Improvements in Scalp Outcomes With Roflumilast Foam 0.3% for Psoriasis of the Scalp and Body From the Phase 3 ARRECTOR Trial

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INTRODUCTION

- Plaque psoriasis, a chronic inflammatory skin condition, can occur anywhere on the body[1]
- Psoriasis of the scalp has a substantial negative impact on patient quality of life[2]
  - The scalp is one of the most common locations for development of psoriatic plaques, with approximately half of patients reporting involvement of the scalp[2,3] and up to 80% reporting psoriasis-associated scalp itch[4]
- The use of cosmetically unacceptable formulations, such as creams and ointments, on hair-bearing areas can make treatment of psoriasis of the scalp challenging[3] and contribute to dissatisfaction with treatment and nonadherence[5]
- TCS are commonly used to treat psoriasis, but because of their limitations and growing concerns about their safety, recently approved advanced targeted topical treatments that are not steroids are increasingly used[6–8]
  - TCS are not reccommended 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
- Roflumilast foam 0.3% is a water-based PDE4 inhibitor formulation that contains excipients that help maintain the skin barrier and does not contain ethanol, isopropyl alcohols, propylene glycol, polyethylene glycol, formaldehyde-releasing agents, or fragrances that can lead to contact sensitization, irritate the skin, and/or damage hair[9,10]
- 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[11]
  - The cream formulation (roflumilast cream 0.3%) is approved for the topical treatment of plaque psoriasis in patients aged ≥6 years[12]
- Efficacy, safety, and tolerability of roflumilast foam 0.3% were demonstrated in patients with plaque psoriasis of the scalp and body in the phase 3 ARRECTOR[13] trial
- The efficacy of roflumilast foam 0.3% to improve scalp symptoms and reduce scalp involvement in patients from the ARRECTOR trial are reported here

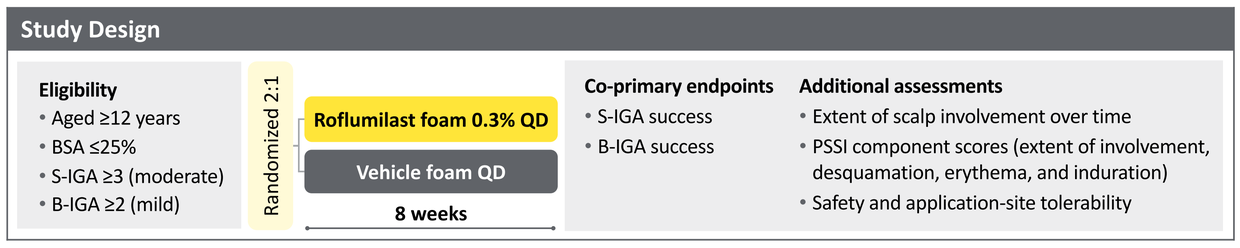
METHODS

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

Key secondary endpoints
- S-IGA clear (0)
- PSSI-75, defined as ≥75% improvement in PSSI from baseline

Study Design



RESULTS

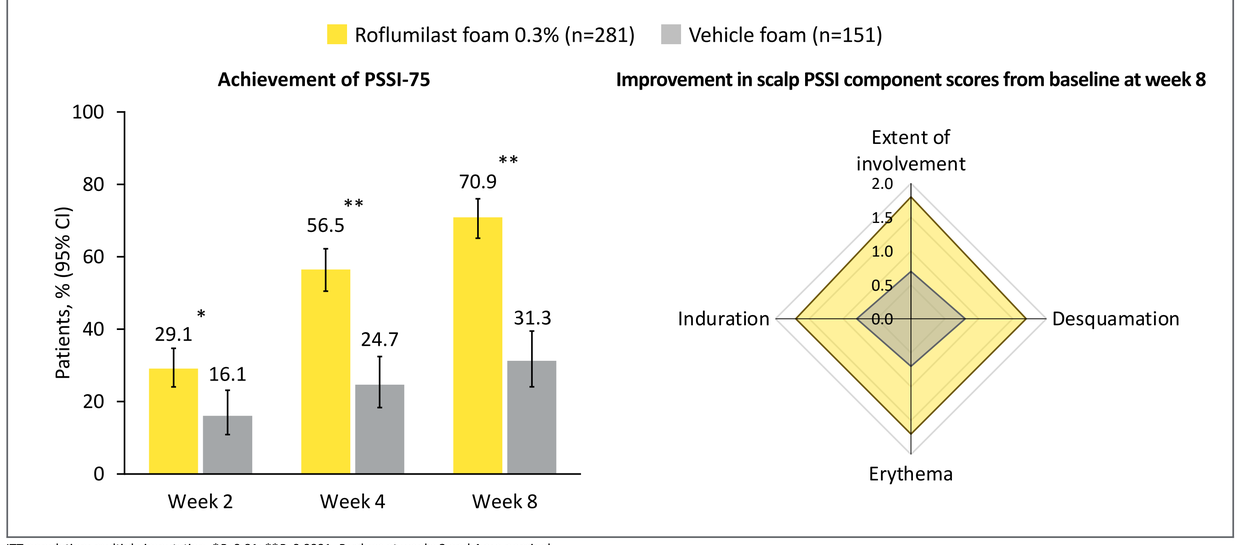
- Mean age of patients was 47.3 years, and demographics and baseline clinical characteristics were balanced between groups
  - The majority of patients (≥80%) were White and not Hispanic or Latino
- Significantly higher proportions of patients in the roflumilast foam 0.3% versus vehicle foam group achieved S-IGA success (P<0.0001) and S-IGA 0 (P≤0.0055) at weeks 2, 4, and 8
- Mean improvement in extent of scalp involvement (ESI) from baseline to week 8 was greater with roflumilast than with vehicle
  - Higher proportions of patients treated with roflumilast versus vehicle achieved ESI 0 throughout the study
- Higher proportions of patients in the roflumilast than vehicle group achieved PSSI-75 at all timepoints (P≤0.0056)
- Topical roflumilast was well tolerated with SAEs reported for <1% of patients
  - No evidence of irritation at the application site was reported by investigators for >99% of patients and no/mild sensation was reported by >94% of patients, at all time points[12]

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, 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 or African American	12 (4.3)	6 (4.0)
	Asian	26 (9.3)	4 (2.6)
	Other	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)
PSSI, mean (SD)		21.4 (11.1)	22.2 (11.0)

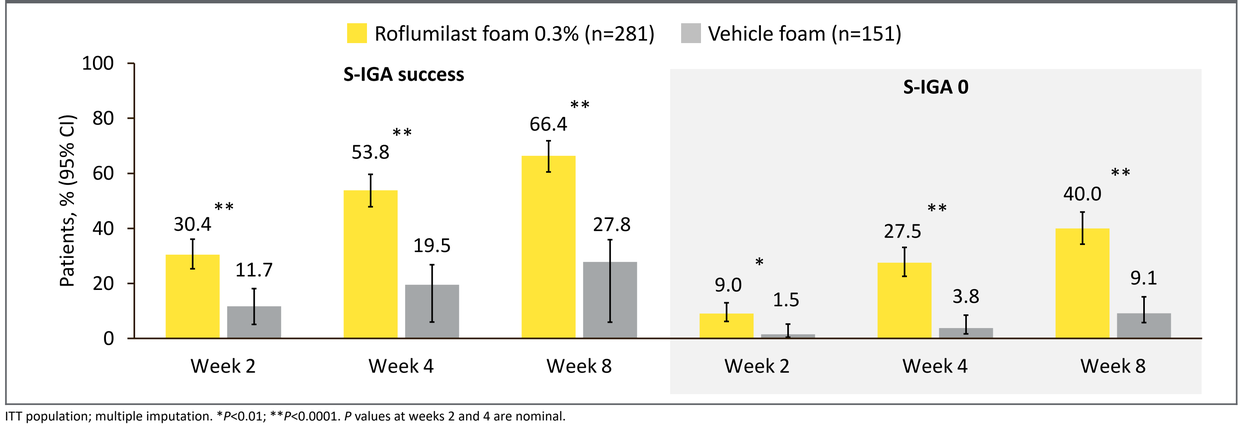
ITT population.

Improvement in Scalp Symptom Severity



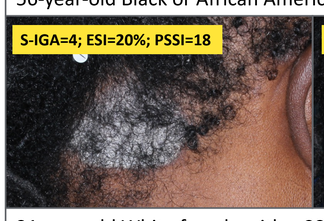
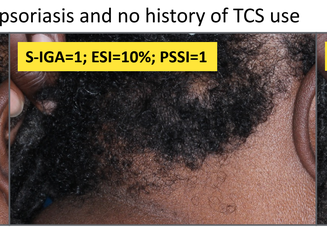
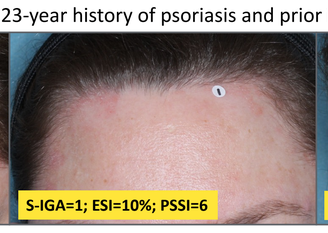
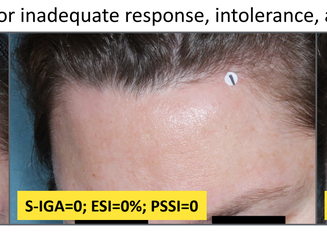
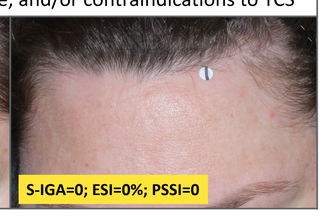
ITT population; multiple imputation. *P<0.01; **P<0.0001. P values at weeks 2 and 4 are nominal.

Improvement in Scalp Psoriasis

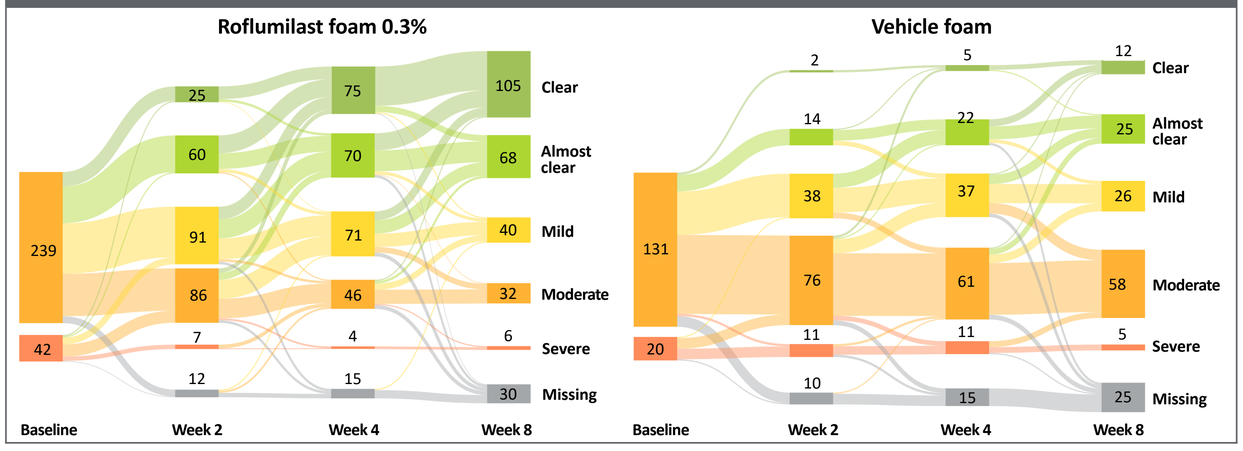


ITT population; multiple imputation. *P<0.01; **P<0.0001. P values at weeks 2 and 4 are nominal.

Improvement in Psoriasis of the Scalp With Roflumilast Foam 0.3%

Baseline	Week 2	Week 4	Week 8
56-year-old Black or African American male with a 4-year history of psoriasis and no history of TCS use			
 S-IGA=4; ESI=20%; PSSI=18	 S-IGA=3; ESI=20%; PSSI=18	 S-IGA=1; ESI=10%; PSSI=1	 S-IGA=1; ESI=10%; PSSI=1
31-year-old White female with a 23-year history of psoriasis and prior inadequate response, intolerance, and/or contraindications to TCS			
 S-IGA=3; ESI=100%; PSSI=36	 S-IGA=1; ESI=10%; PSSI=6	 S-IGA=0; ESI=0%; PSSI=0	 S-IGA=0; ESI=0%; PSSI=0

S-IGA Scores Over Time

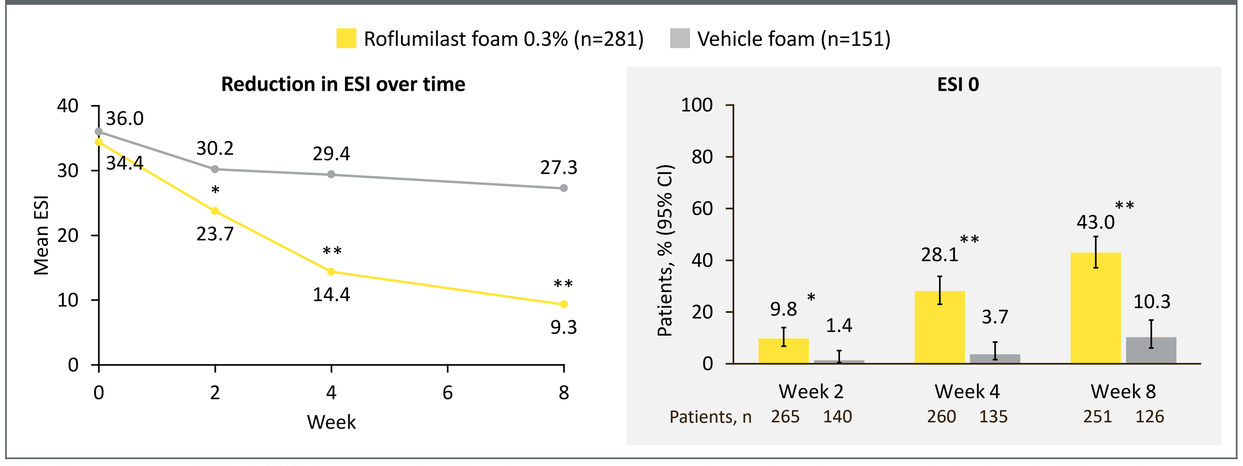


Safety Summary

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).

Improvement in Extent of Scalp Involvement (ESI)



ITT population, observed data. *P<0.01; **P<0.0001. P values for reduction in ESI over timerepresent least squares mean difference of roflumilast foam from vehicle foam. P values for ESI 0 are nominal.

CONCLUSIONS

- Roflumilast foam 0.3% significantly reduced scalp symptom severity and scalp involvement compared with vehicle throughout 8 weeks of once-daily treatment
  - 43% of patients achieved complete clearance of plaques on the scalp (ie, ESI 0) at week 8
- PSSI-75 was achieved by >70% of patients treated with roflumilast foam 0.3%
  - Roflumilast foam 0.3% also reduced PSSI component scores for extent of involvement, desquamation, erythema, and induration to a greater extent than vehicle
- Roflumilast foam 0.3% was well tolerated, with few patients discontinuing study treatment because of TEAEs
- These results support the use of roflumilast foam 0.3% as an advanced targeted topical treatment that is not a steroid, for patients with moderate-to-severe psoriasis of the scalp and body, who may otherwise receive systemic therapy

ABBREVIATIONS

AE, adverse event; B-IGA, Body Investigator Global Assessment; BSA, body surface area affected; ESI, extent of scalp involvement; ITT, intent-to-treat; PDE4, phosphodiesterase 4; PSSI, Psoriasis Scalp Severity Index; QD, once daily; S-IGA, Scalp Investigator Global Assessment; SAE, serious adverse event; TCS, topical corticosteroid; TEAE, treatment-emergent AE.

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DISCLOSURES

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