

Roflumilast Foam 0.3% in Patients With Psoriasis of the Scalp and Body: Improvements in Patient-Reported Outcomes and Quality of Life

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INTRODUCTION

- Plaque psoriasis is a chronic inflammatory skin condition with a substantial burden of disease¹
- Commonly used topical therapies for psoriasis (eg, corticosteroids and calcineurin inhibitors) may have side effects, limitations on duration of use, and restrictions for use in thin-skinned areas, depending on potency^{2,3}
 - There may also be difficulties with application that decrease adherence for some individuals¹
- Topical roflumilast is a PDE4 inhibitor formulated as a water-based foam or cream, which do not contain ethanol, propylene glycol, or fragrances that can irritate skin⁴
- In the phase 3 ARRECTOR (NCT05028582) trial, roflumilast foam 0.3% demonstrated significant improvements in disease signs and symptoms compared with vehicle in patients aged ≥12 years with psoriasis of the scalp and body⁵
 - Safety and application-site tolerability profiles were favorable
 - Patients reported improvements in symptoms and PRO total scores⁶
- Detailed results of PROs from the ARRECTOR trial are reported here

METHODS

- ARRECTOR was a randomized, parallel-group, double-blind, vehicle-controlled, multicenter, phase 3 trial of roflumilast foam 0.3% applied once daily for 8 weeks in adolescent and adult patients with psoriasis of the scalp and body
- Assessments through 8 weeks of study treatment included the following:
 - S/B-IGA success (co-primary endpoints): clear (0) or almost clear (1) plus ≥2-grade improvement from baseline when rated from clear (0) to severe (4)
 - SI/WI-NRS: proportion of patients with 0/1, on a scale from 0 (no itch) to 10 (worst itch imaginable)
 - PSSI-75/100: ≥75% and 100% reduction in PSSI, respectively
 - PSD: a validated 16-item questionnaire assessing various psoriasis symptoms, including itch, pain, and scaling
 - Scalpdx: a validated 23-item survey assessing quality of life in patients with scalp dermatitis
 - Safety and application-site tolerability

Study Design

Eligibility

- Aged ≥12 years
- At least moderate scalp (S-IGA 3) and at least mild body (B-IGA 2) psoriasis
- BSA ≤25%; ≤20% non-scalp BSA
- PSSI ≥6
- ≥10% scalp involvement
- PASI ≥2

Randomize 2:1

Roflumilast foam 0.3% QD (n=281)

Vehicle foam QD (n=151)

8 weeks

Endpoints

Co-primary

- S-IGA success at Week 8
- B-IGA success at Week 8

Secondary/exploratory efficacy

- SI-NRS, WI-NRS, PASI, PSSI
- PSD
- Scalpdx
- DLQI

Safety and tolerability

RESULTS

- Demographics and baseline disease characteristics were similar across treatment groups
 - Most patients (81.9%) had previously used topical corticosteroids for treatment of their psoriasis of the scalp and body
- Roflumilast foam 0.3% was well tolerated, consistent with safety outcomes reported in previous trials of roflumilast cream 0.3% in patients with psoriasis⁷
 - Most TEAEs were mild or moderate in both the roflumilast (96.0%) and vehicle (92.0%) groups, and 5.7% and 2.0% were considered related to study treatment, respectively
 - Discontinuations of the study due to TEAEs were limited and similar between the roflumilast (n=5 [1.8%]) and vehicle (n=2 [1.3%]) groups
- At Week 8, significantly greater ($P<0.0001$) proportions of patients in the roflumilast group achieved S-IGA success, B-IGA success, SI-NRS 0/1, WI-NRS 0/1, PSSI-75, PSSI-100, and improvement in PROs, compared with patients in the vehicle group
 - Improvements in patient-reported Scalpdx and PSD component scores were observed with roflumilast as early as Week 2 and continued through Week 8

Patient Demographics and Baseline Disease Characteristics

	Roflumilast foam 0.3% (n=281)	Vehicle foam (n=151)
ITT*		
Age, years, mean (SD) [range]	48.6 (14.9) [12–87]	45.0 (14.3) [32–56]
Female sex at birth, n (%)	152 (54.1)	91 (60.3)
S-IGA, mean (SD)	3.1 (0.36)	3.1 (0.34)
3 (moderate), n (%)	239 (85.1)	131 (86.8)
4 (severe), n (%)	42 (14.9)	20 (13.2)
B-IGA, mean (SD)	2.8 (0.52)	2.8 (0.54)
2 (mild), n (%)	76 (27.0)	43 (28.5)
3 (moderate), n (%)	191 (68.0)	99 (65.6)
4 (severe), n (%)	14 (5.0)	9 (6.0)
BSA, %, mean (SD)	6.1 (4.3)	6.0 (4.3)
PSSI, mean (SD)	21.4 (11.1)	22.2 (11.0)
Scalpdx total, mean (SD)	47.2 (22.9)	50.5 (20.4)
PSD total, mean (SD)	73.4 (40.2)	75.2 (36.9)
PSD itch/pain/scaling aggregate score, mean (SD)	15.7 (7.3)	16.2 (6.7)

*All randomized patients.

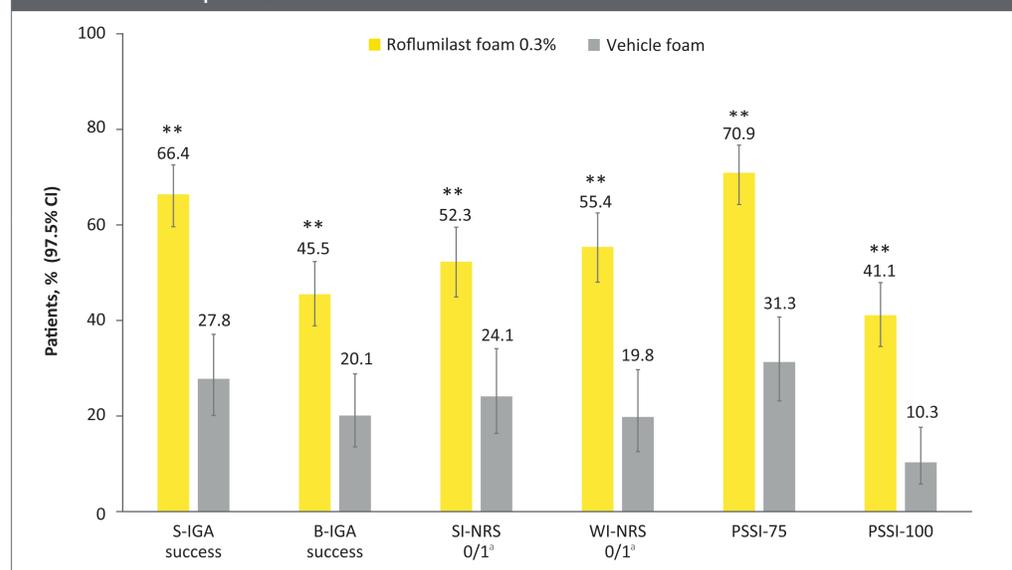
Summary of Adverse Events

n (%) ^a	Roflumilast foam 0.3%	Vehicle foam (n=151)
Patients with any TEAE	75 (26.7)	25 (16.6)
Patients with any treatment-related TEAE	16 (5.7)	3 (2.0)
Patients with any SAE ^b	2 (0.7)	1 (0.7)
Patients with any treatment-related SAE	1 (0.4)	0
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

^aSafety population (all patients who enrolled and received ≥1 confirmed dose of trial medication).

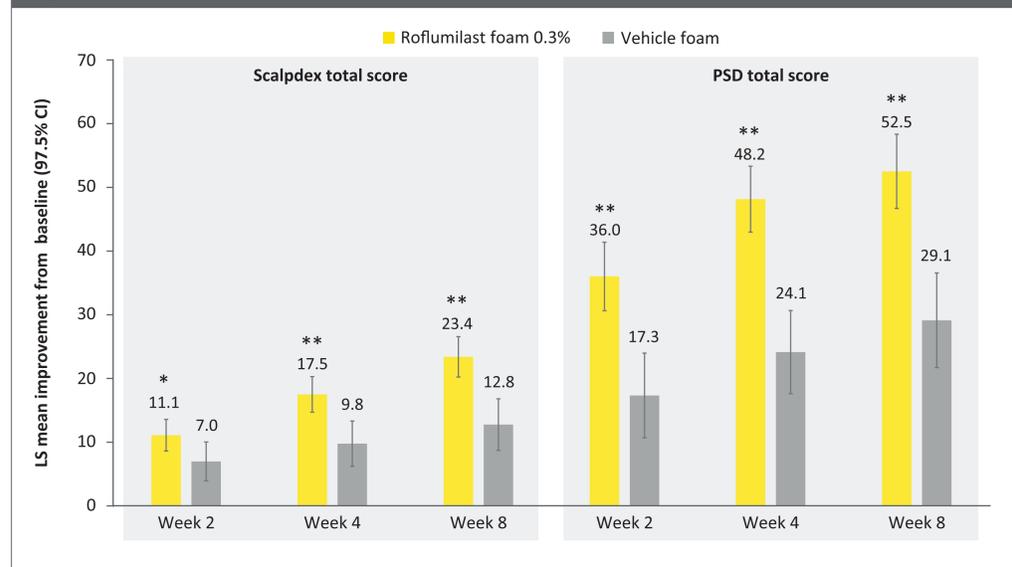
^bSAEs in the roflumilast group were gastritis and bipolar disorder and in the vehicle group were joint dislocation and radius fracture.

Achievement of Response at Week 8



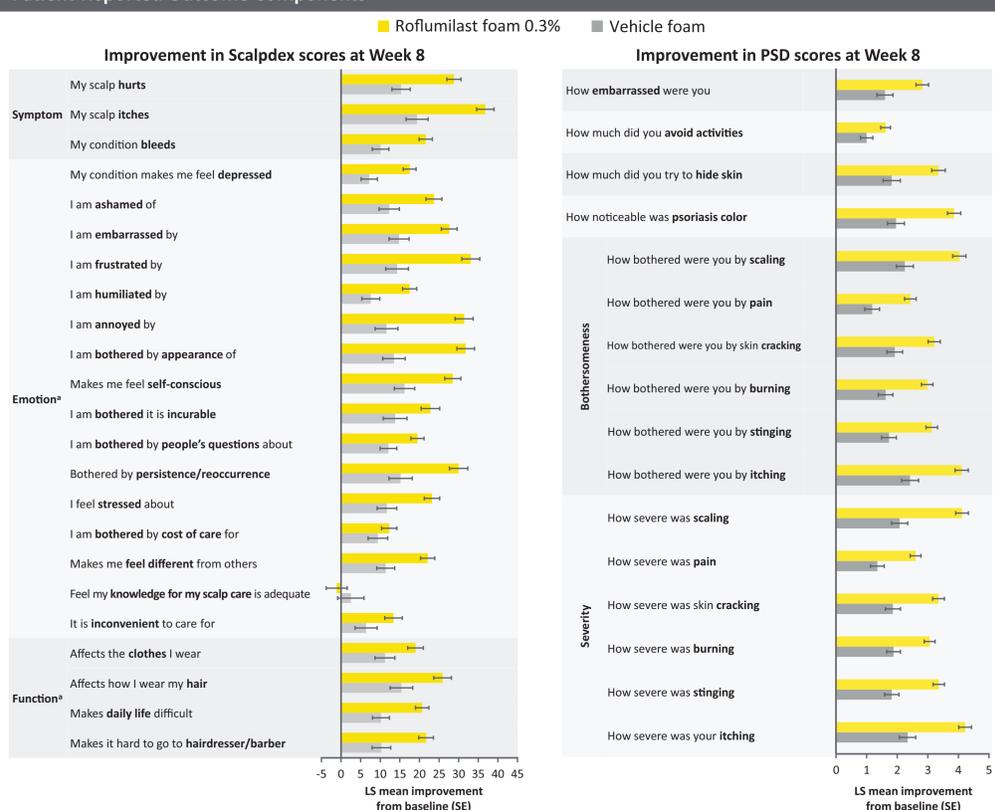
** $P<0.0001$. ITT population. Multiple imputation. ^aIn patients with daily SI-NRS (roflumilast, n=253; vehicle, n=141) or WI-NRS (roflumilast, n=255; vehicle, n=131) ≥2 at baseline.

Improvement in PROs Over Time



* $P<0.01$; ** $P<0.0001$. ITT population. Observed data.

Patient-Reported Outcome Components



ITT population. Observed data. ^aEmotion and function statements are related to impact of scalp condition.

CONCLUSIONS

- Once-daily roflumilast foam 0.3% was effective and well tolerated throughout 8 weeks of treatment in patients with psoriasis of the scalp and body.
- Roflumilast demonstrated improvements in psoriasis signs and symptoms across efficacy measures
 - Improvements were observed as early as the first assessment at 2 weeks and were maintained or improved through 8 weeks
 - This is also in line with significant improvement ($P<0.05$) in scalp itch (SI-NRS) and worst itch (WI-NRS) previously observed within 24 hours after the first application of roflumilast foam 0.3%⁸
 - Safety and efficacy are consistent with previous trials of roflumilast foam 0.3%⁹ and roflumilast cream 0.3%⁷ in patients with psoriasis
 - Roflumilast foam 0.3% significantly improved quality of life and other PROs throughout study treatment.
 - Patients reported improvements in symptoms, as well as a reduction in how psoriasis symptoms impacted daily life
 - Improvements with roflumilast were observed for the 23 components of the Scalpdx assessment, including psoriasis symptoms and mental and emotional state

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DISCLOSURES

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ABBREVIATIONS

B-IGA, Body-Investigator Global Assessment; BSA, body surface area affected; DLQI, Dermatology Life Quality Index; ITT, intent-to-treat; LS, least-squares; PSSI, Psoriasis Area and Severity Index; PDE4, phosphodiesterase 4; PRO, patient-reported outcome; PSD, Psoriasis Symptom Diary; PSSI, Psoriasis Scalp Severity Index; QD, once daily; S-IGA, Scalp-Investigator Global Assessment; SAE, serious adverse event; SI-NRS, Scalp Itch-Numeric Rating Scale; TEAE, treatment-emergent adverse event; WI-NRS, Worst Itch-Numeric Rating Scale.

REFERENCES

1. Agarwal K, et al. *Indian J Dermatol*. 2022;67:387–391. 2. Elmers CA, et al. *J Am Acad Dermatol*. 2021;84:432–470. 3. Burshstein J, et al. *Dermatol Online J*. 2025;31(1). doi: 10.5070/D31164978. 4. Draelos ZD, et al. *J Drugs in Dermatol*. 2024;23:834–840. 5. Gooderham M, et al. *JAMA Dermatol*. 2025;161(7):698–706. 6. Gooderham M, et al. Presented at the American Academy of Dermatology Annual Meeting; March 8–12, 2024; San Diego, CA. Abstract 276. 7. Lebowitz M, et al. *JAMA*. 2022;328(11):1073–1084. 8. Yosipovich G, et al. Presented at the 12th World Congress on Itch; November 5–7, 2023; Miami, FL. 9. Kircik LH, et al. *Br J Dermatol*. 2023;189:392–399.