Efficacy and Tolerability of Roflumilast Cream 0.3% and Foam 0.3% in Patients With Plaque Psoriasis Involving the Face and/or Genitals: Outcomes From the Phase 3 DERMIS-1/2 and ARRECTOR Trials

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INTRODUCTION

- Plaque psoriasis is a chronic inflammatory skin disease that can occur anywhere on the body, with psoriasis on the face and genitals being among the most distressing for patients and genital psoriasis often being both underreported and undertreated[1,2]
- Topical therapies commonly prescribed to treat psoriasis (eg, TCS and TCIs) have limitations on duration of use and the potential for causing local and systemic side effects[3,4]
  - TCS are not approved for long-term use because of an increased risk of cutaneous and systemic AEs[3,4]
  - Adverse reactions and hypersensitivity can have a strong impact in thin-skinned areas (eg, face and genitals) where absorption is greater; higher potency TCS are not recommended for use in these areas[5]
- Cutaneous reactions may occur because of ingredients and/or irritating excipients in a topical treatment[5]
- Roflumilast is a PDE4 inhibitor that has been formulated as a topical water-based cream or foam that does not contain ethanol, propylene glycol, or fragrances that can irritate skin[6]
- Efficacy, safety, and tolerability of roflumilast cream 0.3% and roflumilast foam 0.3% have been demonstrated in patients with plaque psoriasis in the phase 3 DERMIS-1/2[7] and ARRECTOR[8] trials, respectively
  - Outcomes from these trials in patient subgroups with psoriasis involvement on the face and/or genitals were assessed

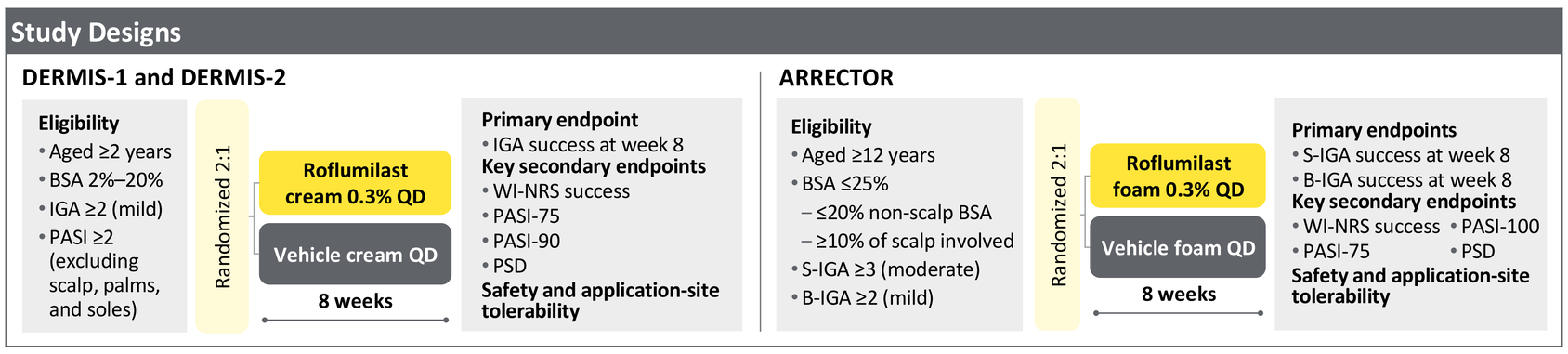
METHODS

- DERMIS-1 (NCT04211363) and DERMIS-2 (NCT04211389) were identically designed, phase 3, randomized, double-blind, vehicle-controlled, 8-week studies of roflumilast cream 0.3% in patients aged ≥2 years with psoriasis
- 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

Outcomes

- IGA, B-IGA (body, non-scalp), and S-IGA (scalp only) success, defined as achievement of clear (0) or almost clear (1) plus ≥2-grade improvement from baseline
- WI-NRS success, defined as ≥4-point improvement from baseline for patients with baseline score ≥4
- PASI-75/90/100, defined as ≥75%/≥90%/100% improvement in PASI from baseline

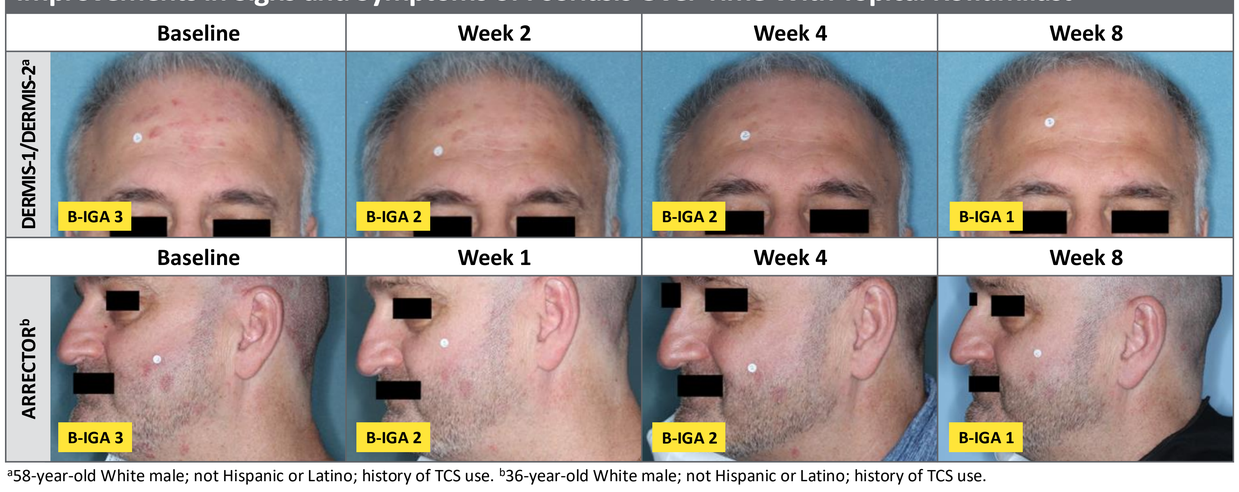
Study Designs



RESULTS

- Mean age across treatment groups in the studies was ~47 years; 57.1% of patients were male; the majority of patients were White (82.1%) and not Hispanic or Latino (76.3%)
- At baseline, proportions of patients with psoriasis with facial and genital involvement were 26.6% and 15.6% in DERMIS-1/2, respectively, and 36.3% and 17.4% in ARRECTOR
- Higher proportions of patients in the roflumilast versus vehicle group in the DERMIS-1/2 and ARRECTOR trials achieved IGA or B-IGA success, IGA or B-IGA 0/1, and WI-NRS success at week 8 in the overall population, as well as in the subpopulations with baseline facial and genital involvement
- Roflumilast cream and foam were both well tolerated; SAEs were reported for <1% of patients (1 patient in the roflumilast group with gastritis, considered possibly related to treatment)
  - Of patients who received roflumilast, application-site pain AEs were reported for 6 (1.0%) patients in the DERMIS-1/2 trial and for 1 (0.4%) patient in the ARRECTOR trial
  - Across studies at weeks 4 and 8, <2% of investigators reported any irritation at the application site of roflumilast
  - After the first application of roflumilast, on week 4, and on week 8, a severe, hot tingling/stinging sensation that caused definite discomfort was reported by 0.4%, 0%, and 0.2% of patients in the DERMIS-1/2 trials and by 0.4%, 0%, and 0% of patients in the ARRECTOR trial, respectively

Improvements in Signs and Symptoms of Psoriasis Over Time With Topical Roflumilast



[a]58-year-old White male; not Hispanic or Latino; history of TCS use. [b]36-year-old White male; not Hispanic or Latino; history of TCS use.

Patient Demographics and Baseline Disease Characteristics

		DERMIS-1 and DERMIS-2		ARRECTOR	
		Roflumilast cream 0.3% (n=576)	Vehicle cream (n=305)	Roflumilast foam 0.3% (n=281)	Vehicle foam (n=151)
Age, y, mean (SD) [range]		47.2 (14.6) [6–86]	47.9 (15.0) [8–88]	48.6 (14.9) [12–87]	45.0 (14.3) [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)
Race, n (%)	White	474 (82.3)	250 (82.0)	225 (80.1)	129 (85.4)
	Asian	41 (7.1)	20 (6.6)	26 (9.3)	4 (2.6)
	Black or African American	21 (3.6)	17 (5.6)	12 (4.3)	6 (4.0)
	Other	28 (4.9)	12 (3.9)	14 (5.0)	11 (7.3)
	Multiple	3 (0.5)	1 (0.3)	4 (1.4)	1 (0.7)
IGA/B-IGA, n (%)	Mild (2)	101 (17.5)	44 (14.4)	76 (27.0)	43 (28.5)
	Moderate (3)	426 (74.0)	240 (78.7)	191 (68.0)	99 (65.6)
	Severe (4)	49 (8.5)	21 (6.9)	14 (5.0)	9 (6.0)
Mean (median) [range]	BSA, %	6.7 (5.0) [2–20]	7.6 (6.0) [2.0–20.0]	6.1 (5.0) [0.6–23.0]	6.0 (5.0) [1.0–22.0]
	PASI	6.4 (5.6) [2–19]	6.9 (6.0) [2–25]	6.7 (6.0) [1.4–23.2]	6.0 (5.1) [1.6–18.0]
	WI-NRS	5.7 (6.0) [0–10]	5.9 (6.0) [0–10]	5.7 (6.0) [0.0–10.0]	5.5 (6.0) [0.0–10.0]
Involvement, n (%)	Facial	150 (26.0)	84 (27.5)	98 (34.9)	59 (39.1)
	Genital	97 (16.8)	40 (13.1)	47 (16.7)	28 (18.5)

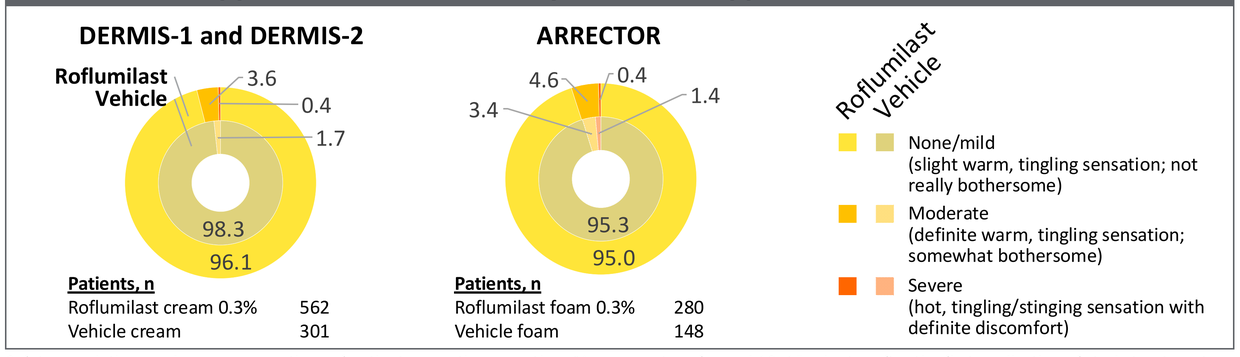
ITT populations.

Summary of Adverse Events

		DERMIS-1 and DERMIS-2		ARRECTOR	
Patients, n (%)		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
Most common TEAEs[a] by preferred term	Headache	14 (2.4)	3 (1.0)	13 (4.6)	3 (2.0)
	Diarrhea	18 (3.1)	0	9 (3.2)	4 (2.6)
	COVID-19	3 (0.5)	0	8 (2.8)	4 (2.6)
	Nausea	7 (1.2)	1 (0.3)	6 (2.1)	0

Safety populations. [a]Common TEAEs reported for ≥2% of patients in any treatment group.

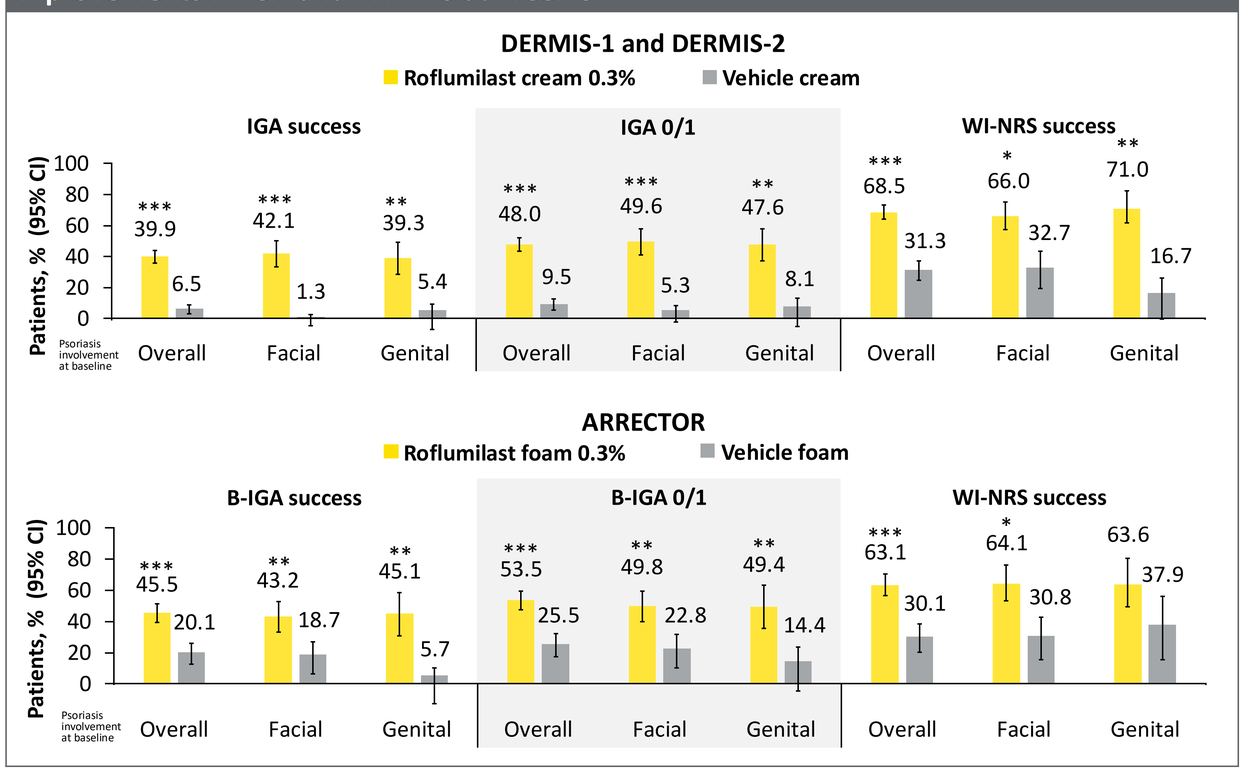
Patient-Rated Application-Site Tolerability After First Application[a]



Patients, n		Patients, n	
Roflumilast cream 0.3%	562	Roflumilast foam 0.3%	280
Vehicle cream	301	Vehicle foam	148

Safety populations. Values are proportions of patients reporting sensation. [a]Assessment performed 10–15 minutes after the first application of study treatment.

Improvements in IGA and WI-NRS at Week 8



ITT populations. Multiple imputation. *P<0.03; **P<0.005; ***P<0.0001.

CONCLUSIONS

- Both roflumilast cream 0.3% and roflumilast foam 0.3% were well tolerated and improved signs and symptoms of plaque psoriasis across several efficacy assessments at 8 weeks
  - Improvements in subgroups with facial and/or genital involvement were comparable with those in the overall population
- Observed improvements, safety, and tolerability were consistent between the cream and foam formulations
- These data suggest that roflumilast cream 0.3% and roflumilast foam 0.3% are both alternatives to traditional topical therapies for the treatment of psoriasis with facial and/or genital involvement, providing additional treatment options for patients and providers

ABBREVIATIONS

AE, adverse event; B-IGA, body-IGA; BSA, body surface area; IGA, Investigator Global Assessment; ITT, intention to treat; PASI, Psoriasis Area Severity Index; PDE4, phosphodiesterase 4; PSD, Psoriasis Symptoms Diary; QD, once daily; SAE, serious AE; S-IGA, scalp-IGA; TCIs, topical calcineurin inhibitors; TCS, topical corticosteroids; TEAE, treatment-emergent AE; WI-NRS, Worst Itch-Numeric Rating Scale.

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DISCLOSURES

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