

Efficacy and Safety of Once-Daily Roflumilast Foam 0.3% for Psoriasis of the Scalp and Body Involving Knees/Elbows: Subgroup Results From the Phase 3 ARRECTOR Trial

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ABBREVIATIONS

AE, adverse event; B-IGA, Body Investigator Global Assessment; BSA, body surface area affected; ITT, intent-to-treat; PASI, Psoriasis Area and Severity Index; PDE4, phosphodiesterase 4; QD, daily; S-IGA, Scalp Investigator Global Assessment; SAE, serious adverse event; TCS, topical corticosteroid; TEAE, treatment-emergent AE; WI-NRS, Worst Itch-Numeric Rating Scale.

REFERENCES

1. National Psoriasis Foundation. About Psoriasis. Updated March 18, 2025. <https://www.psoriasis.org/about-psoriasis/>. 2. Blakely K, et al. *Psoriasis (Auckl)*. 2016;6:33–40. 3. Cannavò SP, et al. *Skin Res Technol*. 2017;23(1):41–47. 4. Stein Gold L, et al. *Cutis*. 2020;105(2):197–102.E1. 5. Elmets CA, et al. *J Am Acad Dermatol*. 2021;84:432–470. 6. Burshtein J, et al. *Dermatol Online J*. 2025;31(1). doi: 10.5070/D331164978. 7. Berk D and Osborne DW. Poster presented at the Society for Investigative Dermatology Annual Meeting; May 18–22, 2022, Portland, OR. 8. Draelos ZD, et al. *J Drugs Dermatol*. 2024;23:834–840. 9. ZORIVE® (roflumilast) foam. Prescribing information. Arcutis Biotherapeutics, Inc.; December 2023.

ACKNOWLEDGMENTS

Thank you to the investigators and their staff for their participation in the trials. We are grateful to the study participants and their families for their time and commitment. Writing support was provided by Emily Bewick, PhD, and Andrea Michels, of Ashfield MedComms, an Inizio company, and was funded by Arcutis Biotherapeutics, Inc.

DISCLOSURES

M/JG, TB, MY, AA, ML, MB, and LKF are investigators and/or consultants for and have received grants/research funding and/or honoraria from Arcutis Biotherapeutics, Inc. MSS, SK, DK, and DHC are employees of Arcutis Biotherapeutics, Inc. Additional disclosures provided upon request. This study was funded by Arcutis Biotherapeutics, Inc.

Presented at the Society for Investigative Dermatology Annual Meeting
May 7–10, 2025; San Diego, CA

INTRODUCTION

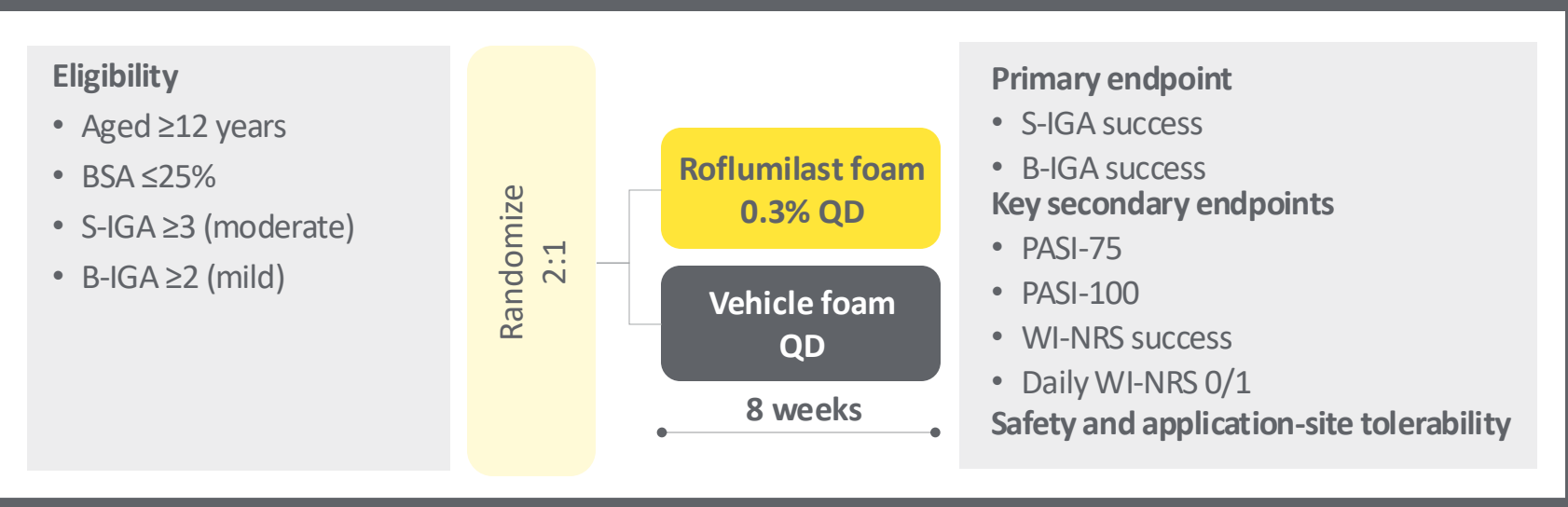
- Plaque psoriasis, a chronic inflammatory skin condition, can occur anywhere on the body, including the scalp, elbows, and knees¹
 - Topical application of creams and ointments to hair-bearing areas can make treatment of scalp psoriasis challenging²
 - Thick stratum corneum on knees/elbows can complicate topical psoriasis treatment as topical treatments are sometimes poorly absorbed^{3,4}
- There have been recent advances and approvals in topical treatment of psoriasis; however, TCS are still commonly used, despite limitations and growing concerns with their safety^{5,6}
 - TCS are recommended for acute treatment of inflammatory skin diseases and are not approved for long-term use because of an increased risk of cutaneous and systemic AEs
 - High-potency TCS are not recommended for areas where systemic absorption is greater (eg, thin skin)
- Roflumilast foam 0.3% is a once-daily, water-based formulation that does not contain ethanol, propylene glycol, penetration enhancers, or fragrances that can irritate skin^{7,8}; it is approved for seborrheic dermatitis in patients aged ≥9 years,⁹ and is being investigated for psoriasis of the scalp and body

METHODS

Study Design

- ARRECTOR (NCT05028582) was a double-blind, randomized, parallel group, vehicle-controlled, phase 3 trial of roflumilast foam 0.3% in patients with psoriasis of the scalp and body
- Involvement of psoriasis on the knees and/or elbows was documented at screening
- Endpoints**
 - B-IGA (body, non-scalp) and S-IGA (scalp only) success, defined as clear (0) or almost clear (1) plus a ≥2 grade improvement from baseline
 - PASI-75/100, defined as ≥75%/100% improvement in PASI from baseline
 - WI-NRS success, defined as ≥4-point improvement from baseline for patients with a baseline score ≥4
 - Daily WI-NRS 0/1, defined as no (0) or minimal (1) itch rated on a scale from 0 to 10 (worst possible itch)
- Safety and application-site tolerability

Study Design



RESULTS

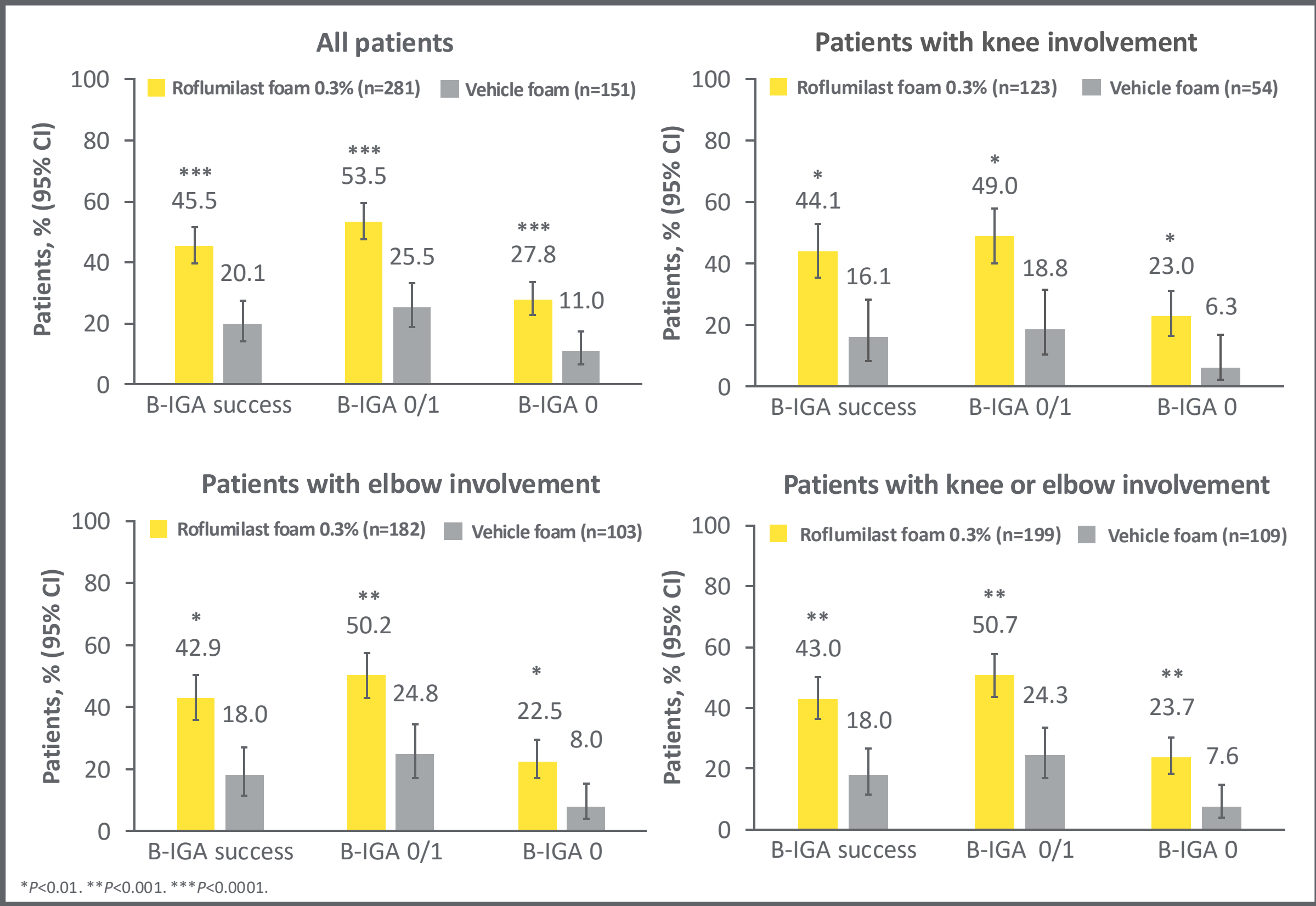
- Mean age (SD) of patients in the roflumilast foam 0.3% and vehicle foam groups was 48.6 years (14.9) and 45.0 years (14.3), respectively
 - 54.1% and 60.3% of patients in the roflumilast foam 0.3% and vehicle foam groups, respectively, were female
 - Overall, the majority of patients were White (81.9%) and not Hispanic or Latino (79.9%)
- At baseline, 70.8% of the roflumilast group and 72.2% of the vehicle group had knee or elbow involvement
- After 8 weeks, B-IGA success rates for patients with knee or elbow involvement were significantly higher with roflumilast vs vehicle (43.0% vs 18.0%; $P=0.0002$)
- Roflumilast foam 0.3% significantly improved disease severity compared with vehicle foam in patients with knee and/or elbow involvement
 - At week 8, PASI-75/100 for the upper and lower extremity regions were achieved by significantly higher proportions of patients treated with roflumilast versus vehicle regardless of elbow (both $P\leq0.003$) or knee (both $P<0.005$) involvement
- Improvements were also observed with roflumilast for individual PASI components in both upper and lower extremity regions (data not shown)
- Overall, WI-NRS success and WI-NRS 0/1 were achieved by significantly higher proportions of patients treated with roflumilast foam 0.3% versus vehicle foam at 8 weeks ($P<0.0001$)
- Roflumilast foam 0.3% was well tolerated; most (≥95%) patients reported no/slight warm, tingling sensation at the application site at all time points assessed

Baseline Disease Characteristics

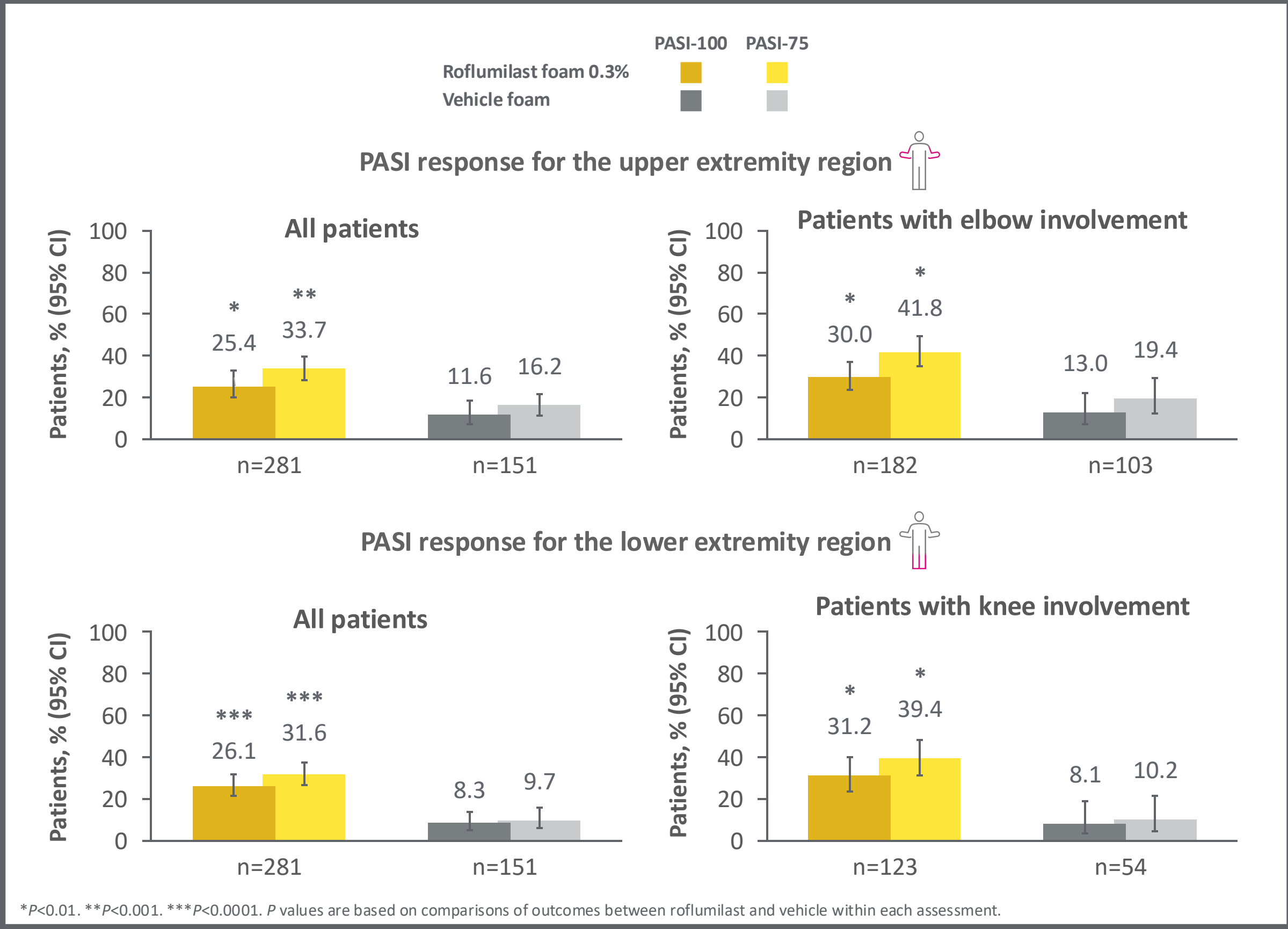
	Roflumilast foam 0.3% (n=281)	Vehicle foam (n=151)
	2 (mild)	43 (28.5)
B-IGA, n (%)	3 (moderate)	99 (65.6)
	4 (severe)	9 (6.0)
PASI total, mean (SD)	6.70 (3.59)	6.00 (3.28)
Psoriasis involvement, n (%)	Elbows	103 (68.2)
	Knees	54 (35.8)
	Elbows or knees	109 (72.2)

ITT population.

B-IGA Outcomes at Week 8



Regional PASI-100 and PASI-75 at 8 Weeks



Improvement With Roflumilast Foam 0.3%



Summary of Adverse Events

n (%)	Roflumilast foam 0.3% (n=281)	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 treatment-emergent SAE ^a	2 (0.7)	1 (0.7)
Patients with any treatment-related SAE	1 (0.4)	0
Patients who discontinued study drug due to an AE	7 (2.5)	2 (1.3)
Most common TEAEs by preferred term, ≥2% in any 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

^aSAEs include bipolar disorder (roflumilast; unrelated), gastritis (roflumilast; possibly related), joint dislocation, peripheral artery occlusion, and radius fracture (vehicle; all unrelated).

CONCLUSIONS

Once-daily roflumilast foam 0.3% was well tolerated and provided improvement across multiple efficacy measures in patients with psoriasis of the scalp and body involving knees and/or elbows

- A higher proportion of patients with knee and/or elbow involvement achieved B-IGA 0 with roflumilast compared with patients receiving vehicle
- Disease severity on the lower and upper extremities, which include the knees and elbows, also improved at week 8
 - Notably, one-quarter to nearly one-third of patients achieved clearance (ie, PASI-100) at week 8
- Efficacy results in knee and elbow involvement subgroups were generally consistent with the overall population in ARRECTOR