Roflumilast Cream 0.15% Provides Improvement Across Eczema Area and Severity Index Body Regions and Clinical Signs in Patients Aged ≥6 Years With Mild-to-Moderate Atopic Dermatitis

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INTRODUCTION

- Clinical signs of AD can occur across the body, often simultaneously in multiple areas involving the head/neck, trunk, upper extremities, and lower extremities[1]
  - Compared with other AD-affected areas of the body, AD in visible areas is considered most bothersome and has greater negative impact on patients' quality of life[2]
- TCS and TCIs remain common treatments for AD, despite limitations to their use as well as approvals for other advanced topical therapies for AD[3,4]
  - TCS are not recommended for long-term use and the application of higher-potency TCS in thin-skinned areas where absorption is greater can lead to increased risk of cutaneous and systemic AEs[3]
  - Burning/stinging at the application site has been reported with the use of TCIs and the topical PDE4 inhibitor crisaborole[3]
- Roflumilast cream is an advanced targeted topical PDE4 inhibitor formulation that does not contain fragrances or potential cutaneous irritants, such as ethanol or propylene glycol[5]
  - Roflumilast cream 0.15% demonstrated safety and efficacy in patients aged ≥6 years with AD in two 4-week randomized, vehicle-controlled, phase 3 trials (INTEGUMENT-1 [NCT04773587] and INTEGUMENT-2 [NCT04773600])[6]
- The impact of roflumilast cream 0.15% versus vehicle on AD area of involvement and symptom severity in specific body regions (ie, head/neck, trunk, upper and lower extremities) from the INTEGUMENT-1/2 studies is reported here

METHODS

- INTEGUMENT-1/2 were 4-week randomized, vehicle-controlled, phase 3 trials that enrolled patients aged ≥6 years with mild-to-moderate AD
- Mean improvements from baseline EASI total score and EASI body area and component scores (erythema, excoriation, infiltration, and lichenification) were assessed across four body regions: head/neck, trunk, upper extremities, and lower extremities

Study Design

Eligibility
- Aged ≥6 years
- Diagnosis of mild-to-moderate AD (vIGA-AD 2 or 3)
- BSA ≥3% (no upper limit)
- EASI ≥5

Randomized 2:1

- Roflumilast cream 0.15% QD
- Vehicle cream QD

4 weeks[b]

Primary endpoint
- vIGA-AD success at week 4[a]

Additional assessments
- EASI total and component scores (mean improvement)

Safety and application-site tolerability

[a]Clear/almost clear (0/1) skin plus ≥2-grade improvement from baseline. [b]Nonmedicated emollients or moisturizers could be applied QD after study treatment to areas where study treatment was not applied.

RESULTS

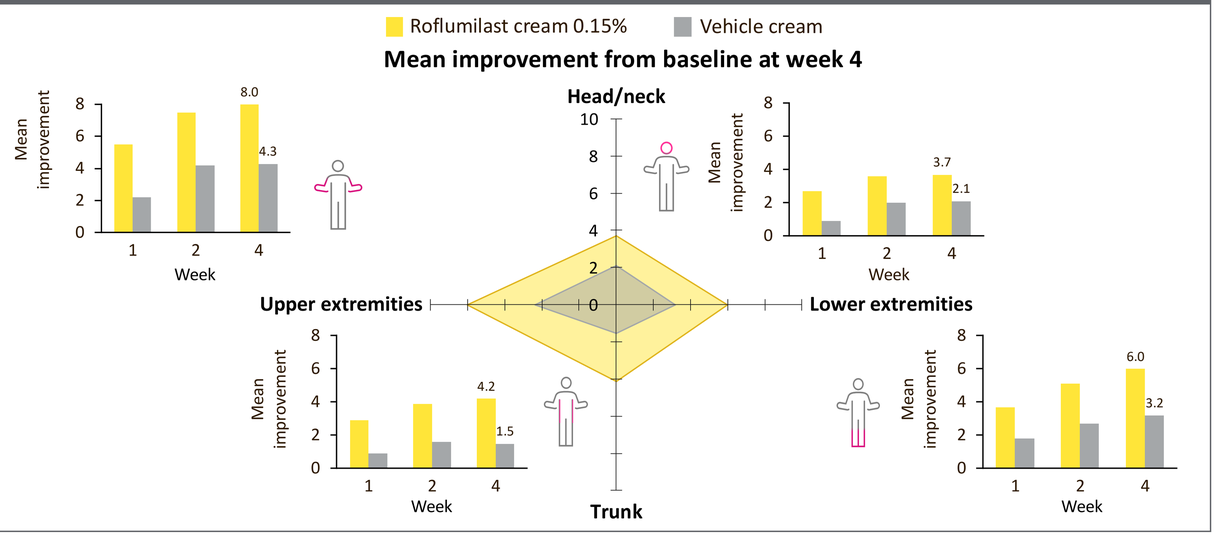
- Demographics and baseline clinical characteristics were balanced among 884 and 453 patients randomized to receive roflumilast cream 0.15% and vehicle cream, respectively
  - 834 and 431 patients in the roflumilast and vehicle groups were assessed at week 1, respectively (week 2: 818 and 423; week 4: 816 and 419)
- Patients treated with roflumilast cream 0.15% versus vehicle cream had greater improvements in EASI total scores per body region throughout the study
- Improvements with roflumilast compared with vehicle were also reflected in the body region area scores, as well as scores for erythema, excoriation, infiltration, and lichenification, across body regions
- Roflumilast cream 0.15% was well tolerated, with treatment-related AEs and an application-site pain AE reported for 6.0% and 1.5% of patients, respectively

Patient Demographics and Baseline Clinical Characteristics

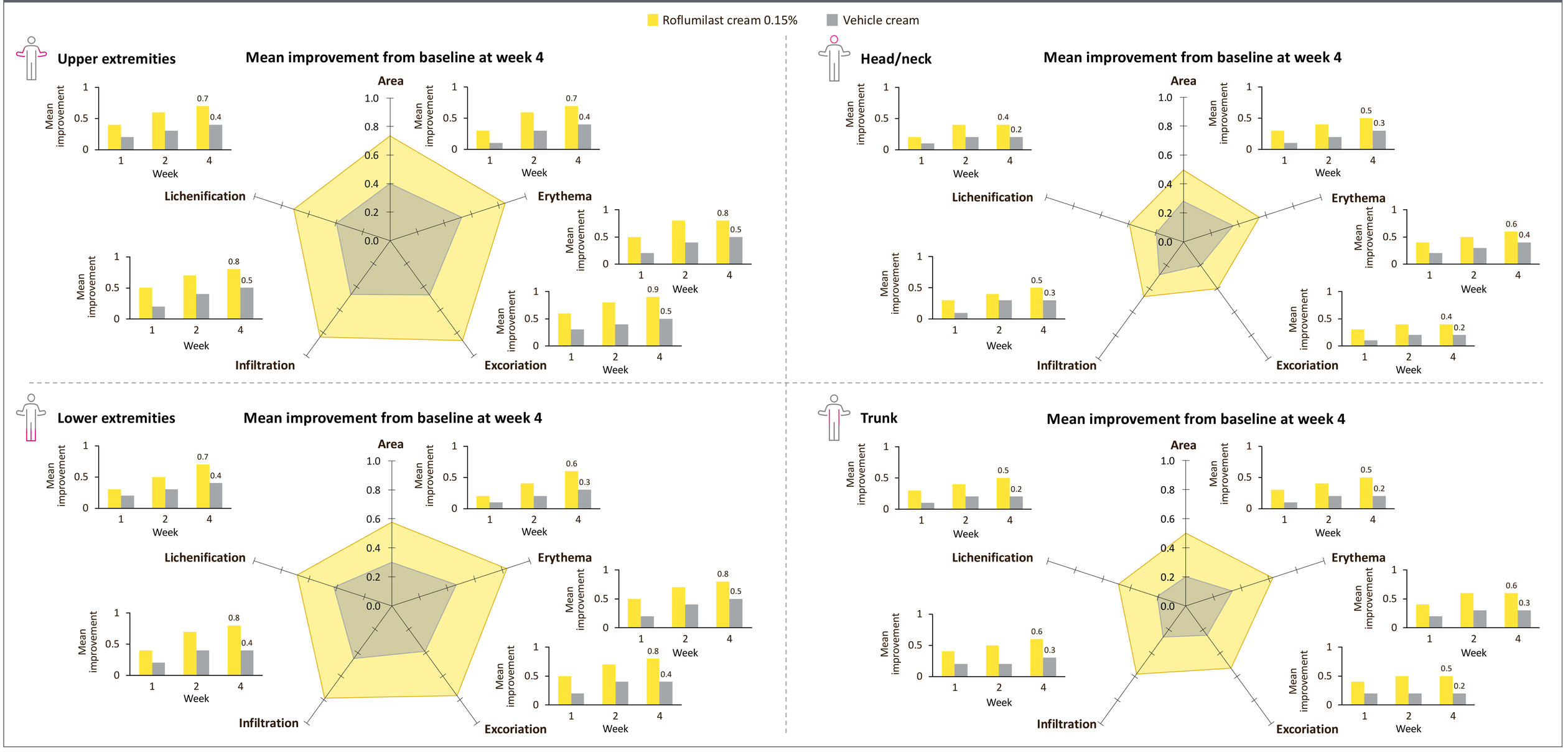
		Roflumilast cream 0.15% (n=884)	Vehicle cream (n=453)
Age, years, mean, (median) [range]		27.9 (20.0) [6–91]	27.3 (20.0) [6–84]
Female at birth, n (%)		489 (55.3)	272 (60.0)
Not Hispanic or Latino, n (%)		730 (82.6)	377 (83.2)
Race, n (%)	White	529 (59.8)	267 (58.9)
	Black/African American	176 (19.9)	96 (21.2)
	Asian	114 (12.9)	62 (13.7)
	Other[a]	41 (4.6)	14 (3.1)
	Multiple	24 (2.7)	14 (3.1)
Fitzpatrick skin type, n (%)	I–III	481 (54.4)	238 (52.5)
	IV–VI	403 (45.6)	215 (47.5)
vIGA-AD, n (%)	Mild (2)	211 (23.9)	112 (24.7)
	Moderate (3)	673 (76.1)	341 (75.3)
BSA, %, mean (median) [range]		13.5 (9.7) [3.0–88.0]	13.9 (10.0) [3.0–86.0]
Average weekly WI-NRS score, mean (median) [range]		6.1 (6.3) [0.0–10.0]	5.9 (6.0) [0.0–10.0]
EASI total score, mean (median) [range]		10.1 (8.4) [4.4–52.5]	10.0 (8.4) [3.4–37.9]

ITT population. [a]Other includes American Indian or Alaskan Native (roflumilast, n=7; vehicle, n=1) and Native Hawaiian/Pacific Islander (roflumilast, n=1).

Improvements in Total EASI Score Across Body Regions

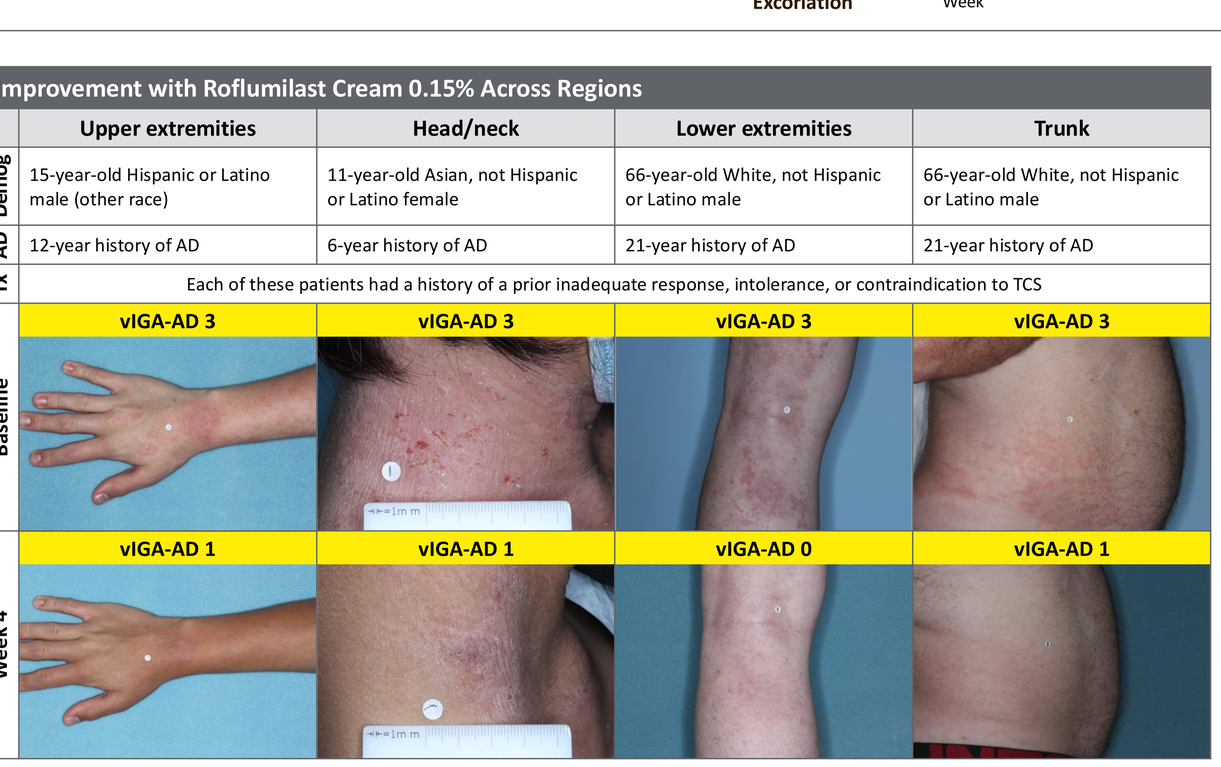


Improvements in EASI Component Scores



Improvement with Roflumilast Cream 0.15% Across Regions

	Upper extremities	Head/neck	Lower extremities	Trunk
Demog	15-year-old Hispanic or Latino male (other race)	11-year-old Asian, not Hispanic or Latino female	66-year-old White, not Hispanic or Latino male	66-year-old White, not Hispanic or Latino male
AD	12-year history of AD	6-year history of AD	21-year history of AD	21-year history of AD
Tx	Each of these patients had a history of a prior inadequate response, intolerance, or contraindication to TCS			
Baseline	vIGA-AD 3	vIGA-AD 3	vIGA-AD 3	vIGA-AD 3
Week 4	vIGA-AD 1	vIGA-AD 1	vIGA-AD 0	vIGA-AD 1



CONCLUSIONS

- Once-daily roflumilast cream 0.15% improved the clinical signs of AD versus vehicle cream, as reflected by reduced EASI total and component scores
  - Improvements with roflumilast cream were observed as early as the first assessment (week 1), and throughout the INTEGUMENT-1/2 studies
- Improvements in AD severity (area, erythema, excoriation, infiltration, and lichenification) were reported with roflumilast cream 0.15% across the head/neck, trunk, upper extremities, and lower extremities
- These results support that roflumilast cream 0.15% provides rapid and consistent benefit across body regions affected by AD, offering an advanced targeted topical therapy alternative to commonly used topical therapies (ie, TCS and TCIs)

ABBREVIATIONS

AD, atopic dermatitis; AE, adverse event; BSA, body surface area affected; Demog, demographics; EASI, Eczema Area and Severity Index; ITT, intention-to-treat; PDE4, phosphodiesterase 4; QD, once daily; TCIs, topical calcineurin inhibitors; TCS, topical corticosteroids; Tx, treatment; vIGA-AD, Validated Investigator Global Assessment for AD; WI-NRS, Worst Itch-Numeric Rating Score.

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DISCLOSURES

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