Improvements in Psoriasis, Including Sexual Function and Personal Relationships, With Roflumilast Cream 0.3% and Foam 0.3%: Outcomes From the Phase 3 DERMIS-1/2 and ARRECTOR Trials

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ABBREVIATIONS

AE, adverse event; B-IGA, body-IGA; BSA, body surface area affected; DLQI, Dermatology Life Quality Index; IGA, Investigator Global Assessment; ITT, intent-to-treat; MID, minimally important difference; PASI, Psoriasis Area Severity Index; PDE4, phosphodiesterase 4; QD, once daily; S-IGA, scalp-IGA; TCI, topical calcineurin inhibitor; TCS, topical corticosteroids; WI-NRS, Worst Itch-Numeric Rating Scale.

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DISCLOSURES

This study was funded by Arcutis Biotherapeutics, Inc. MP, TB, MY, AA, MJG, SMJ, SA, JRJ, TM, JZ, and JC are investigators and/or consultants for and have received grants/research funding and/or honoraria from Arcutis Biotherapeutics, Inc. TL, MSS, DH, and KB are employees of Arcutis Biotherapeutics, Inc. Additional disclosures provided on request.

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INTRODUCTION

- Psoriasis can affect all body regions, including the genitals, and may negatively impact quality of life[1,2]
  - Genital involvement in particular can have an undesirable impact on social life, relationships, and sexual health
- Topical therapies commonly prescribed to treat psoriasis (eg, TCS) have the potential for causing local and systemic side effects and have limitations on duration of use[3,4]
  - TCS are not approved for long-term use because of an increased risk of cutaneous and systemic AEs[3,4]
  - In thin-skinned areas, such as the genitals where absorption is greater, adverse reactions and hypersensitivity to TCS are more common, and higher potency TCS are not recommended for use in these areas[5,6]
- Roflumilast cream 0.3% and roflumilast foam 0.3% are advanced targeted topical PDE4 inhibitors formulated without irritating excipients, such as ethanol, propylene glycol, or fragrances[6]
- Efficacy, safety, and tolerability of roflumilast cream 0.3% and foam 0.3% were demonstrated in patients with plaque psoriasis in the phase 3 DERMIS-1/2[7] and ARRECTOR[8] trials, respectively
  - Outcomes from these trials for patients with psoriasis with genital involvement were assessed, including patient-reported outcomes regarding sexual function and relationships

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)

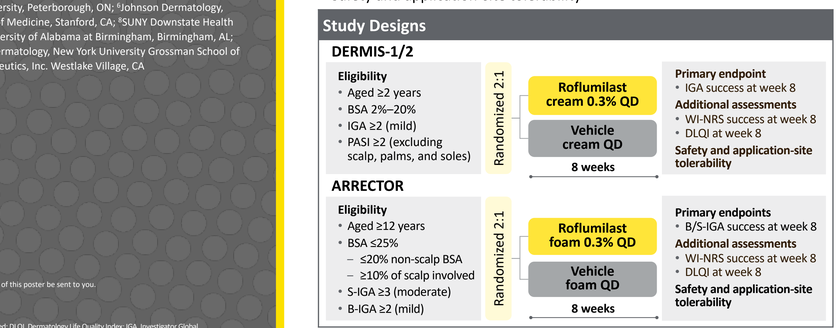
Primary endpoints

- 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 assessments

- WI-NRS success, defined as ≥4-point improvement from baseline for patients with baseline score ≥4
- DLQI MID, defined as ≥4-point reduction from baseline in patients aged ≥17 years with baseline DLQI ≥4
- DLQI scores for items related to sexual health and relationships scored on a scale from 0 (not at all/not relevant) to 4 (very much)
- Safety and application-site tolerability

Study Designs



RESULTS

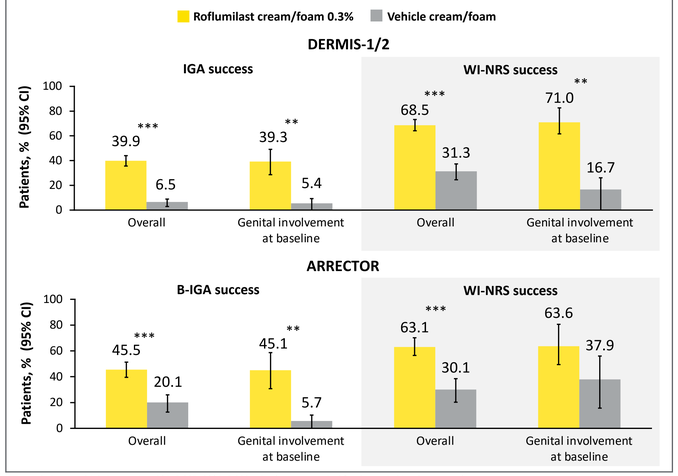
- Patient characteristics were well-balanced between treatment groups within the DERMIS-1/2 and ARRECTOR trials and similar across the trials, with a mean age of ~47 years and >80% of patients being White
  - In DERMIS-1/2, 63.7% of patients were male, as were 43.8% of patients in ARRECTOR
  - At baseline, 15.6% of patients in DERMIS-1/2 and 17.4% of patients in ARRECTOR had psoriasis with genital involvement
- In the overall population and in patients with psoriasis with genital involvement, higher proportions of those in the roflumilast versus vehicle groups achieved IGA/B-IGA success and WI-NRS success at week 8
- Roflumilast cream 0.3% and roflumilast foam 0.3% were well tolerated in patients regardless of body area involvement, and <1% of patients reported a hot, tingling/stinging sensation with definite discomfort after the first application

Patient Demographics and Baseline Disease Characteristics

		DERMIS-1/2		ARRECTOR	
		Roflumilast cream 0.3% (n=576)	Vehicle cream (n=305)	Roflumilast foam 0.3% (n=281)	Vehicle foam (n=151)
Age, y, mean (median) [range]		47.2 (46.0) [6–86]	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)
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/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) [2–20]	6.1 (5.0) [<1–23]	6.0 (5.0) [1–22]
	PASI	6.4 (5.6) [2–19]	6.9 (6.0) [2–25]	6.7 (6.0) [1–23]	6.0 (5.1) [2–18]
	WI-NRS	5.7 (6.0) [0–10]	5.9 (6.0) [0–10]	5.6 (6.0) [0–10]	5.5 (6.0) [0–10]
Genital involvement, n (%)		97 (16.8)	40 (13.1)	47 (16.7)	28 (18.5)

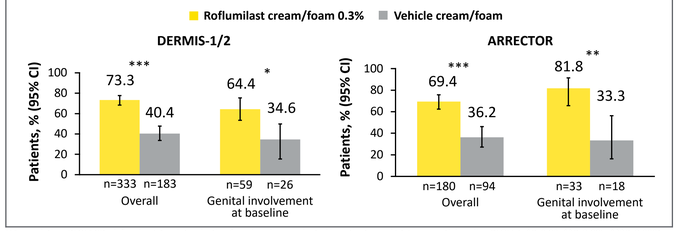
ITT populations.

Improvement in Signs and Symptoms of Psoriasis at Week 8



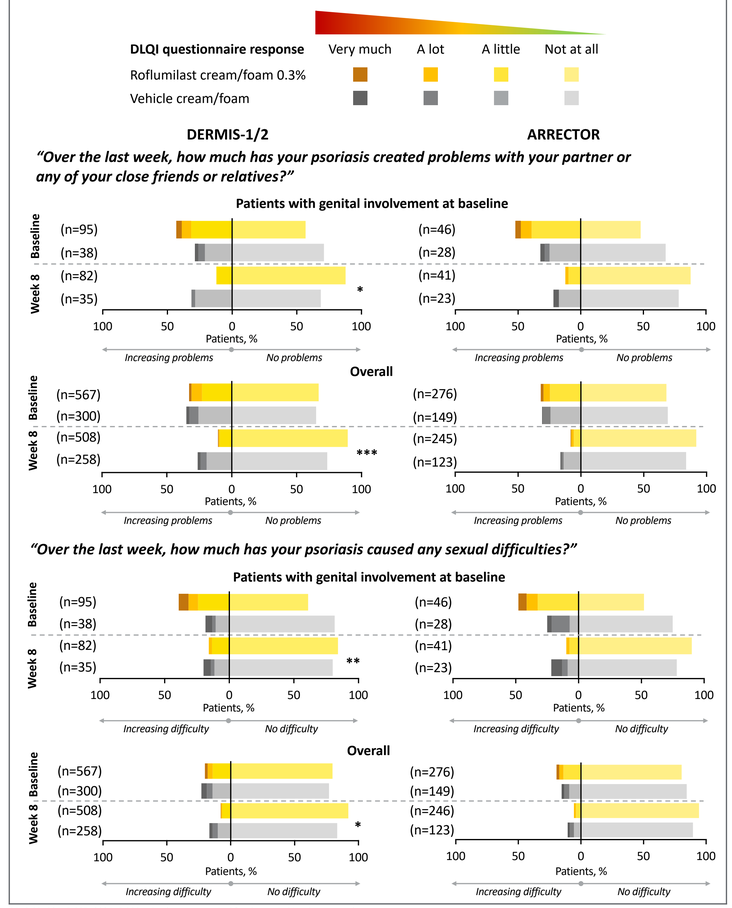
ITT populations; multiple imputation. **P<0.005; ***P<0.0001; *P* values are nominal for the genital involvement subgroups.

Improvement in Quality of Life at Week 8 (DLQI MID)



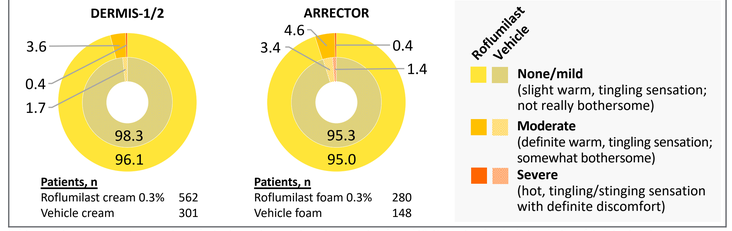
ITT population. DLQI MID: defined as ≥4-point reduction from baseline, evaluated in patients aged ≥17 years with baseline DLQI ≥4. *P<0.03; **P<0.005; ***P<0.0001; *P* values are nominal for the genital involvement subgroups.

Improvement in Sexual Function and Relationships at Week 8 (DLQI Items)



*P<0.03; **P<0.005; ***P<0.0001; *P* values are nominal for the genital involvement subgroups.

Patient-Rated Local 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 the proportions of patients reporting sensation. [a]Assessment performed 10–15 minutes after the first application of study treatment.

CONCLUSIONS

- Roflumilast cream 0.3% and roflumilast foam 0.3% were both well tolerated and improved signs and symptoms of plaque psoriasis over 8 weeks
  - Improvements were observed in the overall populations, as well as in subpopulations with genital involvement at study baseline
- Quality of life, including sexual function and relationships, improved with roflumilast compared with vehicle across the populations assessed
  - Providers should consider discussing the impact of sexual function with patients who have psoriasis and genital involvement
- These results support both roflumilast cream 0.3% and roflumilast foam 0.3% for the treatment of psoriasis of the body, including in those with genital involvement who may have impairments in sexual function or quality of life