Roflumilast Foam 0.3% for the Treatment of Seborrheic Dermatitis in Patients With Diverse Skin Types: Subgroup Analyses of the Phase 3 STRATUM Trial

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Background

- **Seborrheic dermatitis**, and the hypopigmentation and hyperpigmentation often associated with it, are **common dermatologic concerns in populations with skin of color**
  - **Acceptability** of topical treatments **varies** among a diverse spectrum of skin and hair types[1]
- **PDE4 inhibition** can increase melanocyte proliferation and melanin production, **improving pigmentation** alongside the known **anti-inflammatory benefits**[2,3]
- **Roflumilast foam 0.3%** is a selective and highly potent **PDE4 inhibitor formulated without excipients** such as ethanol, isopropyl alcohol, propylene glycol, polyethylene glycol, formaldehyde-releasing agents, or fragrances **that can irritate the skin, cause allergic reactions, or damage hair**[4–6]
  - The **efficacy, safety, and tolerability** of roflumilast foam 0.3% was demonstrated in patients aged ≥9 years with seborrheic dermatitis in the **phase 3 STRATUM trial** (NCT04973228)[7]
  - The efficacy of roflumilast foam 0.3% is further investigated here among **patients with diverse skin types, based on ethnicity, race, and FST**

FST, Fitzpatrick Skin Type; PDE4, phosphodiesterase 4.

1. Sangha AM. *J Clin Aesthet Dermatol.* 2024;17(5–6 Suppl 1):S22–S23. 2. Goldstein NB, et al. *J Invest Dermatol.* 2025;145(4):883–896. 3. Chen Z, et al. *J Dermatol Sci.* 2023;110:44–52. 4. Draelos ZD, et al. *J Drugs Dermatol.* 2024;23(10):834–840. 5. Chovatiya R, et al. *J Clin Aesthet Dermatol.* 2024;17(5):30–33. 6. Polaskey MT, et al. *Dermatol Ther* (Heidelb). 2024;14(5):1071–1077. 7. Blauvelt A, et al. *J Am Acad Dermatol.* 2024;90(5):986–993.

STRATUM Study Design and Patient Population

Eligibility
- Aged ≥9 years
- At least moderate disease (IGA ≥3)
- BSA ≤20%

Randomized 2:1

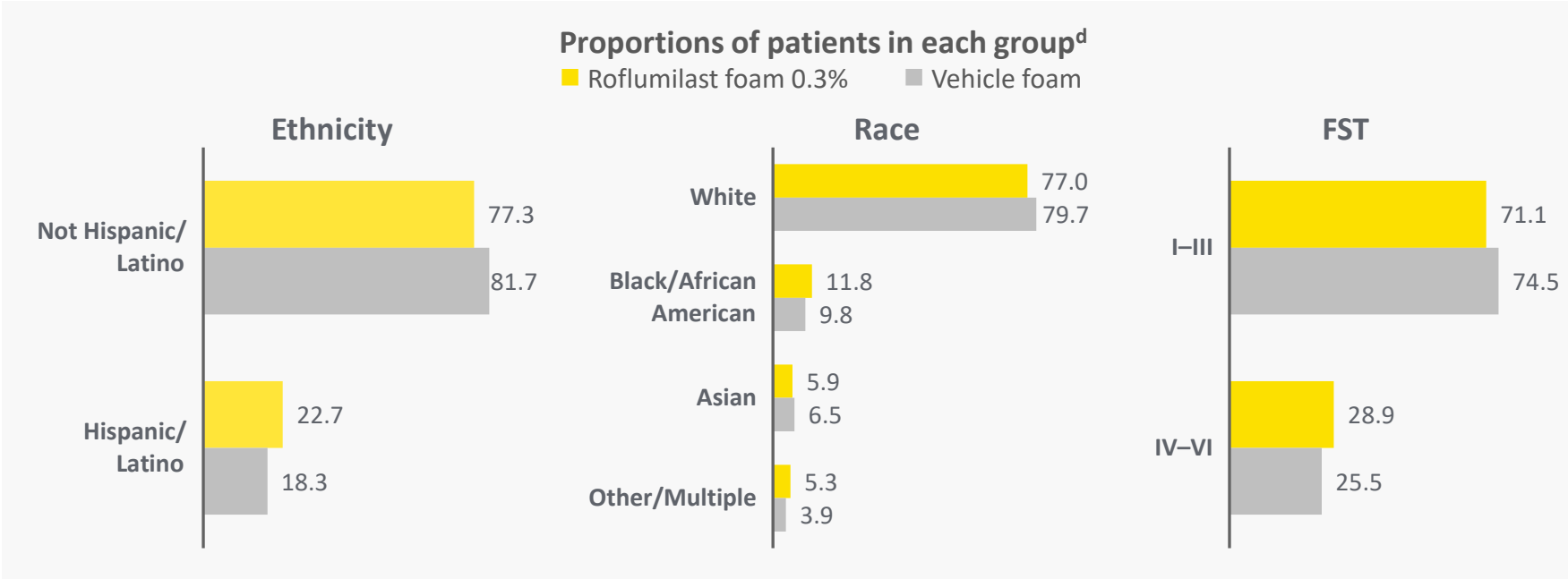
Roflumilast foam 0.3% QD

Vehicle foam QD

8 weeks

Assessments
- IGA success at week 8[a] (primary)
- WI-NRS success at week 8[b] (key secondary)
- Erythema & scaling scores of 0 at week 8 (key secondary)
- Safety and application-site tolerability
- Hypo/hyperpigmentation[c] (additional safety assessment)

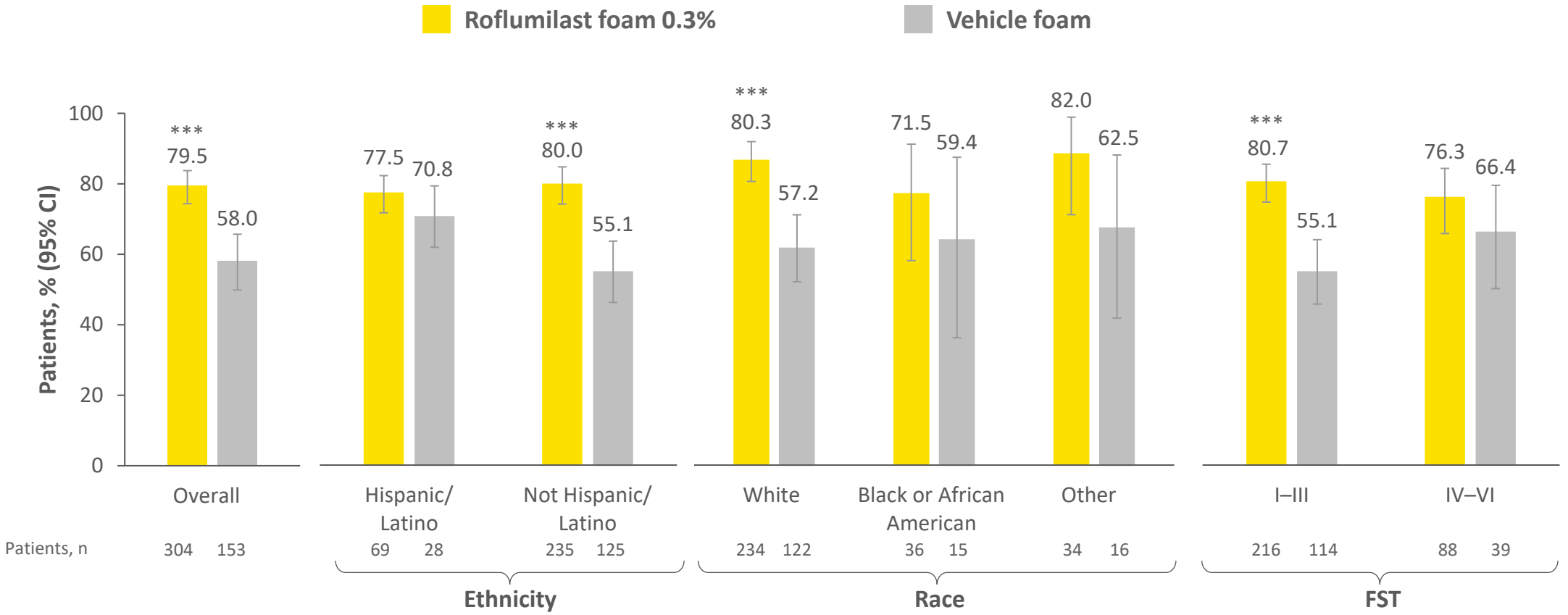
- Demographics and baseline disease characteristics were balanced between the two treatment groups
- Mean age of patients was 42.7 years, and 50.1% were female sex
- Most patients (93.7%) had moderate baseline IGA
- Mean average weekly WI-NRS was 5.0
- Mean BSA was 2.9%



[a]Defined as clear/almost clear (0/1) plus ≥2-point improvement from baseline. [b]Defined as ≥4-point improvement in patients with baseline score ≥4. [c]Areas currently or previously affected by seborrheic dermatitis were assessed for hypopigmentation and hyperpigmentation at baseline and weeks 2, 4, and 8, scored on a scale of 0 (none) to 4 (severe). [d]ITT population.
BSA, body surface area affected; FST, Fitzpatrick Skin Type; IGA, Investigator Global Assessment; ITT, intention-to-treat; QD, once daily; WI-NRS, Worst Itch-Numeric Rating Scale.

IGA Success at Week 8[a]

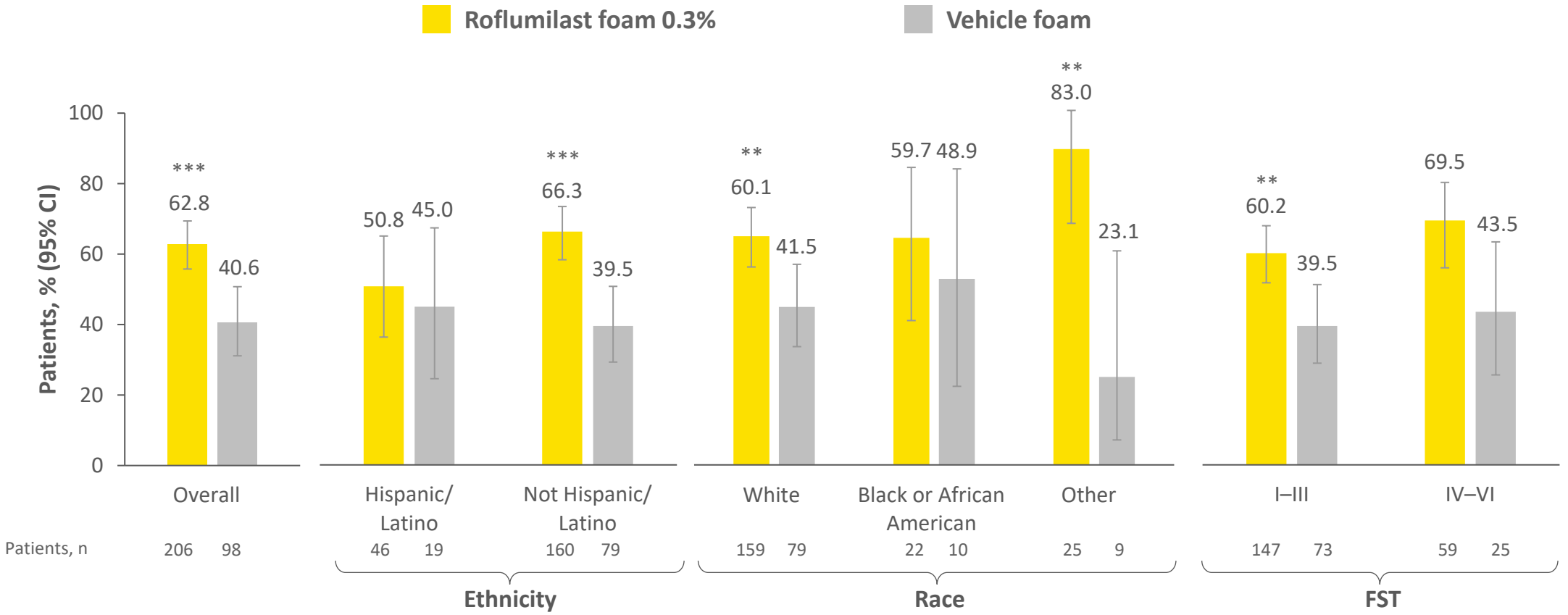
Improvements in signs of seborrheic dermatitis with roflumilast versus vehicle were reported by investigators overall and within ethnicity, race, and FST subgroups



[a]Defined as clear/almost clear (0/1) plus ≥2-point improvement from baseline. ***$P<0.0001$. *P* values are nominal for patient subgroups based on ethnicity, race, and FST.
FST, Fitzpatrick Skin Type; IGA, Investigator Global Assessment.

WI-NRS Success at Week 8[a]

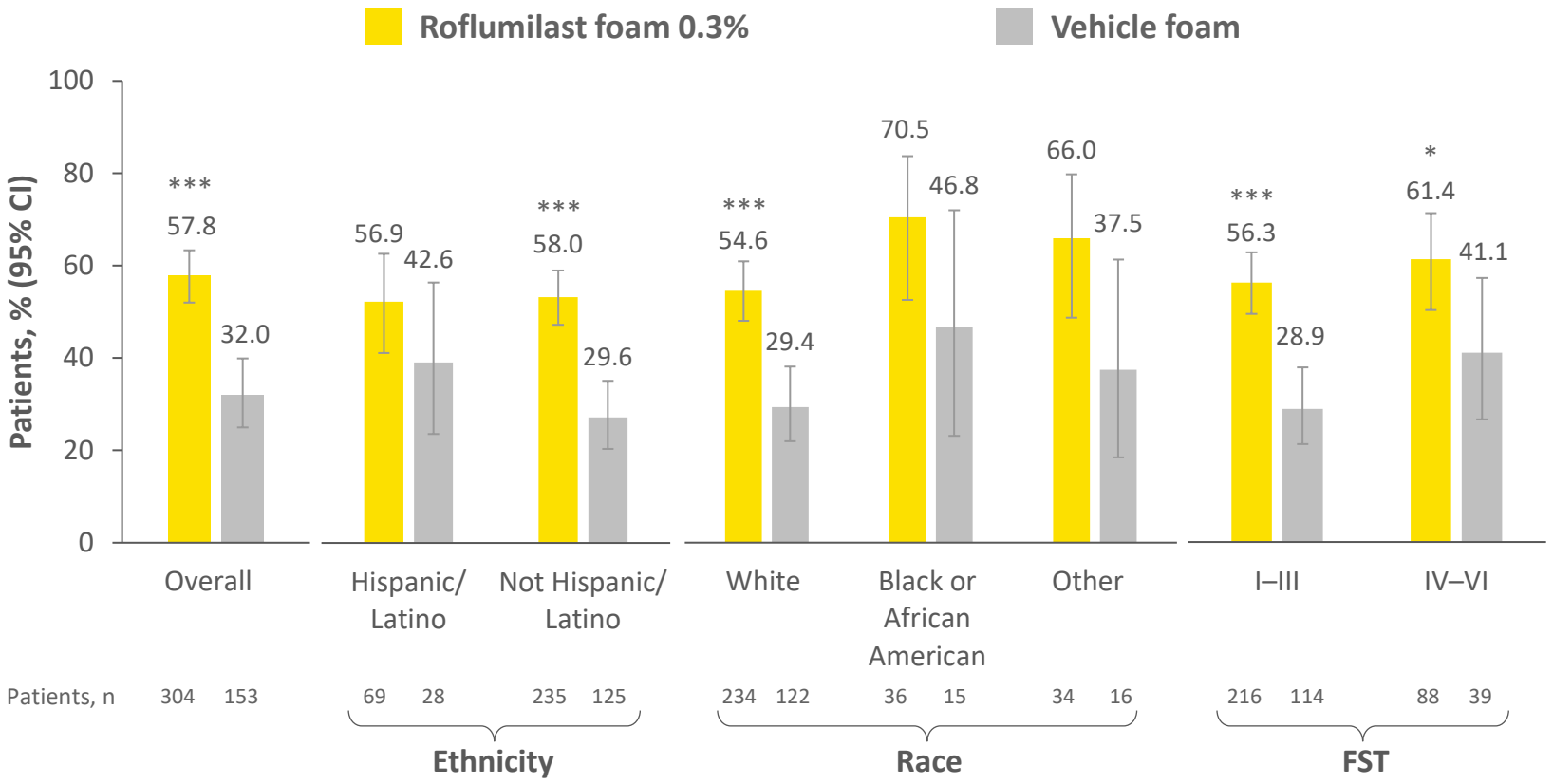
Roflumilast improved itch symptoms of seborrheic dermatitis, in comparison with vehicle, at 8 weeks across subgroups assessed



[a]Defined as a ≥4-point improvement in patients with baseline score ≥4. **$P \leq 0.002$; ***$P < 0.0001$. *P* values are nominal for patient subgroups based on ethnicity, race, and FST.
FST, Fitzpatrick Skin Type; WI-NRS, Worst Itch-Numeric Rating Scale.

Erythema Scores of 0 at Week 8

Higher proportions of patients in the roflumilast group than vehicle group experienced no erythema at 8 weeks



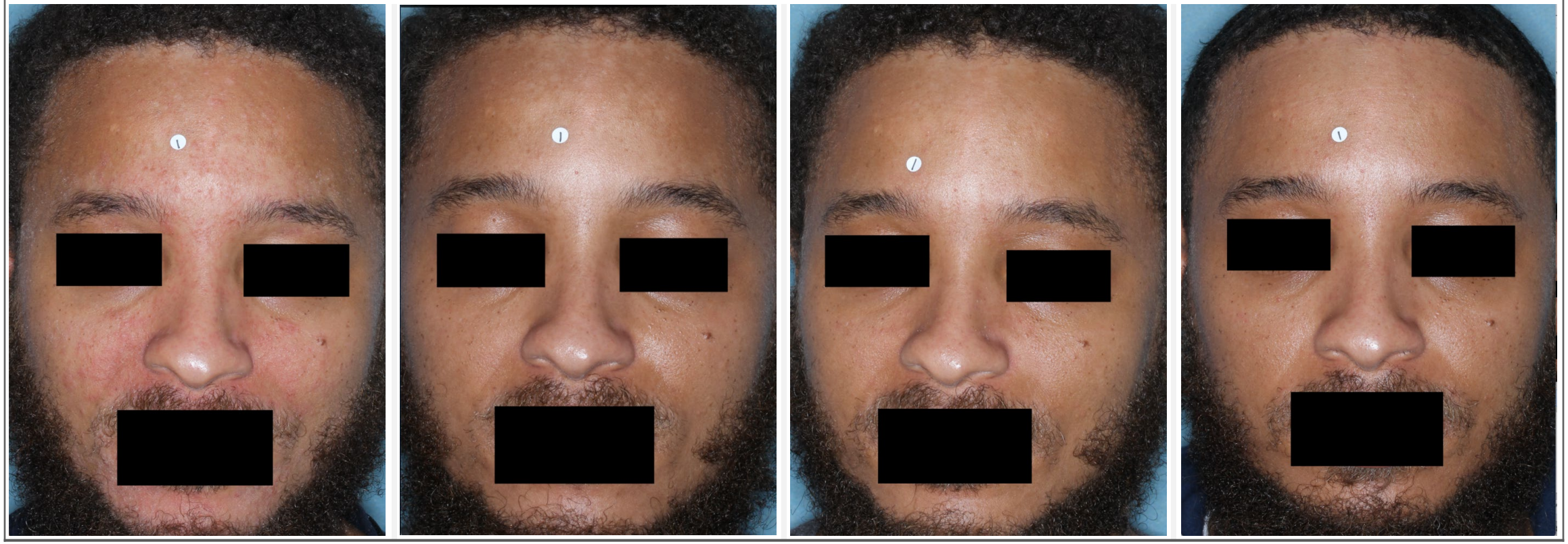
Trends were consistent for **patients achieving a scaling score of 0 with roflumilast versus vehicle** at 8 weeks, overall and among subpopulations

*P<0.01; ***P<0.0001. P values are nominal for patient subgroups based on ethnicity, race, and FST.
FST, Fitzpatrick Skin Type.

Improvement in Signs of Seborrheic Dermatitis Over Time

35-year-old male; Black or African American[a]

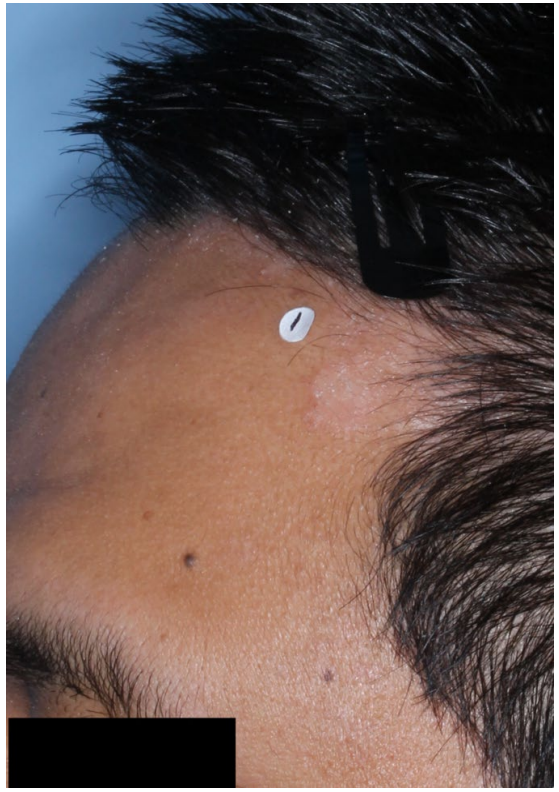
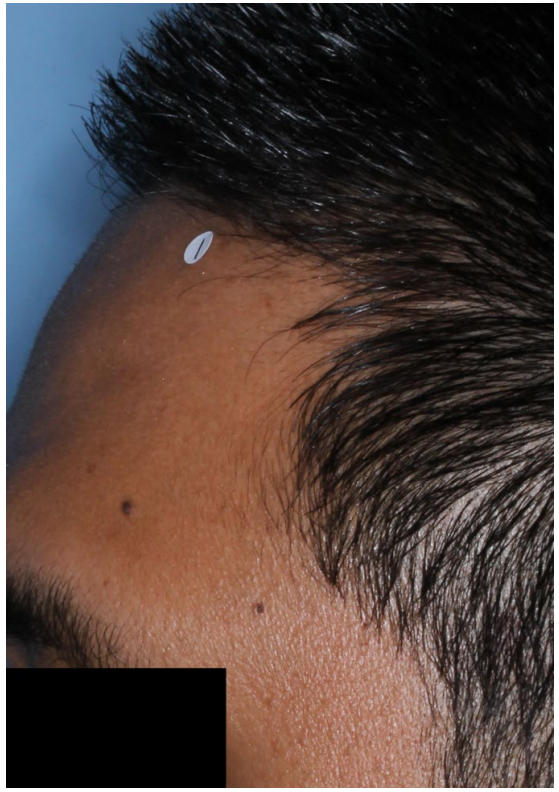
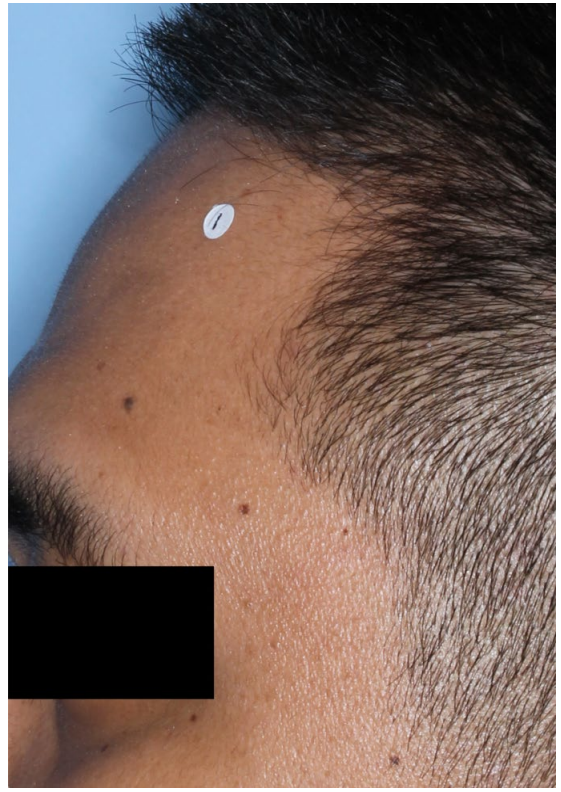
Baseline	Week 2	Week 4	Week 8
IGA=4	IGA=0	IGA=1	IGA=0



Note: Circle sticker is used as a reference point by trial investigators. IGA is a global measure from 0 (clear) to 4 (severe).
[a]History of inadequate response, intolerance, and/or contraindication to TCS; patient had a 13-year history of seborrheic dermatitis.
IGA, Investigator Global Assessment.

Improvement in Signs of Seborrheic Dermatitis Over Time

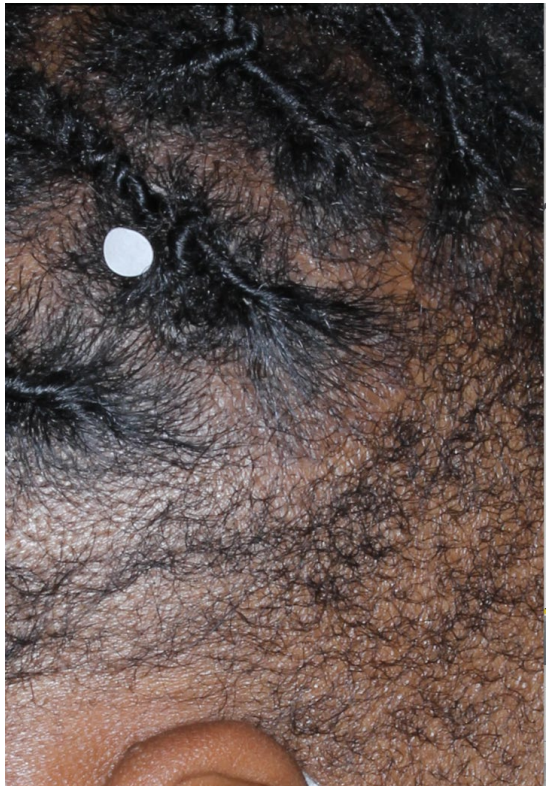
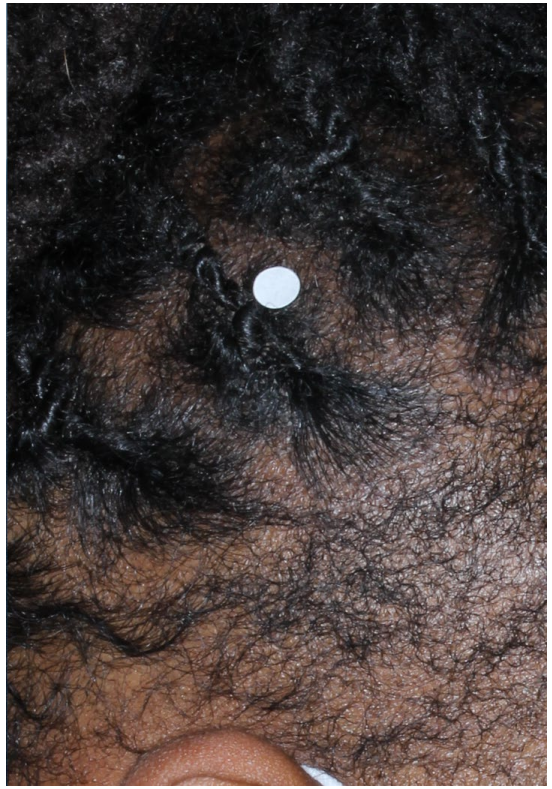
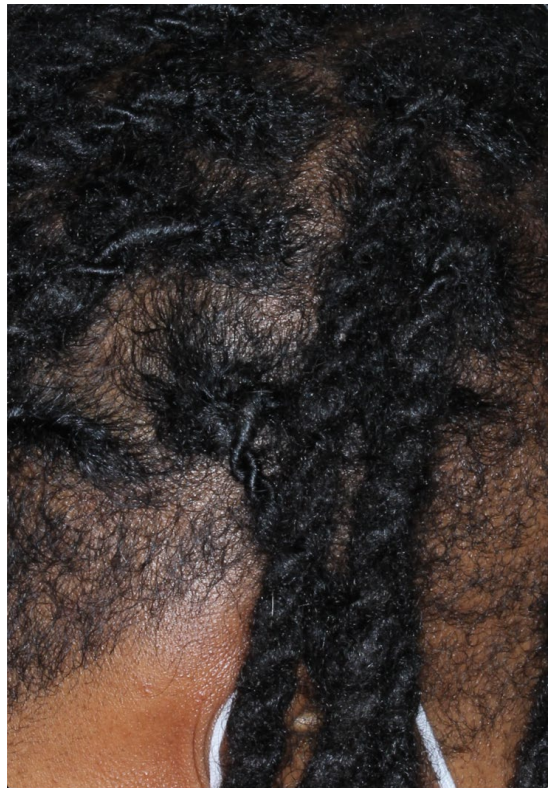
34-year-old male; Asian[a]

Baseline	Week 4	Week 8
IGA=3	IGA=1	IGA=1
		

Note: The patient was not available for a photo at the week-2 assessment. Circle sticker is used as a reference point by trial investigators. IGA is a global measure from 0 (clear) to 4 (severe).
[a]Patient had a 21-year history of seborrheic dermatitis.
IGA, Investigator Global Assessment.

Improvement in Signs of Seborrheic Dermatitis Over Time

33-year-old female; Black or African American[a]

Baseline	Week 2	Week 4	Week 8
IGA=4	IGA=0	IGA=1	IGA=0
			

Note: Circle sticker is used as a reference point by trial investigators. IGA is a global measure from 0 (clear) to 4 (severe).
[a]History of inadequate response, intolerance, and/or contraindication to TCS; patient had a 5-year history of seborrheic dermatitis.
IGA, Investigator Global Assessment.

Safety Summary and Improvement in Hypopigmentation and Hyperpigmentation at Week 8

Safety and tolerability summary

Patients, n (%)	Roflumilast foam 0.3% (n=304)	Vehicle foam (n=153)
≥1 TEAE	70 (23.0)	33 (21.6)
Mild or moderate TEAE	66 (21.7)	33 (21.6)
Treatment-related TEAE	8 (2.6)	5 (3.3)
Common TEAE (≥2.0% of patients in either group)		
COVID-19	11 (3.6)	5 (3.3)
Urinary tract infection	4 (1.3)	3 (2.0)
Application-site pain	1 (0.3)	3 (2.0)

Improvement/resolution of baseline hypopigmentation and hyperpigmentation at week 8 (overall population[a])

Safety population. [a]Roflumilast and vehicle groups combined.
TEAE, treatment-emergent adverse event.

Conclusions

Roflumilast foam 0.3% reduced signs and symptoms of seborrheic dermatitis across multiple efficacy assessments at 8 weeks, overall and in each of the racial, ethnic, and FST subgroups

Roflumilast foam 0.3% was well tolerated through 8 weeks; hypopigmentation and hyperpigmentation present at baseline in the overall study population improved after 8 weeks of treatment

Results from the STRATUM trial suggest that roflumilast foam 0.3% monotherapy is well tolerated and is an effective treatment option for diverse patient populations with seborrheic dermatitis

FST, Fitzpatrick Skin Type.

Q & A

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