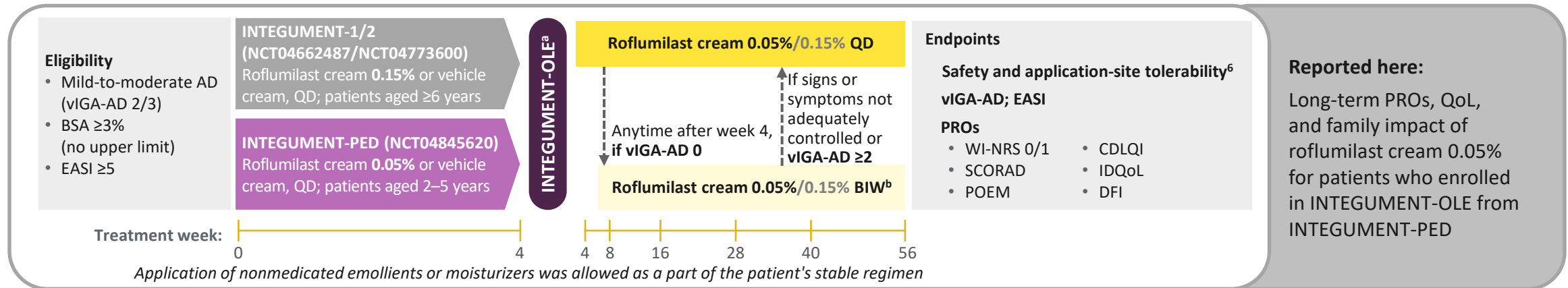


Once-Daily and Proactive Twice-Weekly Roflumilast Cream 0.05% Provides Improvements in Caregiver-Reported Outcomes That Are Maintained Long Term: Results for Patients Aged 2–5 Years With Mild-to-Moderate Atopic Dermatitis in the INTEGUMENT-OLE Trial

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- Signs and symptoms of AD can negatively impact quality of life for both patients and their families¹
 - Complicated treatment regimens, concerns over adverse effects, and treatment limitations of commonly used topical therapies (eg, TCS and TCIs)^a can reduce adherence and prolong signs and symptoms of AD, especially in children^{2,3}
- Roflumilast cream 0.15%/0.05% is a PDE4 inhibitor–based advanced targeted topical therapy that does not contain potentially skin-irritating excipients⁴ and is approved for the treatment of mild-to-moderate AD in patients aged ≥6 years and 2–5 years, respectively⁵
 - Efficacy, safety, and application-site tolerability were demonstrated in patients aged 2–5 years in the 4-week, vehicle-controlled, phase 3 INTEGUMENT-PED trial⁶
 - Positive long-term outcomes and control of AD signs and symptoms were observed in patients aged 2–5 years in the 52-week, phase 3, open-label extension trial, INTEGUMENT-OLE⁷



^aTCS are not approved for long-term use, potent TCS are not recommended for thin-skinned areas where absorption is higher, and a burning/stinging sensation has been reported with the use of TCIs.²

^bApplied on 2 nonconsecutive days per week to areas commonly and/or most recently affected by AD, and any areas where AD was developing. AD, atopic dermatitis; BIW, twice weekly; BSA, body surface area affected; CDLQI, Children's Dermatology Life Quality Index; DFI, Dermatitis Family Impact; EASI, Eczema Area and Severity Index; IDQoL, Infants' Dermatitis Quality of Life Index; OLE, open-label extension; PDE4, phosphodiesterase 4; POEM, Patient-Oriented Eczema Measure; PRO, patient-reported outcome; QD, once daily; QoL, quality of life; SCORAD, SCORing AD; TCI, topical calcineurin inhibitor; TCS, topical corticosteroids; vIGA-AD, Validated Investigator Global Assessment of AD; WI-NRS, Worst Itch-Numeric Rating Scale. 1. Na CH, et al. *Children* (Basel). 2019;6(12):133. 2. AAAAI/ACAAJ JTF Atopic Dermatitis Guideline Panel. *Ann Allergy Asthma Immunol*. 2023;132(3):274–312. 3. Capozza K, Schwartz A. *Pediatr Dermatol*. 2020;37:58–61. 4. Draeos ZD, et al. *J Drugs Dermatol*. 2024;23(10):834–840. 5. ZORYVE® (roflumilast) cream. Prescribing information. Arcutis Biotherapeutics, Inc. October 2025. 6. Eichenfield LF, et al. *Pediatr Dermatol*. 2025;42(2):296–304. 7. Eichenfield LF, et al. Poster presented at 2025 RAD Conference; June 6–7, 2025; Nashville, TN.

Baseline Characteristics and Safety Summary

- 562 patients from INTEGUMENT-PED (roflumilast cream 0.05%, n=382; vehicle cream, n=180) continued in INTEGUMENT-OLE
 - Mean age of patients at parent-study baseline was 3.3 years
 - Most patients were White (71.0%), not Hispanic or Latino (82.7%), and had moderate AD (78.5%)

		Roflumilast cream 0.05% (N=562) ^a
Fitzpatrick skin type, n (%)^b	Type I–III	374 (66.5)
	Type IV–VI	187 (33.3)
vIGA-AD, n (%)	Mild (2)	121 (21.5)
	Moderate (3)	441 (78.5)
Mean (median) [range]	WI-NRS ^c	6.1 (6.0) [0.0–10.0]
	SCORAD	47.0 (46.5) [17.7–89.3]
	POEM	16.2 (16.0) [0–28]
	CDLQI	10.3 (9.0) [0–30]
	IDQoL	10.5 (10.0) [0–30]
	DFI	9.6 (8.0) [0–30]

Full analysis population.

Roflumilast cream 0.05% was well tolerated through up to 56 weeks of application^d

- There were no treatment-related SAEs reported
- An AE of application-site pain was reported for 4 (0.7%) patients

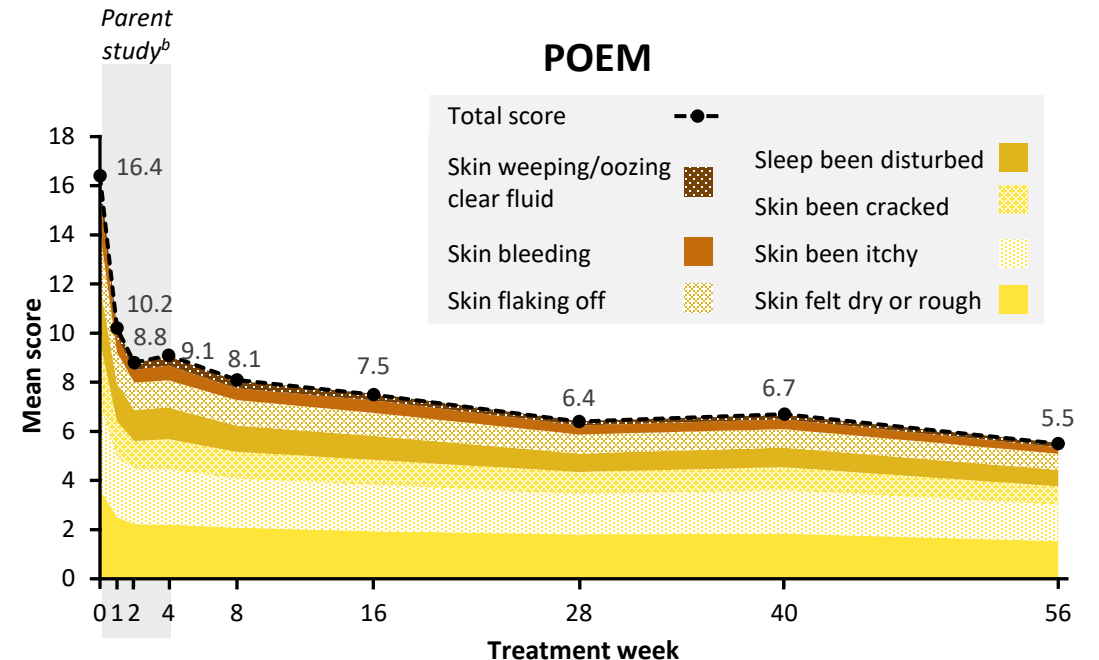
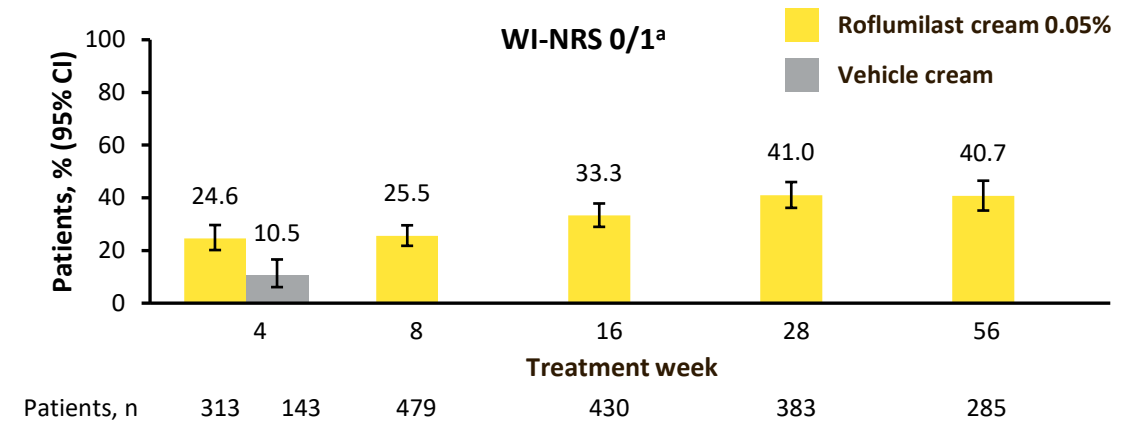
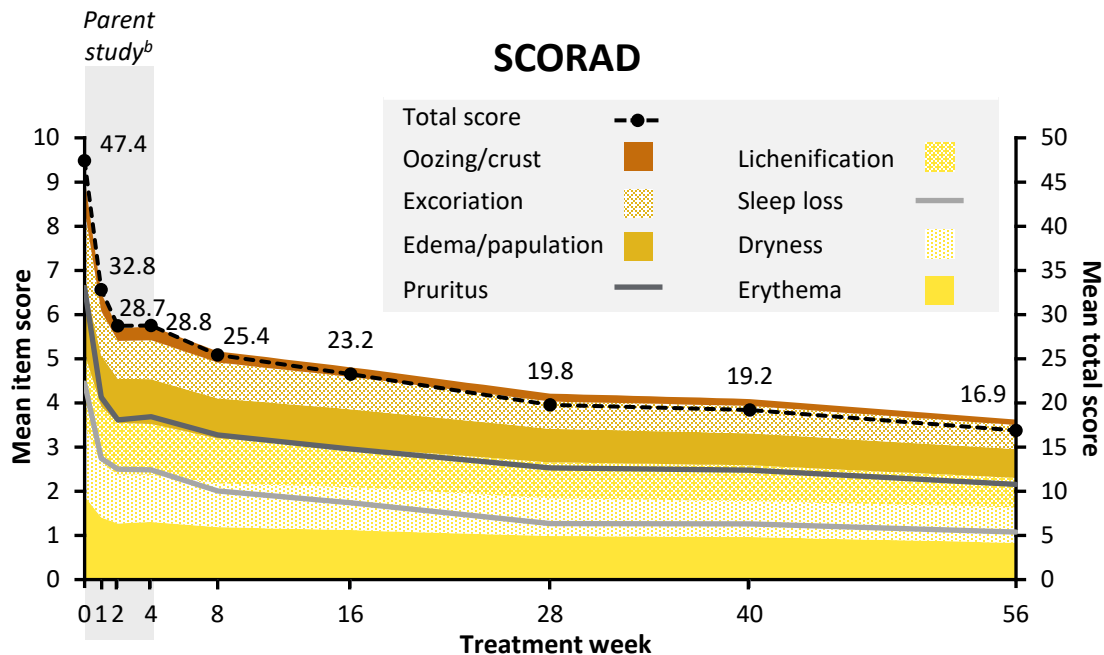
Patients, n (%)	Roflumilast cream 0.05% (N=562)
≥1 TEAE	280 (49.8)
≥1 Treatment-related AE	14 (2.5)
≥1 Serious TEAE^e	18 (3.2)
≥1 Treatment-related SAE	0
≥1 TEAE leading to discontinuation of study/study drug	18 (3.2)/17 (3.0)
Most common TEAEs by preferred term, ≥4.0%	
Upper respiratory tract infection	49 (8.7)
Nasopharyngitis	28 (5.0)
Pyrexia	28 (5.0)

Safety population.

^aClinical characteristic data are baseline of INTEGUMENT-PED. CDLQI administered to patients aged ≥4 years (n=233) and IDQoL to patients aged <4 years (n=327). ^bThere was 1 patient in the vehicle group with a missing baseline Fitzpatrick skin type. ^cWorst itch in the previous 24 hours. ^dSummary of TEAEs occurring during INTEGUMENT-OLE. ^eTwo patients reported 3 SAEs and 4 patients reported 2 SAEs. AD, atopic dermatitis; AE, adverse event; CDLQI, Children's Dermatology Life Quality Index; DFI, Dermatitis Family Impact; IDQoL, Infants' Dermatitis Quality of Life Index; OLE, open-label extension; POEM, Patient-Oriented Eczema Measure; SAE, serious AE; SCORAD, SCORing AD; TEAE, treatment-emergent adverse event; vIGA-AD, Validated Investigator Global Assessment of AD; WI-NRS, Worst Itch-Numeric Rating Scale.

Durable Improvements in AD Sign/Symptom Severity

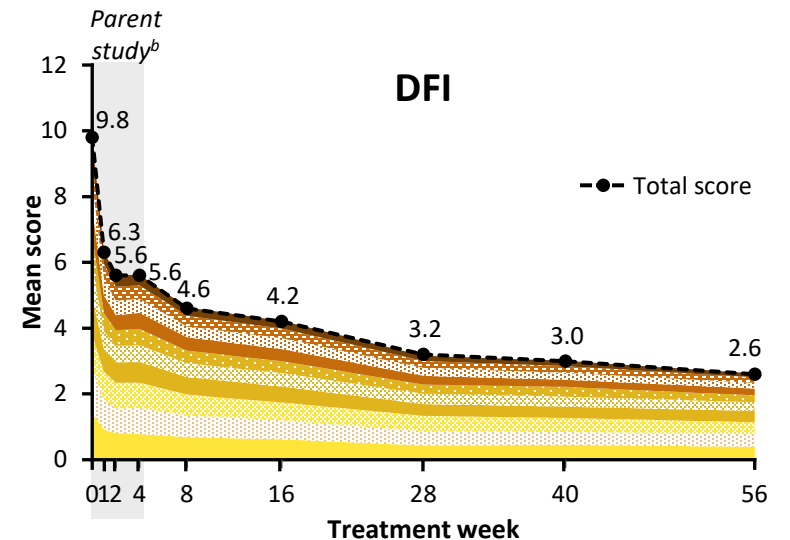
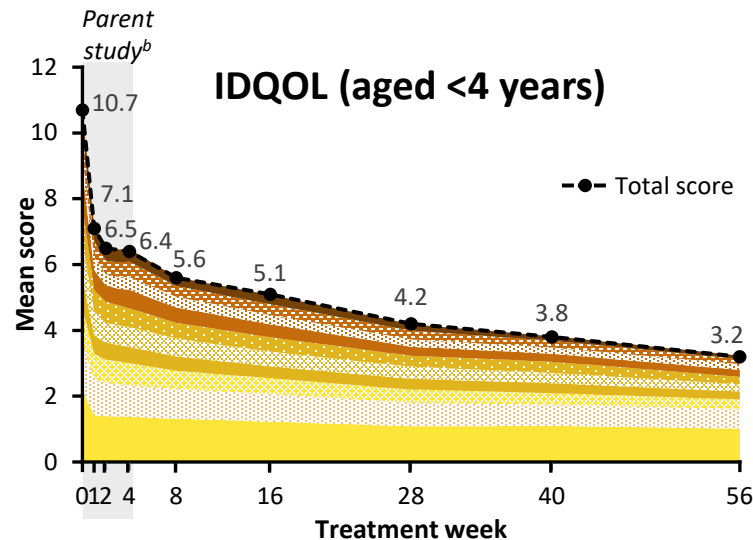
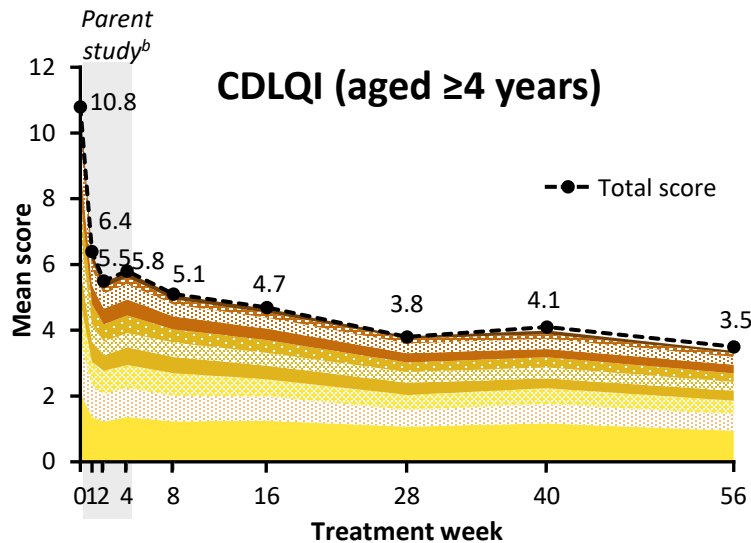
Roflumilast cream 0.05% provided long-term improvements in itch symptoms and caregiver-rated disease severity



^aPatients with no/minimal itch (0/1) itch with WI-NRS ≥ 2 at parent study baseline. ^bParent-study baseline through treatment week 4 includes patients in the roflumilast cream 0.05% group; beyond treatment week 4 are patients enrolled into INTEGUMENT-OLE who received either roflumilast cream or vehicle cream in the parent study. AD, atopic dermatitis; POEM, Patient Oriented Eczema Measure; SCORAD, SCORing AD; WI-NRS, Worst Itch-Numeric Rating Scale.

Durable Improvements in Quality of Life^a

Roflumilast cream 0.05% improved patient quality of life and family impact for up to 56 weeks of treatment



'How much has AD...'

Caused issues with other people ^a	Made you embarrassed/self-conscious/upset/sad	
Affected friendships	Influenced clothing	
Led to sports avoidance	Treatment been a problem	
Affected going out, playing, and/or hobbies	Affected sleep	
Affected school, work, holiday/vacation	Been itchy, "scratchy", sore, or painful	

'How much has AD...'

Caused problems with mealtimes	Caused problems at bathtime	
Interfered with family activities	Interfered with playing or swimming	
Treatment been a problem	Impacted child mood	
Caused dressing/undressing discomfort	Affected time falling asleep	
Disturbed average sleep time	Caused itching and scratching	

'How much has AD...'

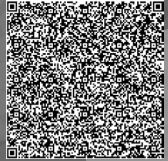
Affected shopping time	Affected expenditure	
Affected family relationships	Caused emotional distress for carers	
Affected food prep and feeding	Treatment affected the carer's life	
Affected housework	Caused tiredness for carers	
Affected family leisure activities	Affected sleep of others in family	

^aIndividual CDLQI (other than missed school/work), IDQOL (other than child mood and sleep), and DFI questions are ranked on a 4-point scale from 'Very much' to 'Not at all'; total scores for each assessment range from 0 to 30, higher scores indicating greater impact. ^aIncludes name-calling, teasing, bullying, people asking questions, or avoiding the patient. ^bParent-study baseline through treatment week 4 includes patients in the roflumilast cream 0.05% group; beyond treatment week 4 are patients enrolled into INTEGUMENT-OLE who received either roflumilast cream or vehicle cream in the parent study. AD, atopic dermatitis; CDLQI, Children's Dermatology Life Quality Index; DFI, Dermatitis Family Impact; IDQOL, Infants' Dermatitis Quality of Life Index.

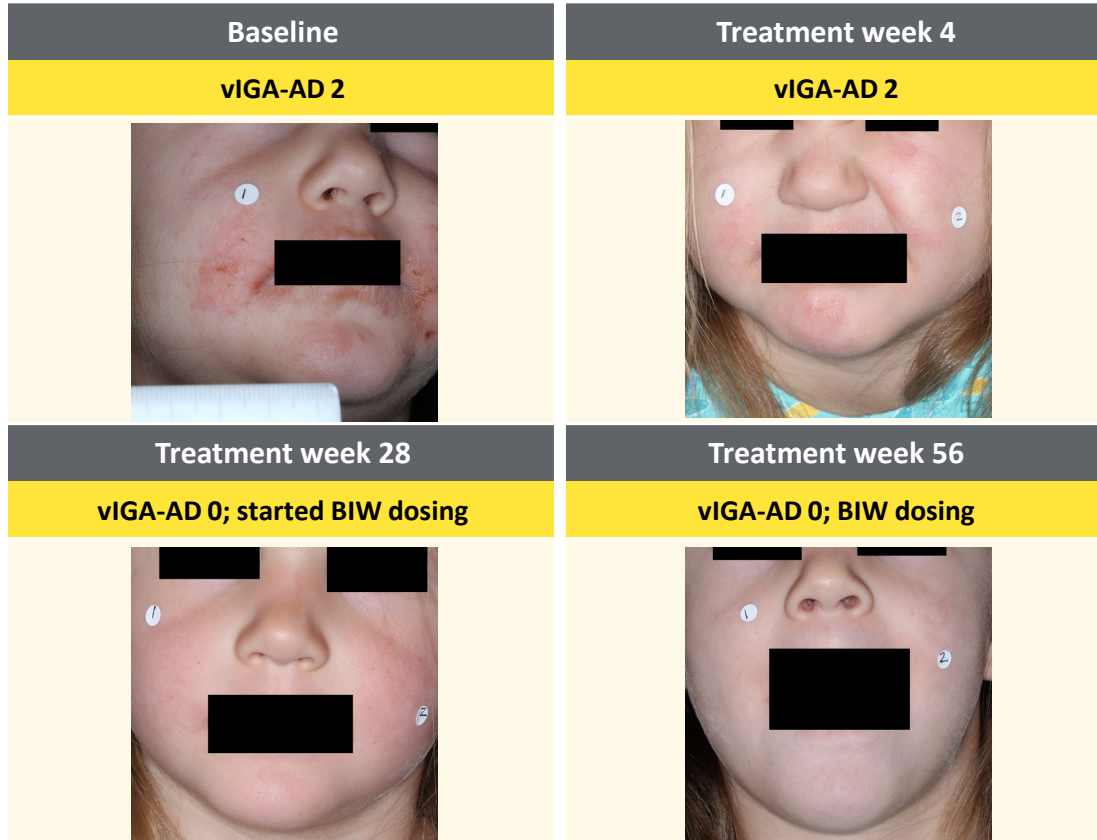
Improvement of AD

Conclusions

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2-year-old White, not Hispanic or Latina female with a 2-year history of AD and a history of inadequate response, intolerance, or contraindications to TCS



Roflumilast cream 0.05% demonstrated durable improvements in PROs in patients aged 2–5 years with mild-to-moderate AD

- There were clinically meaningful improvements in disease severity (SCORAD and POEM), quality of life, and family impact
- Improvements observed at 4 weeks in the parent trial (INTEGUMENT-PED) were maintained/continued to improve through up to 56 weeks of application

Roflumilast cream 0.05% was well tolerated

- There were no treatment-related SAEs
- During this 52-week OLE trial, ~3% of patients discontinued the study/study drug because of a TEAE

AD, atopic dermatitis; BIW, twice weekly; OLE, open-label extension; POEM, Patient Oriented Eczema Measure; PRO, patient-reported outcomes SAE, serious adverse event; SCORAD, SCORing AD; TCS, topical corticosteroids; TEAE, treatment-emergent adverse event; vIGA-AD, Validated Investigator Global Assessment of AD.

Disclosures: This study was funded by Arcutis Biotherapeutics, Inc. LFE, MB, LWL, JB, HCH, RS, VHP, AF, and ES are investigators and/or consultants for and received grants/research funding and/or honoraria from Arcutis Biotherapeutics, Inc. MSS and DH are employees of Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

Acknowledgments: Thank you to the investigators and their staff for their participation in the trials. We are grateful to the study participants and their families for their time and commitment. Writing support was provided by Kelly M. Fahrback, PhD, CMPP, and Andrea M. Michels, of Ashfield MedComms, an Inizio company, and was funded by Arcutis Biotherapeutics, Inc.