

Long-Term Roflumilast Cream 0.05% for Atopic Dermatitis in Patients Aged 2–5 Years (INTEGUMENT-OLE): Patient-Reported Outcomes

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ABBREVIATIONS

AD, atopic dermatitis; AE, adverse event; BIW, twice weekly; BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; DFI, Dermatitis Family Impact; EASI-75, 75% reduction in Eczema Area and Severity Index; IDQoL, Infant's Dermatology Quality of Life Index; MID, minimally important difference; OLE, open-label extension; POEA, phosphodiesterase-4; PED, pediatric; POEM, Patient-Oriented Eczema Measure; PRO, patient-reported outcome; QD, once daily; QoL, quality of life; SAE, serious AE; SCORAD, SCORing Atopic Dermatitis; TCIs, topical calcineurin inhibitors; TCS, topical corticosteroids; TEAE, treatment-emergent AE; vIGA-AD, Validated Investigator Global Assessment for AD; WI-NRS, Worst Itch-Numeric Rating Score.

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ACKNOWLEDGMENTS

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

DISCLOSURES

This study was funded by Arcutis Biotherapeutics, Inc. LFE, MB, RS, GY, and VHP are investigators and/or consultants for Arcutis Biotherapeutics, Inc. and received grants/research funding and/or honoraria. DK, DH, MSS, and PB are employees of Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

Presented at the American College of Allergy, Asthma & Immunology Annual Scientific Meeting; November 6–10, 2025; Orlando, FL.

INTRODUCTION

- AD is a chronic condition that is commonly diagnosed in childhood^{1,2} and includes symptoms (eg, itch) and mental/physical comorbidities that can negatively impact quality of life for both patients and their families³
- Complicated application regimens, concerns over side effects, and treatment limitations of topical therapies commonly used to treat AD (eg, TCS and TCIs) can reduce adherence and prolong AD symptoms, especially in children^{4–6}
 - TCS are not approved for long-term use and potent TCS are not recommended for thin-skinned areas with higher absorption⁴
 - A burning/stinging sensation at the application site has been reported with the use of TCIs and the topical PDE4 inhibitor, crisaborole⁴
- Alternative topical therapies with the potential for proactive, long-term use to maintain disease control are needed⁷
- Roflumilast cream is an advanced targeted topical treatment that is a PDE4 inhibitor and formulated without potentially skin-irritating excipients, such as fragrances, ethanol, or propylene glycol⁸
- The efficacy, safety, and tolerability of roflumilast cream 0.15% and 0.05% were demonstrated in the 4-week, vehicle-controlled, phase 3 trials, INTEGUMENT-1 and -2 (patients aged ≥6 years)⁹ and INTEGUMENT-PED (patients aged 2–5 years),¹⁰ respectively
 - Positive long-term outcomes and control of AD signs and symptoms was observed in the 52-week, phase 3, open-label extension of these trials, INTEGUMENT-OLE^{11,12}
 - Roflumilast cream 0.05% and 0.15% are approved for the topical treatment of mild-to-moderate AD in patients aged 2–5 years and ≥6 years, respectively¹³
- Long-term caregiver-reported PROs, QoL, and family impact of roflumilast cream 0.05% for patients who enrolled in INTEGUMENT-OLE from INTEGUMENT-PED are described here

METHODS

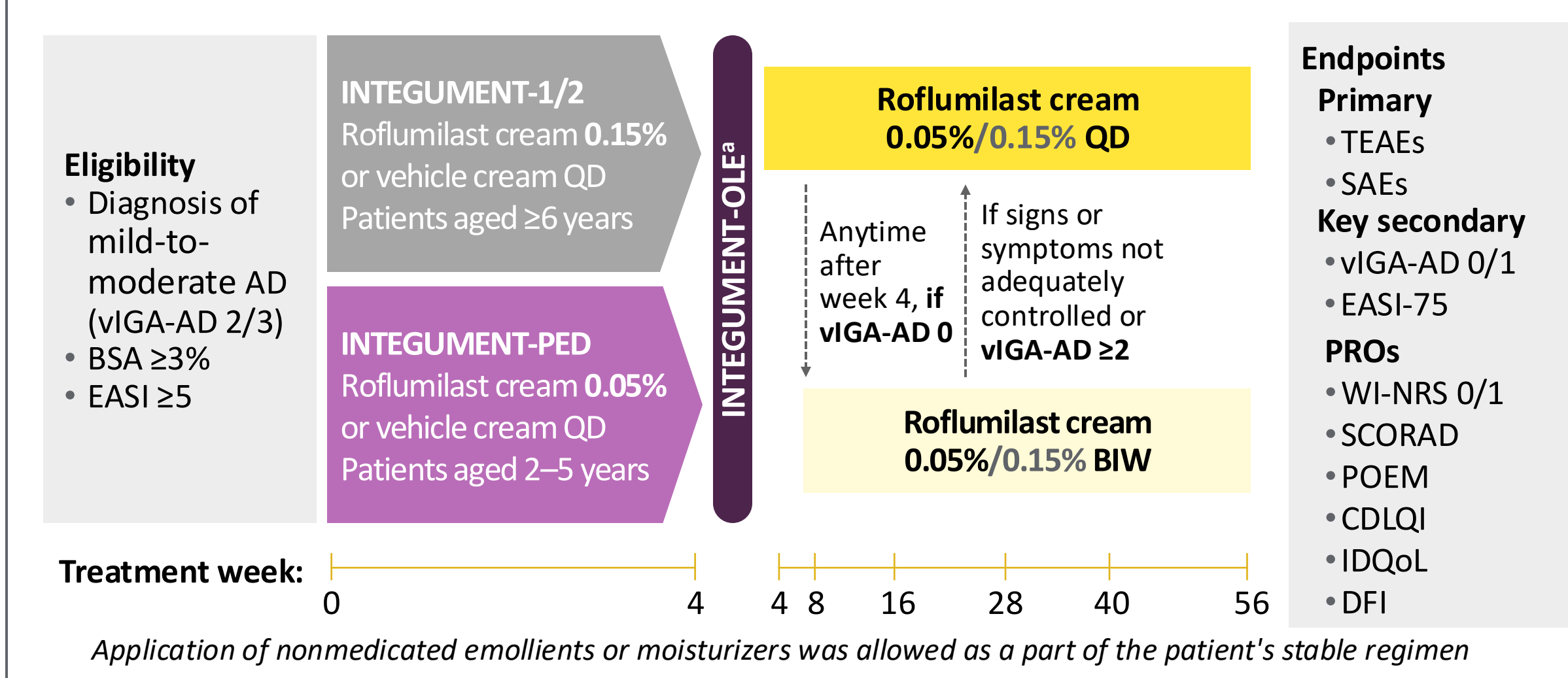
Study design

- 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 (INTEGUMENT-1/2 [aged ≥6 years] or INTEGUMENT-PED [aged 2–5 years]) with no safety concerns were eligible to enroll in the INTEGUMENT-OLE trial
- For patients aged 2–5 years in INTEGUMENT-OLE, roflumilast cream 0.05% was applied once daily for up to 52 weeks by a caregiver
 - Patients who aged to 6 years during the study were to switch to roflumilast cream 0.15% at the first clinic visit after their 6th birthday
 - Patients could switch to BIW application any time after week 4 if they achieved vIGA-AD clear (0); BIW treatment was maintained if signs and symptoms were adequately controlled and vIGA-AD remained clear or almost clear (0/1)

PRO assessments

- WI-NRS 0/1: no/minimal itch, in patients with WI-NRS ≥2 at baseline of INTEGUMENT-PED
- SCORAD: evaluation of AD sign/symptom severity; total scores range from 0 (none) to 103 (most severe); MID ≥8.7
- POEM: measure of AD severity and symptom impact; total scores range from 0 (no impact) to 28 (greatest symptom impact); MID ≥3.4
- CDLQI: assessment of the impact of AD on QoL over the prior week in patients aged 4–16 years; total scores for both range from 0 (no impact) to 30 (highest impact); MID ≥6
 - IDQoL was used for patients aged <4 years; MID not defined
- DFI: measure of how having a child with AD affects QoL of the family for patients aged ≤17 years; total scores range from 0 (no impact) to 30 (highest); MID not defined
- Proportions of patients achieving a MID in SCORAD, POEM, or CDLQI from baseline of INTEGUMENT-PED are reported; patients with a baseline score <MID were excluded from that PRO analysis
 - For IDQoL and DFI, mean improvements from baseline of INTEGUMENT-PED are reported

INTEGUMENT-OLE Study Design



*After 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 ~500 patients aged 6–17 years. Patients must have completed 4 weeks in a parent trial with no safety concerns.

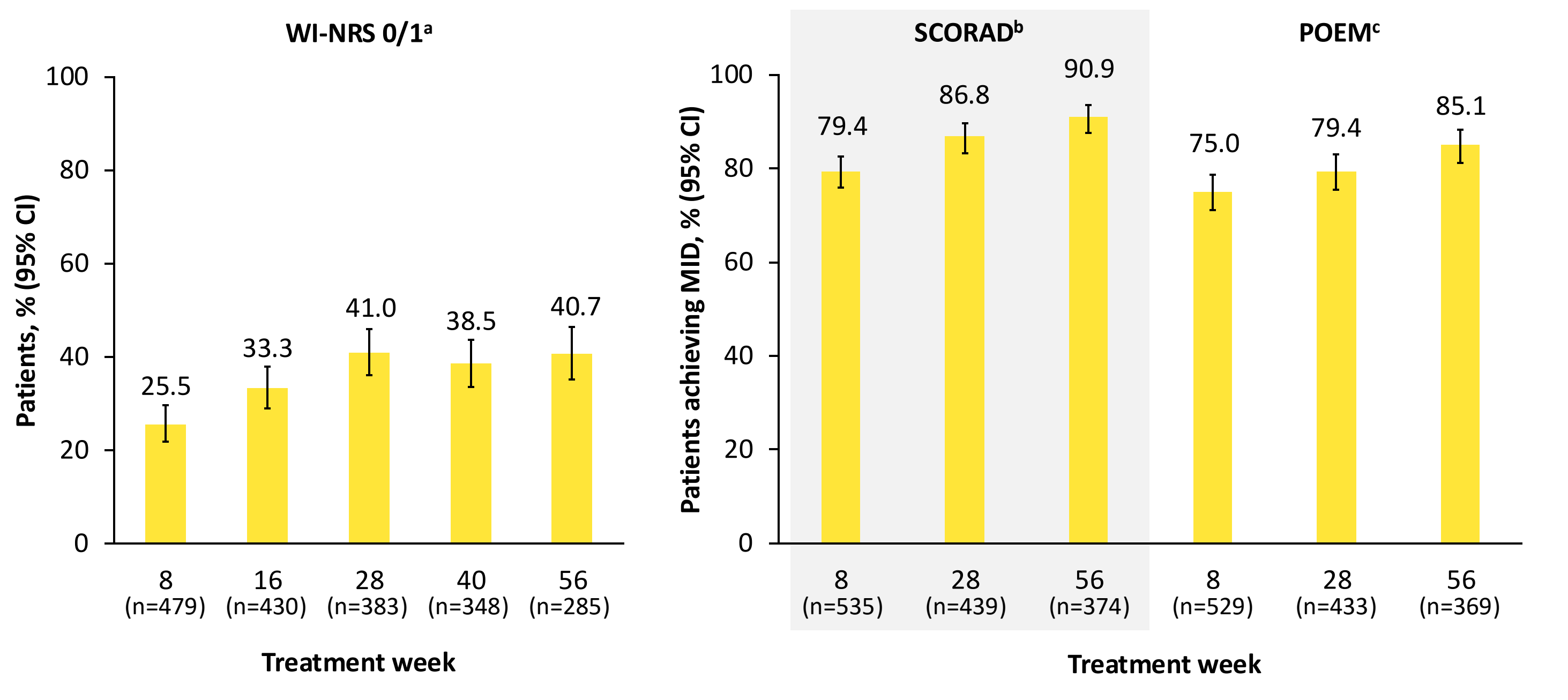
RESULTS

- Among the 562 patients who completed INTEGUMENT-PED and enrolled in INTEGUMENT-OLE, roflumilast cream 0.05% provided clinically meaningful improvements in PROs, which were maintained from INTEGUMENT-PED¹⁴ and/or continued to improve throughout INTEGUMENT-OLE
- At treatment week 56, WI-NRS 0/1 was achieved by 40.7% (116/285) of patients
 - Clinically meaningful improvements (ie, MID) in SCORAD and POEM were achieved by >85% of patients and CDLQI by 69.5% of patients
 - IDQoL and DFI scores improved by means of 7.1 and 6.5 points, respectively
- Roflumilast cream 0.05% was well tolerated with 4 (0.7%) patients reporting an application-site pain AE throughout the trial

Patient Demographics and Baseline Disease Characteristics		
		Roflumilast cream 0.05% (n=562)
Age, mean (SD) [range], years		3.3 (3.0) [2–5]
Male sex at birth, n (%)		286 (50.9)
Ethnicity, n (%)	Not Hispanic or Latino	465 (82.7)
	White	399 (71.0)
	Black or African American	80 (14.2)
	Asian	45 (8.0)
Race, n (%)	Other/Multiple	38 (6.8)
	Type I–III	374 (66.5)
Fitzpatrick skin type, n (%) ^a	Type IV–VI	187 (33.3)
	Mild (2)	121 (21.5)
vIGA-AD, n (%)	Moderate (3)	441 (78.5)
	BSA, %	22.3 (17.5) [3.0–82.0]
Mean (median) [range]	WI-NRS (weekly average)	6.1 (6.0) [0.0–10.0]
	EASI	12.2 (10.2) [4.6–42.0]
	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]

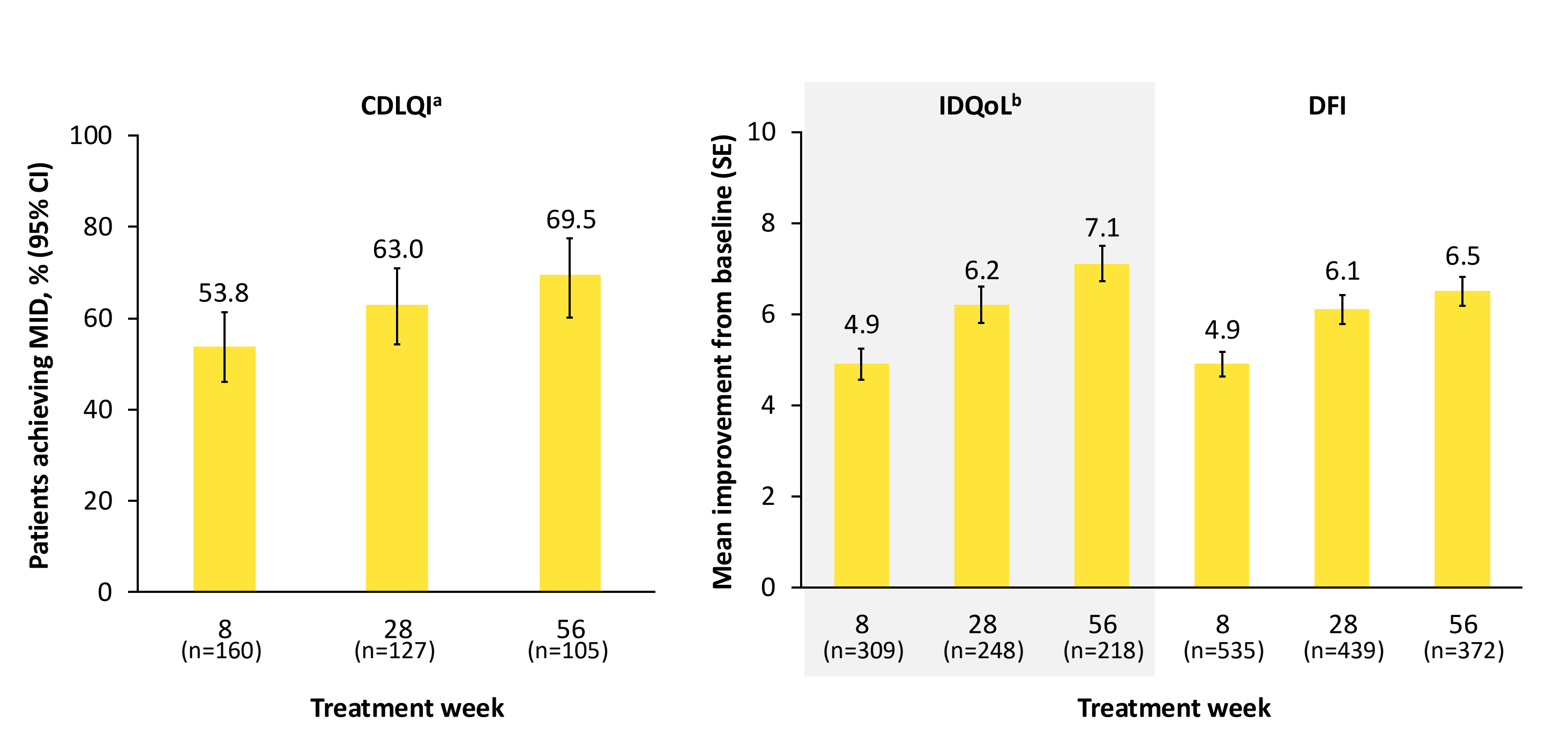
Full analysis population. Values are baseline of INTEGUMENT-PED for patients who enrolled in INTEGUMENT-OLE from either the roflumilast cream 0.05% or vehicle cream group. ^aThere was 1 patient in the vehicle group with a missing baseline Fitzpatrick skin type.

Improvement in Itch Symptoms Over Time

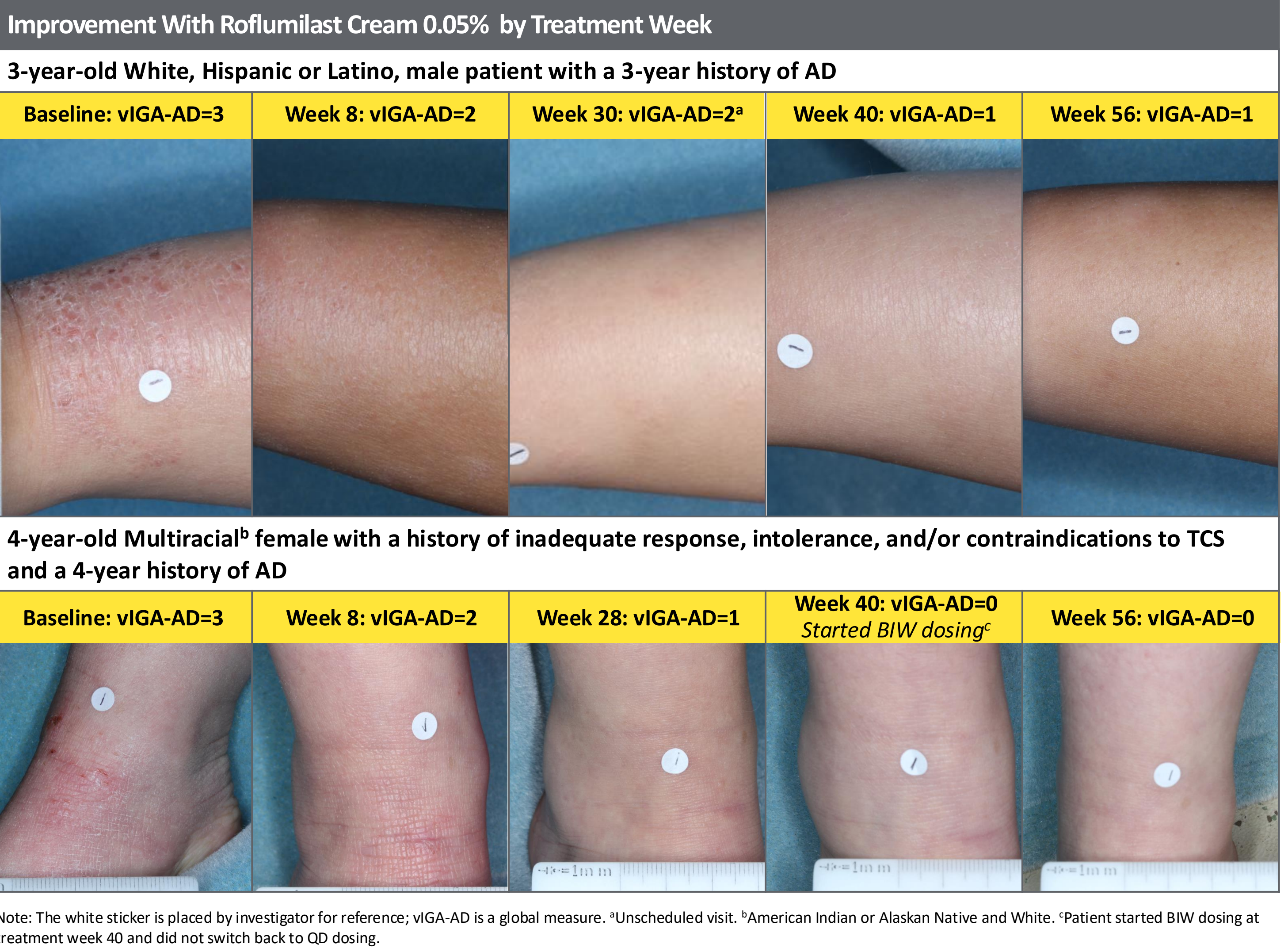


Full analysis population. Observed data. ^aPatients with WI-NRS ≥2 at INTEGUMENT-PED baseline. ^bPatients with SCORAD ≥8.7 at INTEGUMENT-PED baseline. ^cPatients with POEM ≥3.4 at INTEGUMENT-PED baseline.

Improvement in QoL and Family Impact



Full analysis population. Observed data. ^aPatients with CDLQI ≥6 and aged 4–5 years at INTEGUMENT-PED baseline. ^bPatients aged <4 years at INTEGUMENT-PED baseline.



Safety Summary^a

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

Safety population. ^aSummary of TEAEs occurring during INTEGUMENT-OLE.

CONCLUSIONS

- Roflumilast cream 0.05% improved itch symptoms and multiple PROs in patients aged 2–5 years with AD after 4 weeks of treatment¹⁴ and maintained/continued to demonstrate improvements with long-term application
 - Improvement in SCORAD and POEM total scores represent clinically meaningful reductions in AD severity and symptom impact with roflumilast application
 - Roflumilast improved QoL in patients and decreased the negative impact on family
- Roflumilast was well tolerated with no treatment-related SAEs and low rates of treatment-related AEs during INTEGUMENT-OLE
- These results are comparable with those in patients aged ≥6 years with AD who participated in INTEGUMENT-OLE following completion of the INTEGUMENT-1/2 trials¹⁵
- Meaningful improvements in patient-reported AD signs/symptoms (including itch), patient QoL, and family impact were observed with roflumilast cream 0.05% for up to 56 weeks in patients aged 2–5 years with mild-to-moderate AD, providing a long-term treatment option for this chronic condition