

Once-daily Roflumilast Cream or Foam 0.3% for the Treatment of Psoriasis in Patients With Diverse Skin Types: Subgroup Analysis From the Phase 3 DERMIS-1/2 and ARRECTOR Trials

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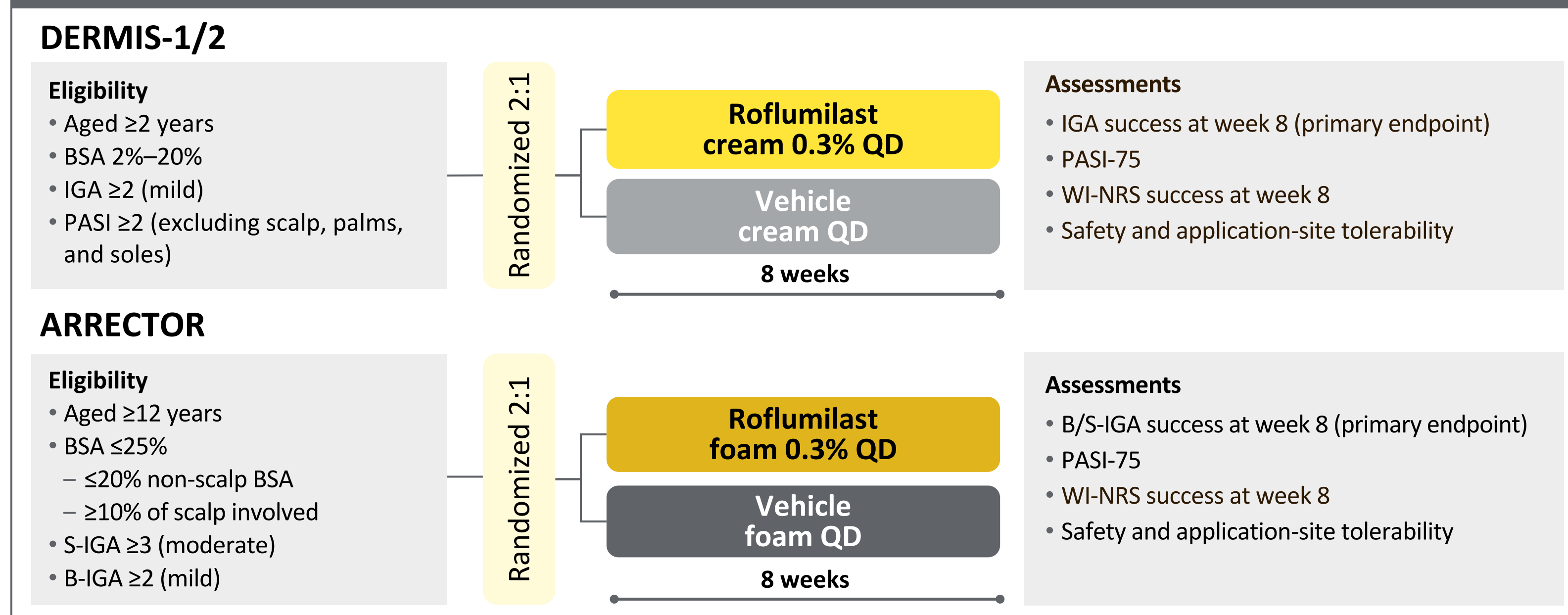
INTRODUCTION

- Psoriasis is a chronic condition that can occur anywhere on the body, with difficult-to-treat areas such as intertriginous, genitals, the scalp, and face being common sites for symptoms¹
- Commonly prescribed topical therapies for psoriasis (eg, TCS) carry a risk of cutaneous and systemic AEs and are not approved for long-term continuous use,^{2,3} and higher-potency TCS are not recommended for thin-skinned areas (eg, face, intertriginous, genitals) with greater absorption^{4,5}
- Roflumilast cream 0.3% and roflumilast foam 0.3% are advanced targeted PDE4 inhibitors formulated without excipients such as ethanol, propylene glycol, or fragrances that may irritate skin, damage hair, or lead to contact sensitization^{5,6}
- Results from the phase 3 clinical trials DERMIS-1/2 and ARRECTOR demonstrated the efficacy and safety of once-daily roflumilast cream 0.3% and foam 0.3%, respectively, for the treatment of plaque psoriasis and psoriasis of the scalp and body^{7,8}
- Response to treatment with roflumilast was investigated in patients with diverse skin types who were enrolled in the DERMIS-1/2 or ARRECTOR trials

METHODS

- DERMIS-1 (NCT04211363) and DERMIS-2 (NCT04211389) were identically designed, phase 3, randomized, double-blind, vehicle-controlled, 8-week trials of roflumilast cream 0.3% in patients aged ≥2 years with at least mild plaque psoriasis
- ARRECTOR (NCT05028582) was a phase 3, randomized, double-blind, vehicle-controlled, 8-week trial of roflumilast foam 0.3% in patients aged ≥12 years with psoriasis of the scalp (at least moderate) and body (at least mild)
- The primary endpoints were IGA (DERMIS-1/2) and B-IGA and S-IGA (ARRECTOR) success at week 8, each defined as clear (0) or almost clear (1), plus ≥2-point improvement from baseline
- Additional efficacy assessments included the following
 - PASI-75, defined as ≥75% improvement from baseline
 - WI-NRS success, defined as ≥4-point improvement from baseline for patients with baseline score ≥4

Study Designs



RESULTS

- Mean age of patients across studies was ~47 years; 63.7% and 43.8% of patients were male in the DERMIS-1/2 and ARRECTOR trials, respectively
- In both studies, baseline clinical characteristics were similar between groups with the majority (65%–78%) having moderate disease
- Higher proportions of patients who applied roflumilast versus vehicle achieved IGA/B-IGA success, PASI-75, and WI-NRS success at week 8 across race and ethnicity subgroups in both DERMIS-1/2 and ARRECTOR
- In ARRECTOR, efficacy was higher with roflumilast foam 0.3% versus vehicle foam for patients based on Fitzpatrick Skin Type (FST was not collected in DERMIS-1/2)
 - B-IGA success: FST I–III, 46.1% vs 19.8% ($P<0.0001$); FST IV–VI, 43.9% vs 21.1%
 - PASI-75: 52.4% vs 16.5% ($P<0.0001$); 44.2% vs 17.6% ($P=0.0046$)
 - WI-NRS success: 66.1% vs 31.0% ($P<0.0001$); 52.9% vs 24.7%
- Roflumilast cream and foam were both well tolerated, with 1.0% and 2.5% of patients, respectively, discontinuing roflumilast because of a TEAE during the 8 weeks of the DERMIS-1/2 and ARRECTOR trials
 - Application-site pain TEAEs were reported for ≤1.0% of patients who received roflumilast (DERMIS-1/2: 6 [1.0%] patients; ARRECTOR: 1 [0.4%] patient)

Patient Demographics and Baseline Disease Characteristics

	DERMIS-1/2		ARRECTOR ^a	
	Roflumilast cream 0.3% (n=576)	Vehicle cream (n=305)	Roflumilast foam 0.3% (n=281)	Vehicle foam (n=151)
Age, years, mean (median) [range]	47.2 (46.0) [16–86]	47.9 (49.0) [8–88]	48.6 (50.0) [12–87]	45.0 (46.0) [15–78]
Male at birth, n (%)	365 (63.4)	196 (64.3)	129 (45.9)	60 (39.7)
Not Hispanic or Latino, n (%)	436 (75.7)	221 (72.5)	224 (79.7)	121 (80.1)
	White	474 (82.3)	250 (82.0)	129 (85.4)
	Asian	41 (7.1)	20 (6.6)	4 (2.6)
Race, n (%) ^b	Black/African American	21 (3.6)	17 (5.6)	6 (4.0)
	Other	28 (4.9)	12 (3.9)	11 (7.3)
	Multiple	3 (0.5)	1 (0.3)	1 (0.7)
IGA/B-IGA, n (%)	Mild (2)	101 (17.5)	44 (14.4)	76 (27.0)
	Moderate (3)	426 (74.0)	240 (78.7)	191 (68.0)
	Severe (4)	49 (8.5)	21 (6.9)	14 (5.0)
Mean (median) [range]	BSA, %	6.7 (5.0) [2–20]	7.5 (6.0) [2–20]	6.1 (5.0) [1–23]
	PASI	6.4 (5.6) [2–19]	6.9 (6.0) [2–25]	6.0 (5.1) [2–18]
	WI-NRS ^c	5.7 (6.0) [0–10]	5.9 (6.0) [0–10]	5.5 (6.0) [0–10]
Prior inadequate response, intolerance, or contraindications to TCS, n (%)	357 (62.0)	183 (60.0)	165 (58.7)	88 (58.3)

ITT populations. ^aBaseline FST in patients from ARRECTOR: I–III, n=318 (73.6%); IV–VI, n=114 (26.4%). ^bThere were 14 patients with missing race details at baseline of the DERMIS-1/2 studies; other includes American Indian or Alaskan Native and Native Hawaiian or Other Pacific Islander. ^cDaily WI-NRS in the previous 24 hours.

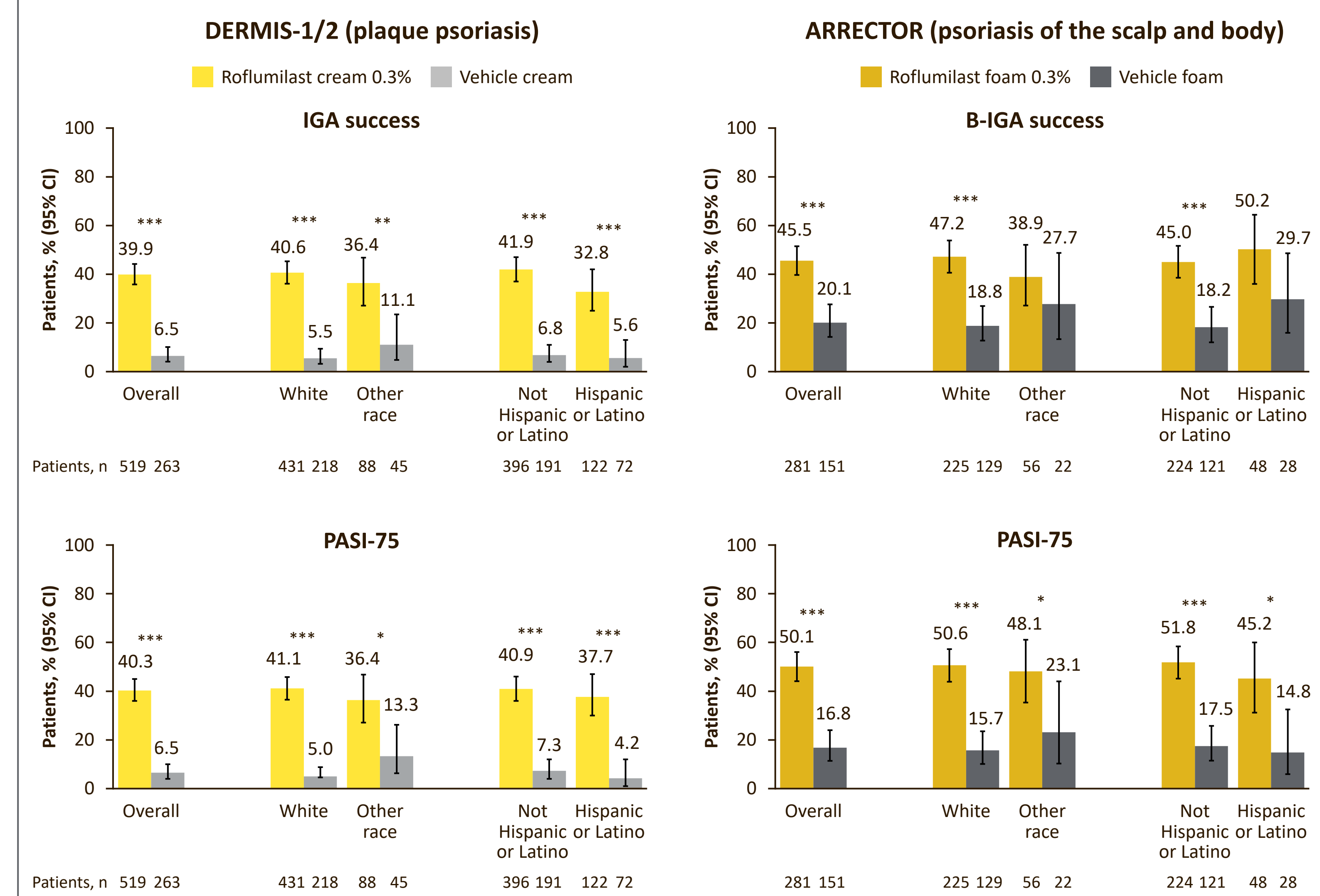
ABBREVIATIONS

AE, adverse event; B-IGA, body-IGA; BSA, body surface area affected; FST, Fitzpatrick Skin Type; IGA, Investigator Global Assessment; ITT, Intention-to-treat; PASI, Psoriasis Area and Severity Index; PDE4, phosphodiesterase 4; QD, once daily; S-IGA, scalp IGA; SAE, serious AE; TCS, topical corticosteroids; TEAE, treatment-emergent AE; WI-NRS, Worst Itch-Numeric Rating Scale.

REFERENCES

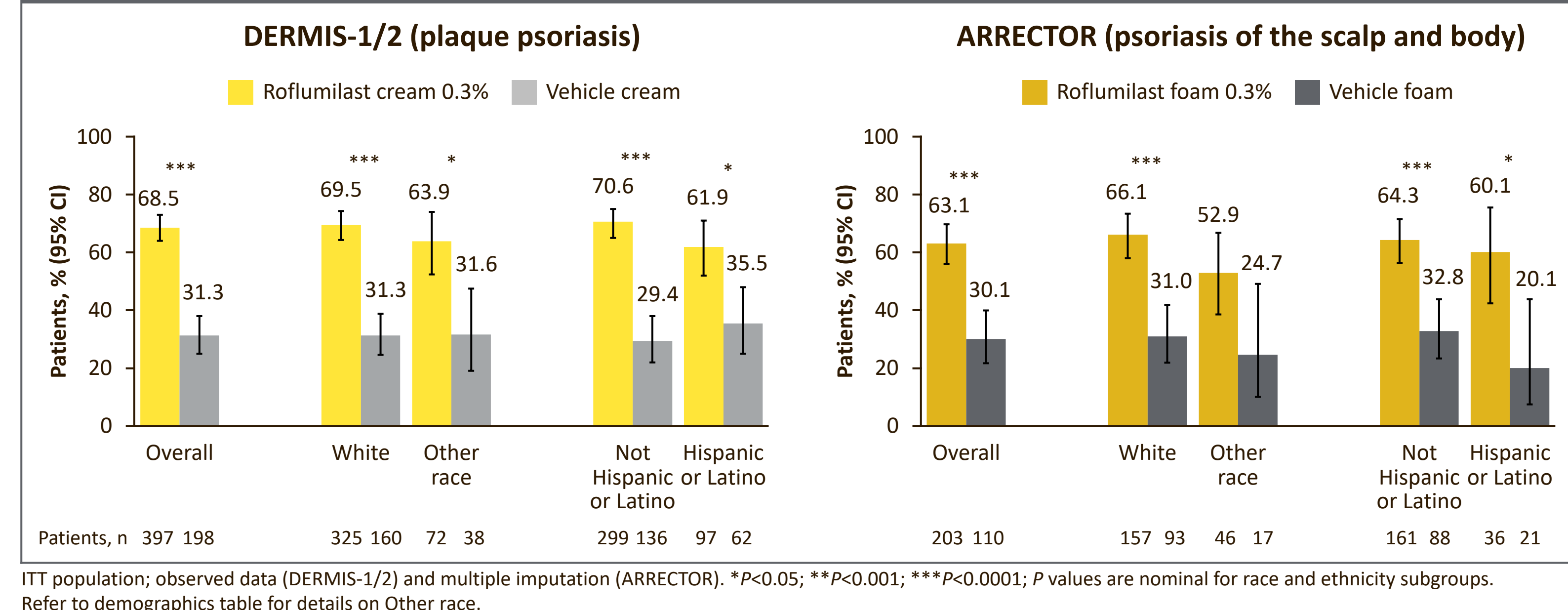
1. National Psoriasis Foundation. About psoriasis. Updated March 24, 2026. <https://www.psoriasis.org/about-psoriasis/>. 2. Elmets CA, et al. *J Am Acad Dermatol*. 2021;84:432–470. 3. Burstein J, et al. *Dermatol Online J*. 2025;31. doi:10.5070/10333164978. 4. Danby SG, et al. *J Dermatolog Treat*. 2022;33:605–608. 5. Draelos ZD, et al. *J Drugs Dermatol*. 2024;23:834–840. 6. Berk DR and Osborne DW. *J Invest Dermatol*. 2022;142(Suppl):S93. 7. Lebwohl MG, et al. *JAMA*. 2022;328:1073–1084. 8. Goudehram M, et al. *JAMA Dermatol*. 2025;161:698–706.

Improvements in Signs and Severity of Psoriasis at Week 8 With Roflumilast



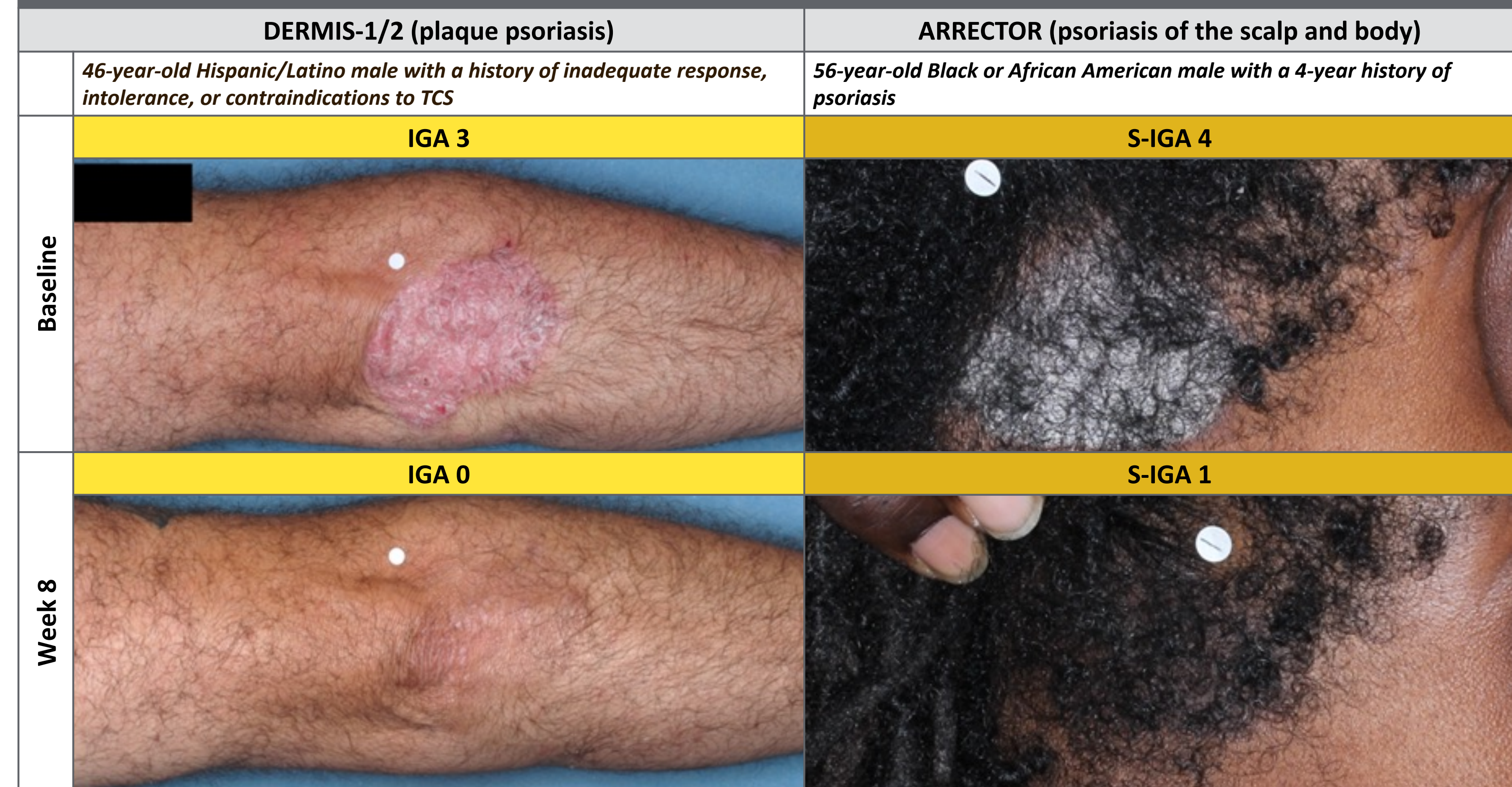
ITT population; observed data (DERMIS-1/2) and multiple imputation (ARRECTOR). * $P<0.05$; ** $P<0.001$; *** $P<0.0001$; P values are nominal for race and ethnicity subgroups. Refer to demographics table for details on Other race.

Improvement in Itch Symptoms With Roflumilast at Week 8 (WI-NRS Success)



ITT population; observed data (DERMIS-1/2) and multiple imputation (ARRECTOR). * $P<0.05$; ** $P<0.001$; *** $P<0.0001$; P values are nominal for race and ethnicity subgroups. Refer to demographics table for details on Other race.

Improvements With Roflumilast Cream 0.3% and Foam 0.3% Over Time



Note: The white sticker is placed by investigator for reference.

Summary of AEs

Patients, n (%)	DERMIS-1/2		ARRECTOR	
	Roflumilast cream 0.3% (n=576)	Vehicle cream (n=305)	Roflumilast foam 0.3% (n=281)	Vehicle foam (n=151)
≥1 TEAE	147 (25.5)	64 (21.0)	75 (26.7)	25 (16.6)
≥1 treatment-related AE	23 (4.0)	11 (3.6)	16 (5.7)	3 (2.0)
≥1 SAE	2 (0.3)	2 (0.7)	2 (0.7)	1 (0.7)
≥1 treatment-related SAE	0	0	1 (0.4)	0
Discontinued study drug due to a TEAE	6 (1.0)	4 (1.3)	7 (2.5)	2 (1.3)
	Headache	14 (2.4)	3 (1.0)	13 (4.6)
Most common TEAEs (≥2% of patients in any group)	Diarrhea	18 (3.1)	0	9 (3.2)
	COVID-19	3 (0.5)	0	8 (2.8)
	Nausea	7 (1.2)	1 (0.3)	6 (2.1)

CONCLUSIONS

- Roflumilast cream 0.3% and foam 0.3% significantly improved signs of psoriasis and disease severity over 8 weeks of treatment
 - Trends in proportions of patients who achieved IGA/B-IGA success and PASI-75 were consistent with the overall population when assessed by race and ethnicity subgroups
 - Higher proportions of patients reported improvements in itch symptoms (WI-NRS success) with roflumilast cream or foam versus vehicle
- Roflumilast cream and foam were well tolerated and improved signs and symptoms of psoriasis across diverse skin types over 8 weeks of once-daily application



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DISCLOSURES

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