Once-daily Roflumilast Cream 0.05% for the Treatment of Atopic Dermatitis in Patients Aged 2–5 Years With Diverse Skin Types: Subgroup Analysis From the Phase 3 INTEGUMENT-PED Trial

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INTRODUCTION

- The epidemiology and clinical presentation of AD may differ on the basis of race, ethnicity, and Fitzpatrick Skin Type (FST)[1–3]
- Topical roflumilast, a PDE4 inhibitor, offers an advanced targeted topical treatment option that is not a steroid for managing AD. Topical roflumilast is formulated as a water-based cream without potentially skin-irritating excipients, such as fragrances, ethanol, or propylene glycol[4]
- Roflumilast cream 0.15% and 0.05% have demonstrated efficacy, safety, and application-site tolerability compared with vehicle cream in patients with AD aged ≥6 years and aged 2–5 years, respectively, in the phase 3 INTEGUMENT-1/2 and INTEGUMENT-PED trials[5,6]

OBJECTIVE

- This analysis reports treatment response in patients from INTEGUMENT-PED across a diverse range of skin types in subgroups defined by race, ethnicity, and FST

METHODS

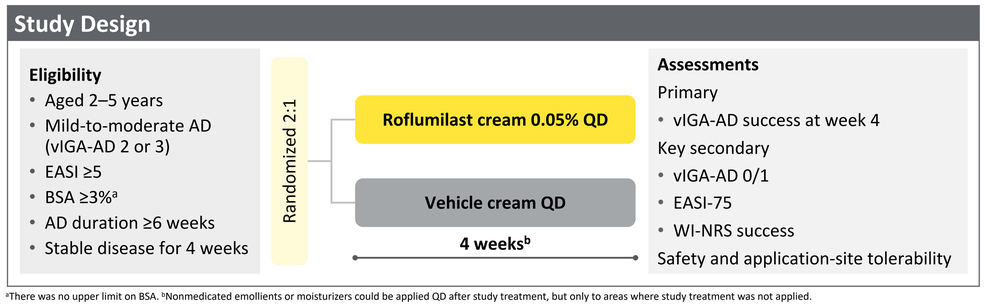
Study design

- INTEGUMENT-PED (NCT04845620) was a phase 3, parallel-group, double-blind, vehicle-controlled study in patients aged 2–5 years with AD for ≥6 weeks that was stable for ≥4 weeks
- Roflumilast cream 0.05% or vehicle cream was applied once daily by a parent/caregiver for 4 weeks

Endpoints

- vIGA-AD success, defined as clear (0) or almost clear (1) plus ≥2-grade improvement
- vIGA-AD 0/1
- EASI-75, defined as ≥75% improvement in EASI
- WI-NRS success, defined as ≥4-point improvement in patients with baseline score ≥4
- Safety and application-site tolerability

Study Design



[a]There was no upper limit on BSA. [b]Nonmedicated emollients or moisturizers could be applied QD after study treatment, but only to areas where study treatment was not applied.

RESULTS

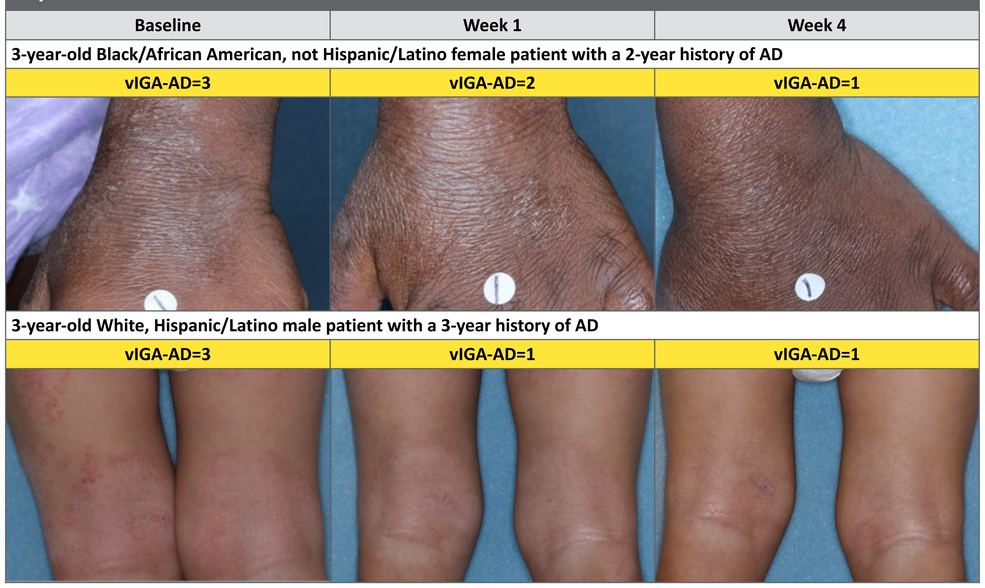
- Among 651 enrolled patients, demographics and baseline disease characteristics were consistent between groups
  - 17.4% of patients were Hispanic or Latino, 15.4% were Black/African American, and 8.3% were Asian
- Roflumilast cream 0.05% improved signs and symptoms of AD compared with vehicle cream overall and across race, ethnicity, and FST subgroups at 4 weeks of treatment
- Roflumilast was well tolerated, with treatment-related AEs reported for 15 (3.4%) patients
  - Across time points, investigators reported no evidence of irritation at the application site in ≥93.3% of patients treated with roflumilast
  - For 2 (0.5%) patients, after the first application of roflumilast, and <1% of patients at subsequent assessments, caregivers reported a hot, tingling/stinging sensation that caused definite discomfort
  - Application-site pain AEs were reported for 7 (1.6%) and 4 (1.9%) patients in the roflumilast and vehicle groups, respectively

Patient Demographics and Baseline Disease Characteristics

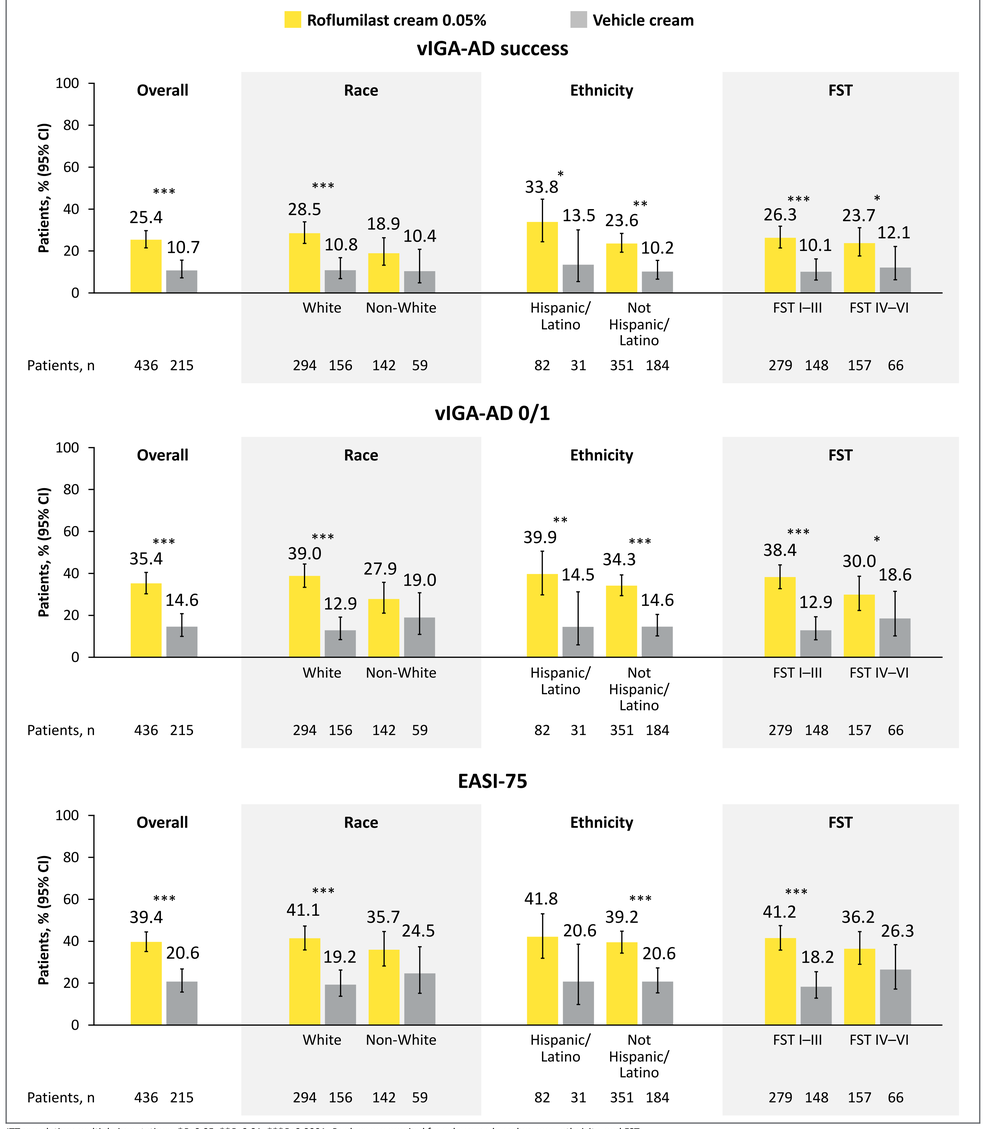
		Roflumilast cream 0.05% (n=436)	Vehicle cream (n=215)
Age, years, mean (SD) [range]		3.3 (1.1) [2–5]	3.2 (1.1) [2–5]
Male at birth, n (%)		225 (51.6)	116 (54.0)
Race, n (%)	White	294 (67.4)	156 (72.6)
	Black/African American	68 (15.6)	32 (14.9)
	Asian	37 (8.5)	17 (7.9)
	Other[a]	37 (8.5)	10 (4.7)
Ethnicity, n (%)[b]	Hispanic or Latino	82 (18.8)	31 (14.4)
FST, n (%)[c]	I–III	279 (64.0)	148 (68.8)
	IV–VI	157 (36.0)	66 (30.7)
vIGA-AD, n (%)	Mild (2)	103 (23.6)	44 (20.5)
	Moderate (3)	333 (76.4)	171 (79.5)
EASI, mean (median) [range]		12.2 (10.3) [4.6–42.0]	11.6 (9.5) [5.0–32.9]
BSA, %, mean (median) [range]		22.5 (17.3) [3.0–82.0]	21.2 (16.5) [4.0–78.8]
Average weekly WI-NRS, mean (median) [range]		6.2 (6.6) [0–10]	5.9 (6.3) [0–10]

ITT population. [a]Other includes American Indian/Alaska Native and Native Hawaiian/other Pacific Islander. [b]Ethnicity was not reported for 3 patients in the roflumilast group. [c]There was 1 patient in the vehicle group with missing data for FST.

Improvement in AD Over Time With Roflumilast Cream 0.05%

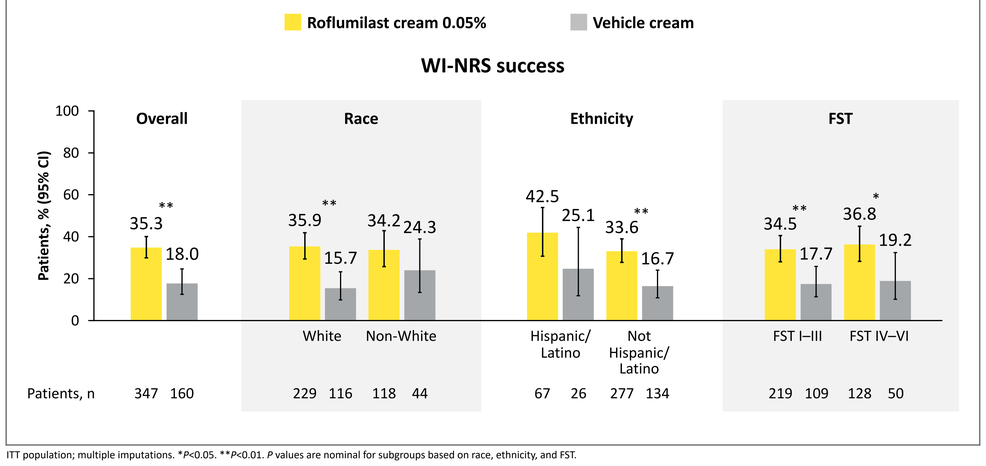


Improvement in Signs of AD at Week 4



ITT population; multiple imputations. *P<0.05. **P<0.01. ***P<0.0001. P values are nominal for subgroups based on race, ethnicity, and FST.

Improvement in Itch at Week 4



ITT population; multiple imputations. *P<0.05. **P<0.01. P values are nominal for subgroups based on race, ethnicity, and FST.

Safety Summary

Patients, n (%)	Roflumilast cream 0.05% (n=437)	Vehicle cream (n=215)
≥1 TEAE	130 (29.7)	47 (21.9)
≥1 treatment-related AE	15 (3.4)	6 (2.8)
≥1 SAE[a]	1 (0.2)	0
≥1 TEAE leading to discontinuation of study/study drug	5 (1.1)/5 (1.1)	4 (1.9)/5 (2.3)
Most common TEAEs by preferred term, ≥2% in either group		
Upper respiratory tract infection	18 (4.1)	3 (1.4)
Pyrexia	12 (2.7)	6 (2.8)
Diarrhea	11 (2.5)	1 (0.5)
Vomiting	9 (2.1)	0
Dermatitis atopic[b]	2 (0.5)	5 (2.3)

Safety population. [a]SAE in the roflumilast group was cellulitis in an area to which treatment was not applied; it was considered unlikely to be related to study treatment. [b]Worsening atopic dermatitis.

CONCLUSIONS

- Roflumilast cream 0.05% applied for 4 weeks improved signs of AD in children aged 2–5 years across a diverse range of skin types
  - Outcomes were generally consistent with those reported for patients aged ≥6 years with AD who participated in the 4-week INTEGUMENT-1 and -2 trials[5,7]
- Roflumilast cream 0.05% was well tolerated with no or minimal evidence of irritation at the application site, including after the first application
- Results from the INTEGUMENT-PED trial demonstrate that roflumilast cream 0.05% is well tolerated and is an effective treatment option for diverse patient populations with AD

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DISCLOSURES

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ABBREVIATIONS

AD, atopic dermatitis; AE, adverse event; BSA, body surface area affected; EASI, Eczema Area and Severity Index; EASI-75, ≥75% improvement in EASI; FST, Fitzpatrick Skin Type; ITT, intent-to-treat; PDE4, phosphodiesterase 4; QD, once daily; SAE, serious adverse event; TEAE, treatment-emergent adverse event; vIGA-AD, validated Investigator Global Assessment for AD; WI-NRS, Worst Itch Numeric Rating Scale.

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