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Long-Term Roflumilast Cream 0.15% for Atopic Dermatitis in Patients Aged 6+ Years (INTEGUMENT-OLE): Patient-Reported Outcomes

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ABBREVIATIONS

AD, atopic dermatitis; AE, adverse event; BIW, twice weekly; BSA, body surface area affected; CDLQI, Children's Dermatology Life Quality Index; DFI, Dermatitis Family Impact; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI-75, ≥75% reduction in EASI; IDQoL, Infant Dermatology Life Quality Index; MID, minimally important difference; OLE, open-label extension; PDE4, 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 Scale.

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DISCLOSURES

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INTRODUCTION

- AD is a chronic inflammatory skin disease[1] with symptoms (eg, itch) and mental/physical comorbidities that can negatively impact QoL for both patients and their families[2,3]
- Topical therapies commonly used to treat AD (eg, TCS and TCIs) have side effects and/or treatment limitations[4,5]
  - TCS are not approved for long-term use and potent TCS are not recommended for thin-skinned areas with higher absorption[4]
  - A burning/stinging sensation at the application site has been reported with the use of topical crisaborole and TCIs[4]
- Reduced adherence with complicated application regimens and concerns over side effects can unnecessarily prolong AD symptoms; therefore, alternative topical treatments with the potential for proactive, long-term use to maintain disease control are needed[3,5,6]
- Roflumilast cream 0.15% is an advanced targeted topical treatment that is a PDE4 inhibitor formulated without potentially skin-irritating excipients, such as fragrances, ethanol, or propylene glycol[7]
- The efficacy, safety, and tolerability of roflumilast cream 0.15% in patients aged ≥6 years with AD were demonstrated in 3 phase 3 trials (INTEGUMENT-1 and -2 [4-week, vehicle-controlled] and INTEGUMENT-OLE [52-week, open-label extension])[8,9]
  - Roflumilast cream 0.15% and 0.05% are approved for the topical treatment of mild-to-moderate AD in patients aged ≥6 years and 2–5 years, respectively[10]
- Long-term PROs, QoL, and family impact of roflumilast cream 0.15% for patients who enrolled in INTEGUMENT-OLE from INTEGUMENT-1/2 are described here

METHODS

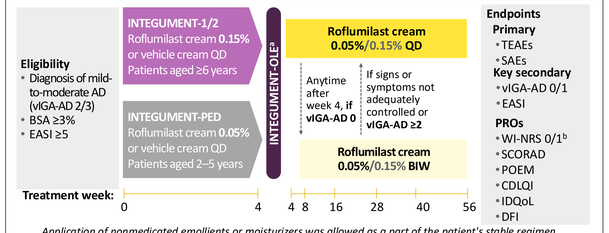
Study design

- 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 [≥6 years] or INTEGUMENT-PED [2–5 years]) with no safety concerns were eligible to enroll in the INTEGUMENT-OLE trial; patients aged ≥6 years initiated or continued application of roflumilast cream 0.15% once daily for up to 52 weeks
  - Patients were to switch to BIW application any time after week 4 of the OLE, 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-1/2
- 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
- DLQI (aged ≥17 years) and CDLQI (aged 4–16 years): assessments of the impact of AD on QoL over the prior week; total scores for both range from 0 (no impact) to 30 (highest impact); MID ≥4 and MID ≥6, respectively
- DFI: measure of how having a child with AD (for patients aged ≤17 years) affects QoL of the family; total scores range from 0 (no impact) to 30 (highest); MID not defined; mean improvements from baseline of INTEGUMENT-1/2 are reported
- Proportions of patients achieving an MID (the smallest change considered a meaningful improvement) in SCORAD, POEM, or DLQI/CDLQI from baseline are reported; patients with a baseline score <MID were excluded from that PRO analysis

INTEGUMENT-OLE Study Design



Application of nonmedicated emollients or moisturizers was allowed as a part of the patient's stable regimen

[a]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 ~550 patients aged 6–17 years. Patients must have completed 4 weeks in a parent trial with no safety concerns. [b]In patients aged ≥12 years and with WI-NRS ≥2 at parent study baseline.

RESULTS

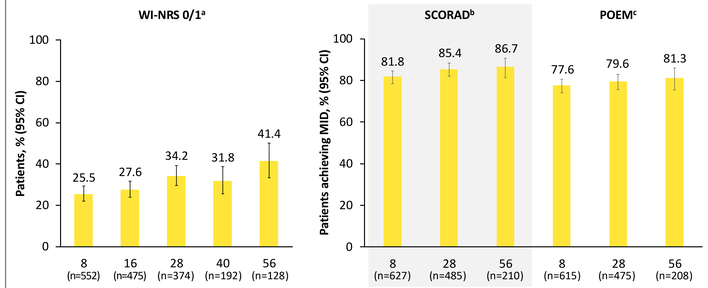
- Among the 658 patients who completed INTEGUMENT-1/2 and enrolled in INTEGUMENT-OLE, roflumilast cream 0.15% provided clinically meaningful improvements (ie, MIDs) in PROs which were maintained from INTEGUMENT-1/2[9] and/or continued to improve throughout INTEGUMENT-OLE
- At treatment week 56, WI-NRS 0/1 was achieved by 41.4% (53/128) of patients
  - MIDs in SCORAD and POEM were achieved by >80% of patients and CDLQI/DLQI by 68.4% of patients
  - DFI scores improved by a mean of 3.4 points
- Roflumilast cream 0.15% was well tolerated with 3 (0.5%) patients reporting an application-site pain TEAE throughout the trial

Patient Demographics and Baseline Disease Characteristics

		Roflumilast cream 0.15% (n=658)
Age, mean (SD) [range], years		19.7 (16.9) [6–84]
Female sex at birth, n (%)		367 (55.8)
Ethnicity, n (%)	Not Hispanic or Latino	544 (82.7)
Race, n (%)	White	412 (62.6)
	Black or African American	89 (13.5)
	Asian	98 (14.9)
	Other/Multiple	59 (9.0)
Fitzpatrick skin type, n (%)	Type I–III	366 (55.6)
	Type IV–VI	292 (44.4)
vIGA-AD, n (%)	Mild (2)	172 (26.1)
	Moderate (3)	486 (73.9)
Mean (median) [range]	BSA, %	14.8 (10.5) [3.0–88.0]
	WI-NRS (weekly average)	5.8 (6.0) [0.0–10.0]
	EASI	10.5 (8.8) [5.0–52.5]
	SCORAD	45.6 (45.0) [18.2–83.5]
	POEM	15.6 (15.5) [0–28]
	DLQI	8.2 (7.0) [0–28]
	CDLQI	7.7 (6.0) [0–28]
	DFI	6.5 (5.0) [0–26]

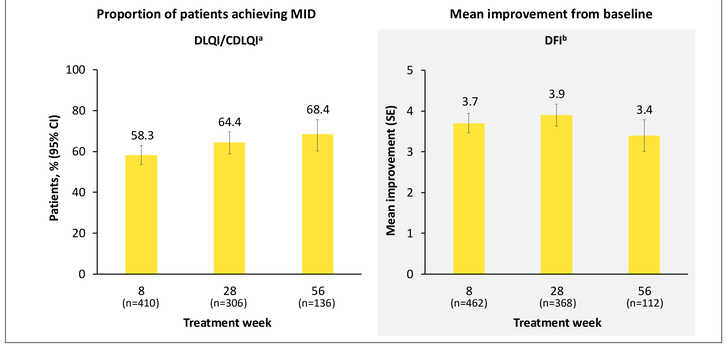
Full analysis population. Values are baseline of INTEGUMENT-1/2 for patients who enrolled in INTEGUMENT-OLE from either the roflumilast cream 0.15% or vehicle cream group

Improvement in Itch Symptoms Over Time



Full analysis population. Observed data. [a]Patients with WI-NRS ≥2 at INTEGUMENT-1/2 baseline. [b]Patients with SCORAD ≥8.7 at INTEGUMENT-1/2 baseline. [c]Patients with POEM ≥3.4 at INTEGUMENT-1/2 baseline.

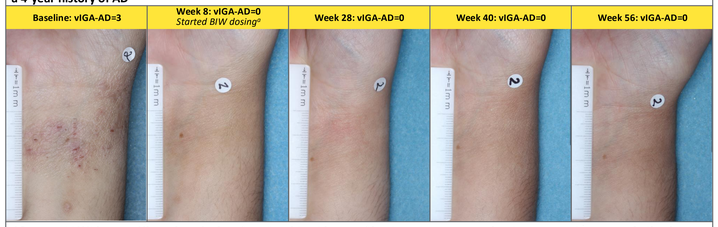
Improvement in QoL and Family Impact



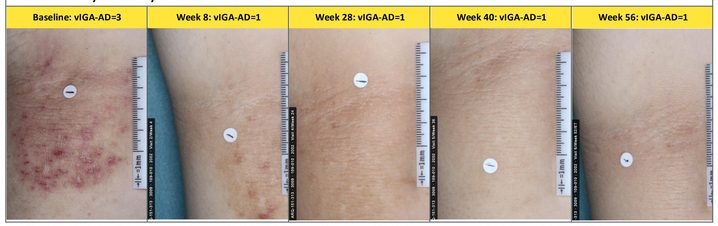
Full analysis population. Observed data. [a]Patients with DLQI ≥4 or CDLQI ≥6. and aged ≥4 years at INTEGUMENT-1/2 baseline. [b]Patients aged ≤17 years at INTEGUMENT-1/2 baseline

Improvement With Roflumilast Cream 0.15%

16-year-old White, Hispanic female with a history of inadequate response, intolerance, and/or contraindications to TCS and a 4-year history of AD



18-year-old White, not Hispanic or Latino, female with a history of inadequate response, intolerance, and/or contraindications to TCS and an 18-year history of AD



Note: The white sticker is placed by investigator for reference; vIGA-AD is a global measure.. [a]Patient started BIW dosing at treatment week 8 and did not switch back to QD dosing.

Safety Summary[a]

Patients, n (%)	Roflumilast cream 0.15% (n=657)
≥1 TEAE	241 (36.7)
≥1 treatment-related AE	31 (4.7)
≥1 SAE	8 (1.2)
≥1 treatment-related SAE	0
≥1 TEAE leading to discontinuation of study/study drug	20 (3.0)/21 (3.2)
Most common TEAEs by preferred term, ≥2.0% of patients	
COVID-19	30 (4.6)
Upper respiratory tract infection	21 (3.2)
Nasopharyngitis	20 (3.0)
Headache	18 (2.7)

Safety population. [a]Summary of TEAEs occurring during INTEGUMENT-OLE.

CONCLUSIONS

- Roflumilast cream 0.15% improved itch symptoms and multiple PROs after 4 weeks of treatment[9] 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
- Meaningful improvements in patient-reported AD signs/symptoms (including itch), patient QoL, and family impact were observed with roflumilast cream 0.15% applied for up to 56 weeks in patients aged ≥6 years with AD, providing a long-term treatment alternative to TCS for this chronic condition