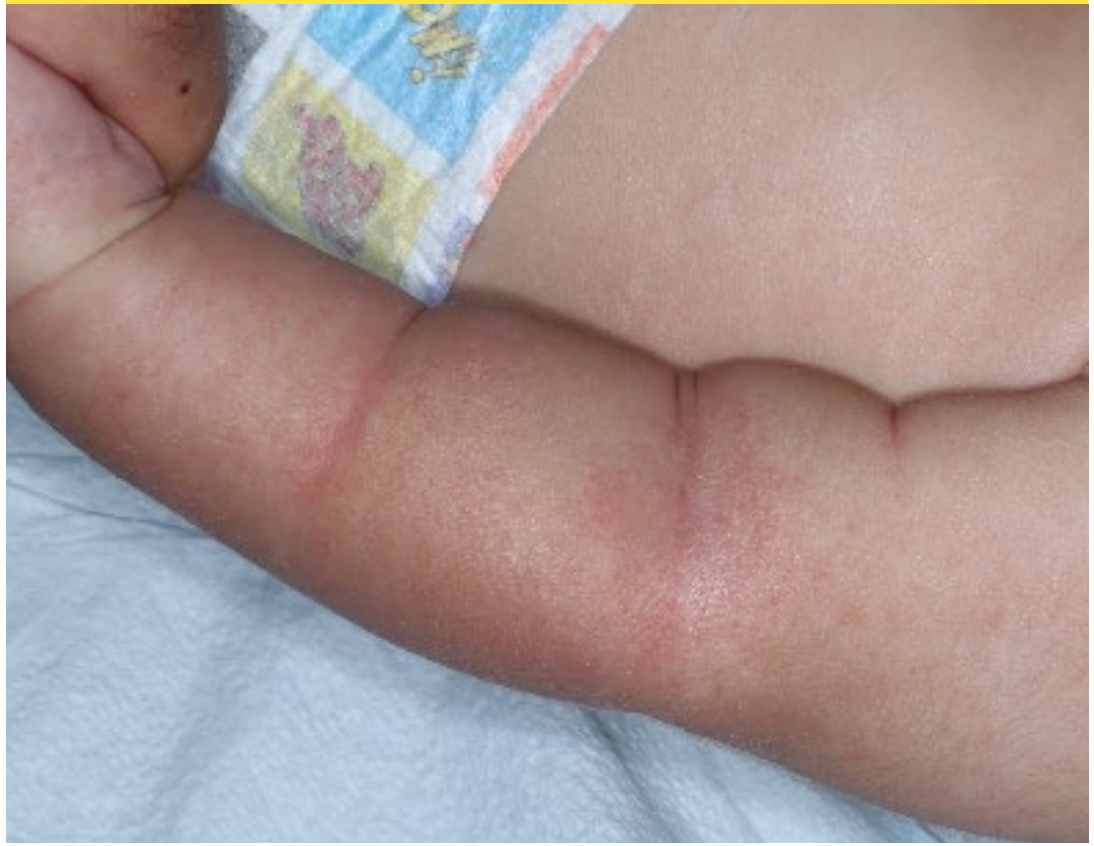


AD, atopic dermatitis; TCS, topical corticosteroids; vIGA-AD, Validated Investigator Global Assessment for AD.

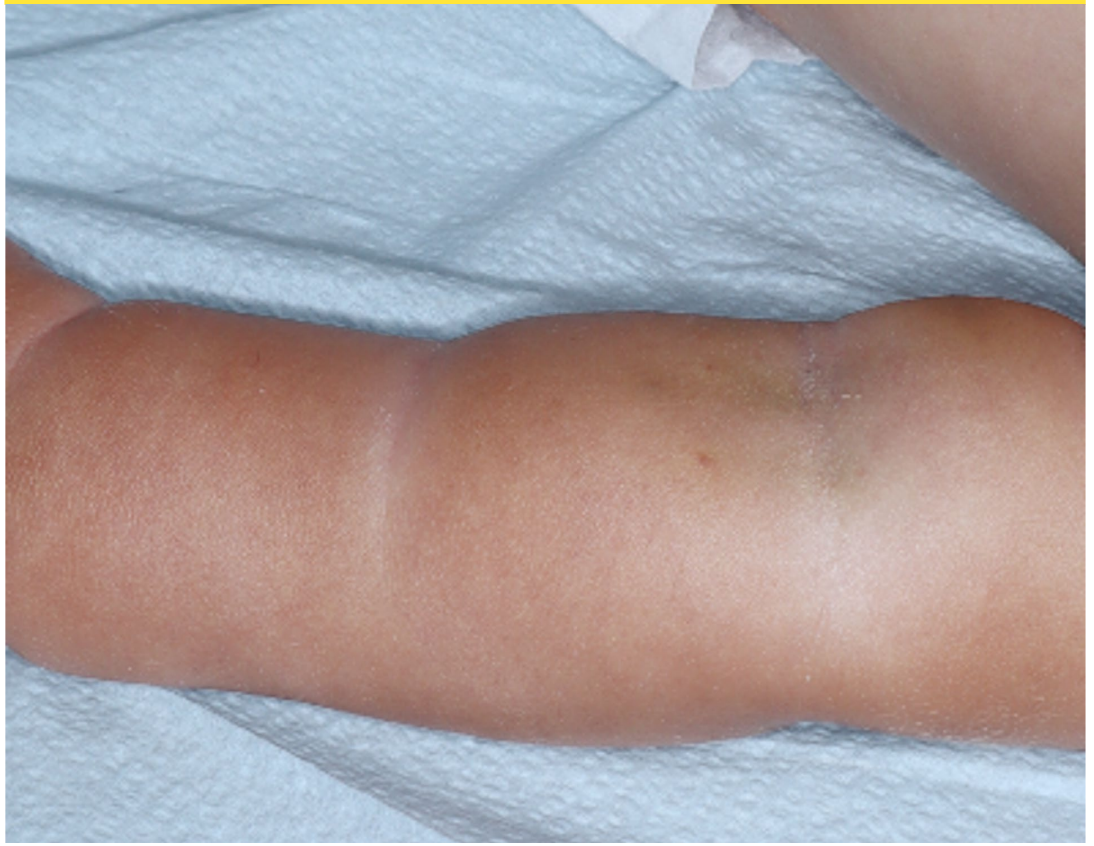
Improvements in AD Over Time

3–month-old Black, Hispanic/Latino boy

Baseline (vIGA-AD 3)



Week 4 (vIGA-AD 1)



AD, atopic dermatitis; vIGA-AD, Validated Investigator Global Assessment for AD.

Conclusions

- Roflumilast cream 0.05% was well tolerated in infants with AD
- Once-daily roflumilast cream 0.05% reduced signs and symptoms of AD, with 49.0% of patients achieving vIGA-AD 0/1 and 67.5% achieving IGA-Scalp success at week 4
- Roflumilast cream 0.05% rapidly and continually reduced caregiver-rated symptoms, including after the first application (10.5% had WSI-NRS success at 24 hours, 46.6% had Dynamic Pruritus Score-25 at 10 min)
- Outcomes in infants were comparable to results from 4-week and 52-week trials with roflumilast cream 0.05% (patients aged 2–5 years) and roflumilast cream 0.15% (patients aged ≥6 years)[1–4]
- These results support safe and efficacious use of roflumilast cream 0.05% in patients aged as young as 3 months, a population with substantial disease burden and limited evidence-based treatment options

AD, atopic dermatitis; IGA, Investigator Global Assessment; min, minutes; Worst Scratch/Itch-Numeric Rating Scale.

1. Eichenfield LF, et al. *Pediatr Dermatol*. 2025;42:296–304. 2. Eichenfield LF, et al. *Pediatr Dermatol.* Published online March 8, 2026. 3. Simpson EL, et al. *JAMA Dermatol.* 2024;160(11):1161–1170.
4. Simpson EL, et al. *Dermatitis.* 2026;37(1):75–83.

Q&A

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