POS-023

Roflumilast Cream in 2–5-Year-Olds With Plaque Psoriasis (DERMIS-OLE) or Atopic Dermatitis (INTEGUMENT-OLE)

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ABBREVIATIONS

AD, atopic dermatitis; *AE*, adverse event; BIW, twice weekly; BSA, body surface area affected; EASI, Eczema Area and Severity Index; IGA, Investigator Global Assessment; NA, not available; OLE, open-label extension; PASI, Psoriasis Area Severity Index; PDE4, phosphodiesterase 4; PED, pediatric; QD, once daily; SAE, serious AE; TCI, topical calcineurin inhibitor; TCS, topical corticosteroids; TEAE, treatment-emergent AE; vIGA-AD, Validated IGA for AD; Wk, week; WI-NRS, Worst Itch-Numeric Rating Scale.

REFERENCES

1. Szczegielniak M, et al. *Forum Dermatologicum*. 2023;9(2):71–74. 2. National Eczema Association. *Eczema in Children*. https://nationaleczema.org/children/. Accessed February 26, 2026. 3. AAAAI/ACAAI JTF Atopic Dermatitis Guideline Panel. *Ann Allergy Asthma Immunol*. 2023;132:274–31. 4. Menter A, et al. *J Am Acad Dermatol*. 2020;82:161–201. 5. Navasero N, et al. *J Allergy Clin Immunol*. 2026;157(2 Abstract 103. 6. Elmets CA, et al. *J Am Acad Dermatol*. 2021;84:432–470. 7. Burshtein J, et al. *DermatolOnline J*. 2025;31. doi: 10.5070/D331164978. 8. Sathishkumar D, et al. *Curr Med Issues*. 2020;18:317–325. 9. Amiri D, et al. *Acta Derm Venereol*. 2023; 103:adv00890. 10. ZORYVE (roflumilast) cream 0.3%, 0.15%, 0.05% [Prescribing Information]. Arcutis Biotherapeutics, Inc. June 2026. 11. Eichenfield LF, et al. *Pediatr Dermatol*. 2025;42:296–304. 12. Draelos ZD, et al. *J Drugs Dermatol*. 2024;23:834–840. 13. Lebwohl MG, et al. *JAMA*. 2022;328:1073–1084.

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DISCLOSURES

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INTRODUCTION

- Plaque psoriasis and AD are chronic conditions that can be diagnosed at any age and cause various symptoms, including pruritus[1,2]
- TCS are often prescribed for children with AD[3] and may be used for children aged <12 years with psoriasis[4]; because of the chronic nature of these conditions and associated comorbidities, the cumulative corticosteroid burden is high[5]
  - Additionally, TCS are not approved for long-term use of cutaneous conditions[4] and higher potency TCS are not recommended for thin-skinned areas (eg, face, younger skin) where there is greater systemic absorption[3,6,7]
  - Notably, higher BSA and BSA-to-weight ratios in children lead to a greater risk for local cutaneous and systemic AEs with topical therapies, highlighting a need for therapeutic alternatives[8]
- TCIs are another option for topical therapy; however, a burning and/or stinging sensation has been reported after their application[3,9]
- Roflumilast cream has been developed as 0.3%, 0.15%, and 0.05% formulations to address differences in skin barrier dysfunction among patients with plaque psoriasis and AD,[10] as well as account for the higher BSA-to-weight ratios in children[11]
  - Roflumilast creams are advanced targeted topical therapies that inhibit PDE4 and do not contain potentially skin-irritating excipients, such as ethanol, propylene glycol, formaldehyde, or fragrances[12]
- Efficacy, safety, and tolerability of roflumilast cream 0.3% and 0.05% were demonstrated in patients with plaque psoriasis in the 4-week, phase 3 DERMIS-1/2 (aged ≥2 years)[13] and INTEGUMENT-PED trials (aged 2–5 years),[11] respectively
- Long-term outcomes for patients aged 2–5 years treated with roflumilast cream for plaque psoriasis or AD in the DERMIS-OLE (NCT04286607) and INTEGUMENT-OLE (NCT04804605) studies were investigated

METHODS

- DERMIS-OLE was a phase 3, open-label study of once-daily roflumilast cream 0.3% in patients aged ≥2 years with chronic plaque psoriasis; two cohorts were enrolled
  - This analysis comprises patients who were naive to therapy with roflumilast cream and were enrolled into cohort 2; there were no patients aged 2–5 years in cohort 1
- INTEGUMENT-OLE was a 52-week, phase 3, multicenter, OLE trial in patients aged ≥2 years with mild-to-moderate AD
  - Patients who completed 4 weeks in one of the parent studies with no safety concerns were eligible to enroll in the INTEGUMENT-OLE trial and initiate or continue roflumilast cream
  - Patients continuing from INTEGUMENT-PED (aged 2–5 years) had roflumilast cream 0.05% applied once daily; those from INTEGUMENT-1/2 (aged ≥6 years) applied roflumilast cream 0.15% once daily
  - Baseline of INTEGUMENT-PED was used for change-from-baseline assessments in INTEGUMENT-OLE; baseline was defined as the last observation before or on the first application of roflumilast cream 0.05% or vehicle cream in INTEGUMENT-PED

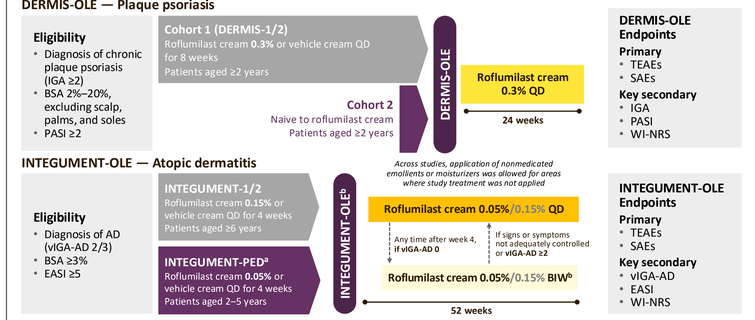
Endpoints and assessments

- Safety (primary endpoint)
- IGA or vIGA-AD success, defined as clear/almost clear (0/1) plus ≥2-point improvement from baseline
- IGA or vIGA-AD 0/1
- PASI-75 or EASI-75, defined as ≥75% improvement from baseline
- WI-NRS success, defined as ≥4-point improvement in patients with baseline WI-NRS ≥4
- BSA over time
- Application-site tolerability

RESULTS

- There were 21 and 562 patients aged 2–5 years enrolled in DERMIS-OLE and INTEGUMENT-OLE, respectively
  - All patients aged 2–5 years enrolled in DERMIS-OLE were from cohort 2 and were naive to roflumilast cream
- Signs and symptoms of plaque psoriasis and AD, as well as their severity, decreased with roflumilast cream in both the DERMIS-OLE and INTEGUMENT-OLE studies at week 24 and week 52, respectively
  - IGA/vIGA-AD success: 77.8% and 46.6%; IGA/vIGA-AD 0/1: 83.3% and 63.1%; PASI-75/EASI-75: 83.3% and 67.7%
- Mean BSA decreased throughout both studies
- Both roflumilast cream 0.3% and roflumilast cream 0.05% were well tolerated
  - No serious or related TEAEs leading to study-drug discontinuation were reported in DERMIS-OLE
  - Serious TEAEs and TEAEs leading to study-drug discontinuation were each reported for 3.2% of patients in INTEGUMENT-OLE
  - Investigators reported no evidence of application-site irritation in 97.5%–100% of patients throughout both studies

Study Designs



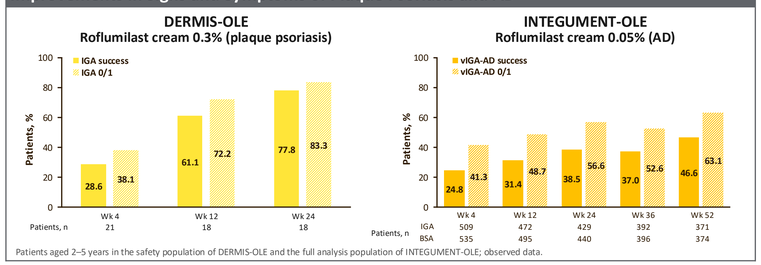
[a]After INTEGUMENT-OLE study enrollment commenced, the protocol was amended to allow patients (aged 2–5 years) who completed INTEGUMENT-PED to enroll, as well as a 24-week cohort consisting of an additional ~550 patients aged 6–17 years. Patients must have completed 4 weeks in a parent trial with no treatment-related AEs or SAEs that precluded further treatment with roflumilast cream. [b]Anytime at/after OLE week 4, patients who achieved vIGA-AD 0 could switch to BIW application on 2 nonconsecutive days per week to areas commonly/recently affected by AD and areas where AD was newly presenting. BIW application was maintained based on adequate disease control (ie, vIGA-AD clear/almost clear [0/1], with adequate control of AD signs and symptoms).

Patient Demographics and Baseline Clinical Characteristics

		Patients aged 2–5 years	
		DERMIS-OLE Roflumilast cream 0.3% (n=21)	INTEGUMENT-PED[a] Roflumilast cream 0.05% (n=562)
Age, years, mean (median) [range]		4.0 (4.0) [2–5]	3.3 (3.0) [2–5]
Male at birth, n (%)		15 (71.4)	286 (50.9)
Not Hispanic or Latino, n (%)		6 (28.6)	465 (82.7)
Race, n (%)	White	5 (23.8)	399 (71.0)
	Black or African American	15 (71.4)	80 (14.2)
	Asian	1 (4.8)	45 (8.0)
	Multiple	0	28 (5.0)
	Other	0	10 (1.8)[b]
IGA/vIGA-AD, n (%)[c]	2 (mild)	6 (28.6)	126 (22.4)
	3 (moderate)	15 (71.4)	436 (77.6)
	4 (severe)	0	0
Mean (median) [range][c]	PASI/EASI	7.8 (7.6) [1–18]	12.2 (10.2) [4.6–42.0]
	BSA, %	13.7 (13.0) [2.0–24.0]	22.3 (17.5) [3.0–82.0]
	WI-NRS[d]	5.1 (6.0) [0–10]	6.1 (2.6) [0.0–10.0]
Prior inadequate response, intolerance, and/or contraindication to TCS, n (%)		Not collected	297 (52.8)

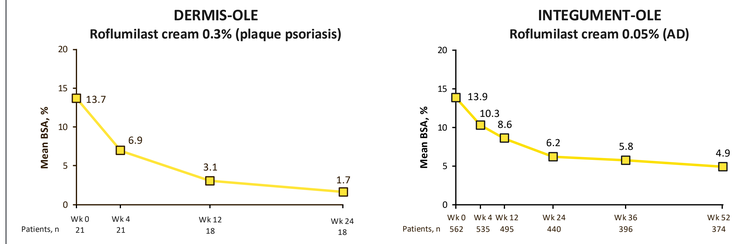
Patients aged 2–5 years in the safety population of DERMIS-OLE and those from INTEGUMENT-PED who enrolled in INTEGUMENT-OLE. [a]At baseline, 66.5% and 33.3% of patients had Fitzpatrick Skin Type I–III and IV–VI, respectively; Fitzpatrick Skin Type was not collected in DERMIS-1/2. [b]Includes 2 patients with American Indian/Alaskan native race. [c]For INTEGUMENT-OLE, baseline was defined as the last observation before or on the first application of roflumilast cream 0.05% or vehicle cream in INTEGUMENT-PED. [d]Worst itch in the previous 24 hours.

Improvements in Signs and Symptoms of Plaque Psoriasis and AD



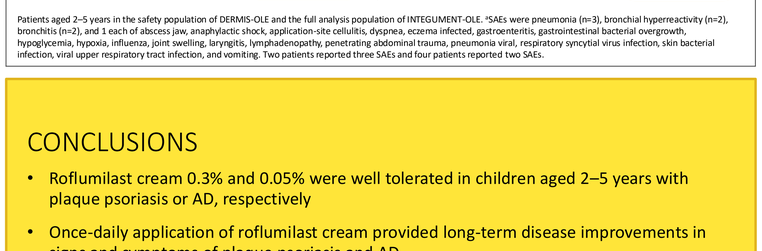
Patients aged 2–5 years in the safety population of DERMIS-OLE and the full analysis population of INTEGUMENT-OLE; observed data.

Improvement in Mean BSA of Plaque Psoriasis and AD



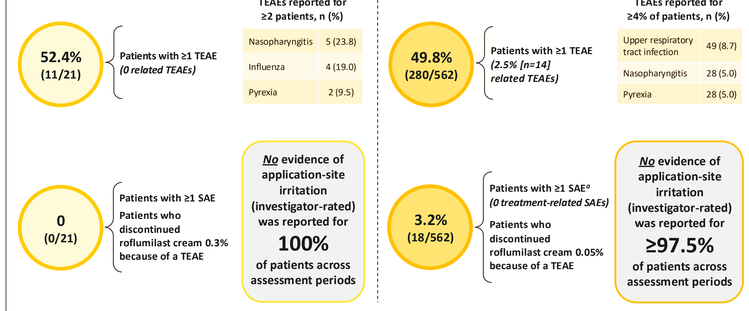
Patients aged 2–5 years in the safety population of DERMIS-OLE and the full analysis population of INTEGUMENT-OLE; observed data. Wk 0 is baseline of DERMIS-OLE and INTEGUMENT-OLE.

Long-term Improvements in Severity and Itch Symptoms of Plaque Psoriasis and AD



Patients aged 2–5 years in the safety population of DERMIS-OLE and the full analysis population of INTEGUMENT-OLE; observed data.

Safety and Application-Site Tolerability



Patients aged 2–5 years in the safety population of DERMIS-OLE and the full analysis population of INTEGUMENT-OLE. [e]SAEs were pneumonia (n=3), bronchial hyperreactivity (n=2), bronchitis (n=2), and 1 each of abscess jaw, anaphylactic shock, application-site cellulitis, dyspnea, eczema infected, gastroenteritis, gastrointestinal bacterial overgrowth, hypoglycemia, hypoxia, influenza, joint swelling, laryngitis, lymphadenopathy, penetrating abdominal trauma, pneumonia viral, respiratory syncytial virus infection, skin bacterial infection, viral upper respiratory tract infection, and vomiting. Two patients reported three SAEs and four patients reported two SAEs.

CONCLUSIONS

- Roflumilast cream 0.3% and 0.05% were well tolerated in children aged 2–5 years with plaque psoriasis or AD, respectively
- Once-daily application of roflumilast cream provided long-term disease improvements in signs and symptoms of plaque psoriasis and AD
- Roflumilast cream 0.3% and 0.05% provide a long-term topical treatment option for children aged 2–5 years with plaque psoriasis or AD, respectively