Pattern of Improvement in Scalp Versus Body Psoriasis With Roflumilast Foam 0.3%: An Analysis of the Phase 3 ARRECTOR Trial

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INTRODUCTION

- Signs and symptoms of chronic plaque psoriasis can occur anywhere on the body[1]
  - Approximately half of patients report psoriasis involvement on the scalp[2,3]
  - The use of creams and ointments on hair-bearing areas can make treatment of psoriasis of the scalp challenging,[3] and patients prefer once-daily treatment regimens that are not complicated[2]
- TCS are commonly used to treat psoriasis; however, they have limitations and patients/clinicians often have safety concerns, leading to the need for advanced targeted topical treatments that are not steroids[4–6]
  - TCS are not recommended for long-term use, and the application of higher-potency TCS in thin-skinned areas, where systemic absorption is greater, can lead to increased risk of cutaneous and systemic AEs[6,7]
- Roflumilast foam 0.3% is an advanced targeted topical treatment that is a PDE4 inhibitor formulated without irritating excipients such as ethanol, isopropyl alcohol, propylene glycol, polyethylene glycol, formaldehyde-releasing agents, or fragrances and does not contain boron[7,8]
  - Roflumilast foam 0.3% is approved for once-daily treatment of plaque psoriasis of the scalp and body in patients aged ≥12 years and of seborrheic dermatitis in patients aged ≥9 years[9]
- Efficacy, safety, and tolerability of roflumilast foam 0.3% in patients with plaque psoriasis of the scalp and body were demonstrated in the phase 3 ARRECTOR trial[10]
  - The efficacy of roflumilast foam 0.3% to improve disease severity and itch symptoms on the scalp and body in patients from the ARRECTOR trial are reported here

METHODS

Study design

- ARRECTOR (NCT05028582) was a double-blind, randomized, parallel-group, vehicle-controlled, phase 3 trial of roflumilast foam 0.3% in patients aged ≥12 years with psoriasis of the scalp and body

Co-primary endpoints

- B-IGA (body, non-scalp) and S-IGA (scalp only) success, defined as clear (0) or almost clear (1) plus ≥2-grade improvement from baseline

Additional assessments

- S-IGA and B-IGA over time
- SI-NRS and WI-NRS success, defined as ≥4-point improvement from baseline
- Improvement in SI-NRS and WI-NRS over time, measured as LSM change from baseline
- Safety and application-site tolerability

RESULTS

- Demographics and baseline clinical characteristics were balanced among patients randomized to the roflumilast foam 0.3% (n=281) and vehicle foam (n=151) groups
  - The majority of patients were White (81.9%) and 56.3% were female
  - Most patients had moderate S-IGA and B-IGA at baseline
- The co-primary endpoints of improvement in disease severity at 8 weeks with roflumilast versus vehicle were met
  - S-IGA success: 66.4% vs 27.8% (*P*<0.0001)
  - B-IGA success: 45.5% vs 20.1% (*P*<0.0001)
- Significant improvements in itch symptoms with roflumilast versus vehicle (LSM improvement) were observed within 24 hours of the first application on both the scalp (SI-NRS: 0.44 vs 0.09; *P*<0.05) and body (WI-NRS: 0.42 vs 0.01; *P*<0.01) and throughout assessments
- Roflumilast foam 0.3% was well tolerated
  - An application-site pain TEAE was reported for 1 (0.4%) patient in the roflumilast group
  - Across assessment time points, investigators reported no evidence of irritation at the application site for ≥99.6% of patients in the roflumilast group
  - After the first application of roflumilast and at the week 2 assessment, a severe hot tingling/stinging sensation was reported by 1 (0.4%) patient and by no patient at subsequent assessments

ABBREVIATIONS

AE, adverse event; B-IGA, Body Investigator Global Assessment; BSA, body surface area affected; ITT, intent-to-treat; LSM, least squares mean; *PDE4*, phosphodiesterase 4; QD, once daily; S-IGA, Scalp Investigator Global Assessment; SAE, serious adverse event; SI-NRS, Scalp Itch-Numeric Rating Scale; TCS, topical corticosteroids; TEAE, treatment-emergent AE; WI-NRS, Worst Itch-Numeric Rating Scale.

REFERENCES

1. National Psoriasis Foundation. https://www.psoriasis.org/about-psoriasis/. 2. Armstrong A, et al. *J Dermatolog Treat*. 2024;35(1):2389174. 3. Lebwohl MG, et al. *J Am Acad Dermatol*. 2014;70(5):871–881.e1-30. 4. Kim T-W, et al. *Ann Dermatol*. 2014;26(6):727–732. 5. Dopytalska K, et al. *Reumatologia*. 2018;56(6):392–398. 6. Elmets CA, et al. *J Am Acad Dermatol*. 2021;84:432–470. 7. Burshtein J, et al. *Dermatol Online J*. 2025;31(1). doi: 10.5070/D331164978. 8. Guo J, et al. *Signal Transduct Target Ther*. 2023;8(1):437. 9. Berk D, Osborne DW. Poster presented at the Society for Investigative Dermatology Annual Meeting; May 18–22, 2022; Portland, OR. 10. Draelos ZD, et al. *J Drugs Dermatol*. 2024;23(10):834–840.

Study Design

Eligibility
- Aged ≥12 years
- BSA ≤25%
- S-IGA ≥3 (moderate)
- B-IGA ≥2 (mild)

Randomized 2:1

- Roflumilast foam 0.3% QD
- Vehicle foam QD

8 weeks

Co-primary endpoints
- S-IGA success
- B-IGA success

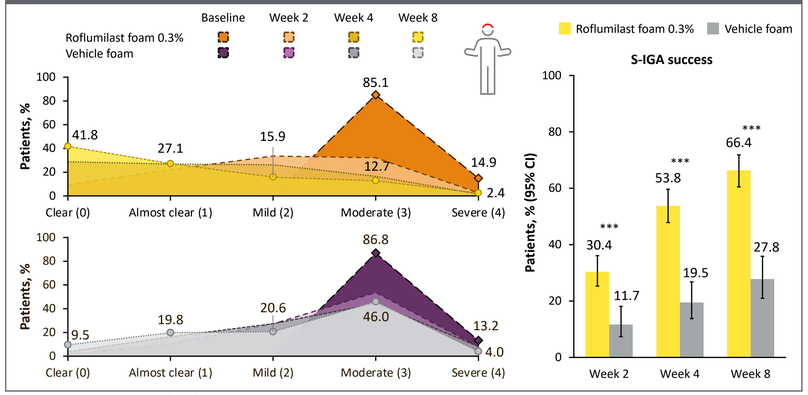
Additional assessments
- S-IGA and B-IGA over time
- SI-NRS and WI-NRS
- Safety and application-site tolerability

Patient Demographics and Baseline Clinical Characteristics

		Roflumilast foam 0.3% (n=281)	Vehicle foam (n=151)
Age, years, mean (median) [range]		48.6 (50.0) [12–87]	45.0 (46.0) [15–78]
Female sex at birth, n (%)		152 (54.1)	91 (60.3)
Not Hispanic or Latino		224 (79.7)	121 (80.1)
Race, n (%)	White	225 (80.1)	129 (85.4)
	Black/African American	12 (4.3)	6 (4.0)
	Asian	26 (9.3)	4 (2.6)
	Other[a]	14 (5.0)	11 (7.3)
	Multiple	4 (1.4)	1 (0.7)
S-IGA, n (%)	3 (moderate)	239 (85.1)	131 (86.8)
	4 (severe)	42 (14.9)	20 (13.2)
B-IGA, n (%)	2 (mild)	76 (27.0)	43 (28.5)
	3 (moderate)	191 (68.0)	99 (65.6)
	4 (severe)	14 (5.0)	9 (6.0)

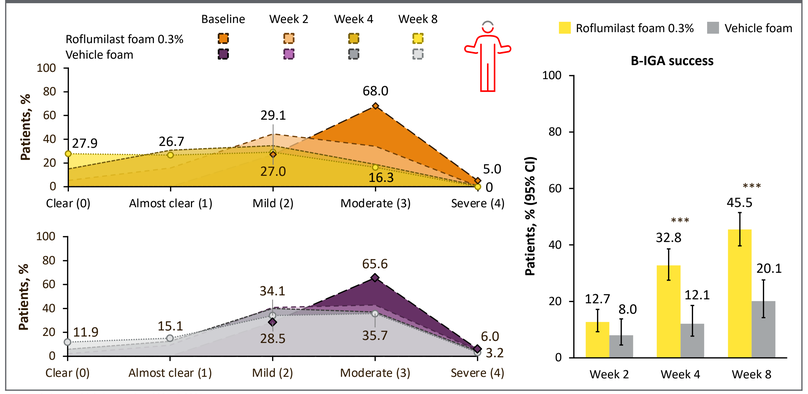
ITT population. [a]Other includes American Indian/Alaskan Native and Native Hawaiian/Other Pacific Islander.

Improvement in Psoriasis Severity Over Time — S-IGA



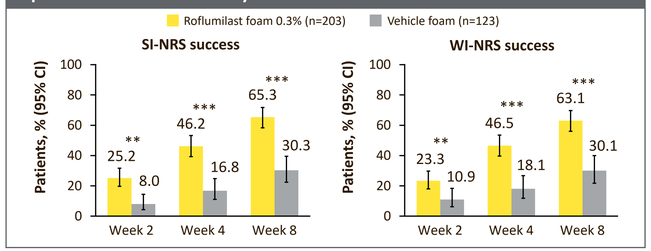
ITT population; multiple imputation. ***P*<0.0001.

Improvement in Psoriasis Severity Over Time — B-IGA



ITT population; multiple imputation. ***P*<0.0001.

Improvement in Itch Intensity Over Time

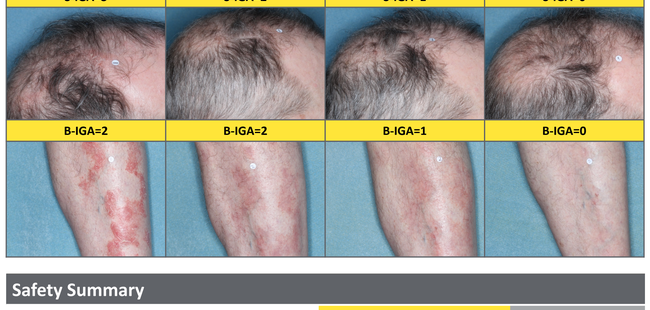


ITT population; multiple imputation. ***P*<0.01; ****P*<0.0001.

Improvement in Psoriasis of the Scalp and Body With Roflumilast Foam 0.3%

56-year-old White, not Hispanic or Latino male with a 1-year history of psoriasis and a history of prior inadequate response, intolerance, or contraindication to TCS

Baseline	Week 2	Week 4	Week 8
S-IGA=3	S-IGA=2	S-IGA=1	S-IGA=0
B-IGA=2	B-IGA=2	B-IGA=1	B-IGA=0



Safety Summary

Patients, n (%)		Roflumilast foam 0.3% (n=281)	Vehicle foam (n=151)
≥1 TEAE		75 (26.7)	25 (16.6)
≥1 treatment-related TEAE		16 (5.7)	3 (2.0)
≥1 treatment-emergent SAE[a]		2 (0.7)	1 (0.7)
≥1 TEAE leading to study/study drug discontinuation		5 (1.8)/7 (2.5)	2 (1.3)/2 (1.3)
Most common TEAEs by preferred term, ≥2% in either group	Headache	13 (4.6)	3 (2.0)
	Diarrhea	9 (3.2)	4 (2.6)
	COVID-19	8 (2.8)	4 (2.6)
	Nausea	6 (2.1)	0

Safety population. [a]In the roflumilast group, SAEs were bipolar disorder (unrelated) and gastritis (possibly related).

CONCLUSIONS

- Roflumilast foam 0.3% significantly reduced psoriasis severity within 8 weeks, as well as improved itch intensity on both the scalp and body, compared with vehicle
  - Significantly higher proportions of patients achieved S-IGA and B-IGA success with roflumilast than with vehicle at 8 weeks
  - Significant improvements in itch intensity (ie, SI-NRS and WI-NRS) were reported within 24 hours of application and throughout 8 weeks of once-daily treatment
- Roflumilast foam 0.3% was well tolerated, with no evidence of irritation at the application site for most patients
- These results support the use of roflumilast foam 0.3% as an alternative to traditional topical treatment options (eg, TCS) for patients with psoriasis of the scalp and body