

Roflumilast Cream 0.3% and Foam 0.3% Provide Improvement in Psoriasis Area and Severity Index (PASI) Across Body Regions and Clinical Signs for Patients With Plaque Psoriasis

Melinda J. Gooderham,¹ Tina Bhutani,² Melodie Young,³ April Armstrong,⁴ Mark G. Lebwohl,⁵ Michael Bukhalo,⁶ Laura K. Ferris,⁷ Stefan C. Weiss,⁸ David Krupa,⁹ Melissa S. Seal,⁹ Diane Hanna⁹

¹SKiN Centre for Dermatology, Probitry Medical Research and Queen's University, Peterborough, ON; ²Synergy Dermatology, San Francisco, CA; ³Mindful Dermatology and Modern Research Associates, Dallas, TX; ⁴David Geffen School of Medicine, University of California Los Angeles, Los Angeles, CA; ⁵Icahn School of Medicine at Mount Sinai, New York, NY; ⁶Rosalind Franklin University of Medicine and Science Chicago Medical School, North Chicago, IL and Arlington Dermatology, Rolling Meadows, IL; ⁷University of North Carolina, Department of Dermatology, Chapel Hill, NC; ⁸Warren J. Alpert School of Medicine at Brown University, Providence, RI and Trillium Clinic, Chapel Hill, NC; ⁹Arcutis Biotherapeutics, Inc., Westlake Village, CA

- Psoriasis can affect any region of the body¹; however, commonly prescribed topical corticosteroids have limitations on duration of use and application in thin-skinned areas, as well as the potential for causing local and systemic side effects^{2,3}
- Efficacy and safety of roflumilast cream 0.3% and foam 0.3% (PDE4 inhibitor–based advanced targeted topical therapies that do not contain potentially skin-irritating excipients) were demonstrated in patients with plaque psoriasis in the phase 3 DERMIS-1/2 and ARRECTOR trials, respectively^{4–6}

DERMIS-1/2 (plaque psoriasis)

Eligibility

- Aged ≥2 years
- BSA 2%–20%
- IGA ≥2 (mild)
- PASI ≥2 (excluding scalp, palms, and soles)

Randomized 2:1

Roflumilast
cream 0.3% QD

Vehicle **cream** QD

8 weeks

Primary endpoint

- IGA success at week 8

Additional assessments

- PASI-75
- PASI total and component scores

Safety and application-site tolerability

ARRECTOR (psoriasis of the scalp and body)

Eligibility

- Aged ≥12 years
- BSA ≤25%
 - ≤20% non-scalp BSA
 - ≥10% of scalp involved
- S-IGA ≥3 (moderate)
- B-IGA ≥2 (mild)

Randomized 2:1

Roflumilast
foam 0.3% QD

Vehicle **foam** QD

8 weeks

Primary endpoints

- S-IGA success at week 8
- B-IGA success at week 8

Additional assessments

- PASI-75
- PASI total and component scores

Safety and application-site tolerability

Mean improvements in PASI total and component scores were assessed overall and for the head and neck, trunk, and upper and lower extremity body regions

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BSA, body surface area affected; B-IGA, body IGA; IGA, Investigator Global Assessment; PASI, Psoriasis Area and Severity Index; PDE4, phosphodiesterase 4; QD, once daily; S-IGA, Scalp IGA.

1. National Psoriasis Foundation. About psoriasis. Updated June 24, 2025. <https://www.psoriasis.org/about-psoriasis/>. 2. Elmets CA, et al. *J Am Acad Dermatol*. 2021;84:432–470. 3. Burshtein J, et al. *Dermatol Online J*. 2025;31. doi: 10.5070/D331164978. 4. Draelos ZD, et al. *J Drugs Dermatol*. 2024;23:834–840. 5. Lebwohl MG, et al. *JAMA*. 2022;328:1073–1084. 6. Gooderham MJ, et al. *JAMA Dermatol*. 2025;161:698–706.

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Patient Baseline Characteristics and Mean Improvement in PASI Total Scores by Body Region

- Baseline characteristics were generally comparable among 881 patients in the DERMIS-1/2 trials and 432 in the ARRECTOR trial
- Mean age was 45.0–48.6 years across treatment groups; ~82% of patients were White
- The DERMIS-1/2 trials had a higher proportion of male patients (63.7%) and ARRECTOR had more female patients (56.3%)

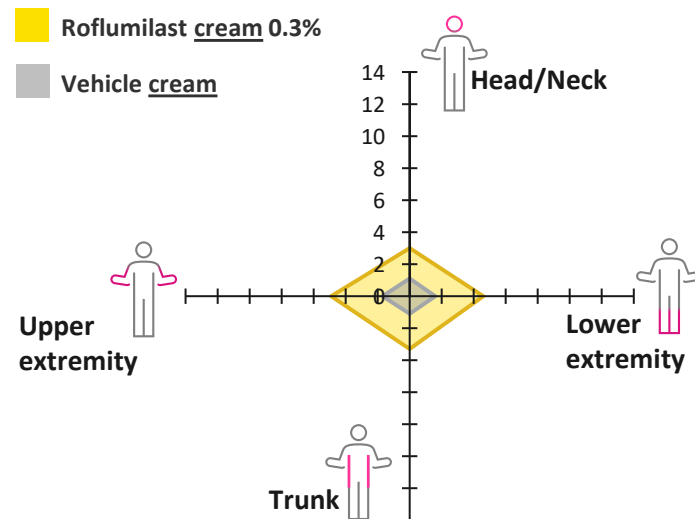
		DERMIS-1/2		ARRECTOR	
		Roflumilast <u>cream</u> 0.3% (n=576)	Vehicle <u>cream</u> (n=305)	Roflumilast <u>foam</u> 0.3% (n=281)	Vehicle <u>foam</u> (n=151)
Not Hispanic or Latino, n (%)		436 (75.7)	221 (72.5)	224 (79.7)	121 (80.1)
	Mild (2)	101 (17.5)	44 (14.4)	76 (27.0)	43 (28.5)
	Moderate (3)	426 (74.0)	240 (78.7)	191 (68.0)	99 (65.6)
IGA/B-IGA, n (%)	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]

Greater mean improvements in PASI total score by body region were observed with roflumilast cream or foam versus vehicle at week 8

DERMIS-1/2 (plaque psoriasis)

Mean improvement in total scores over time

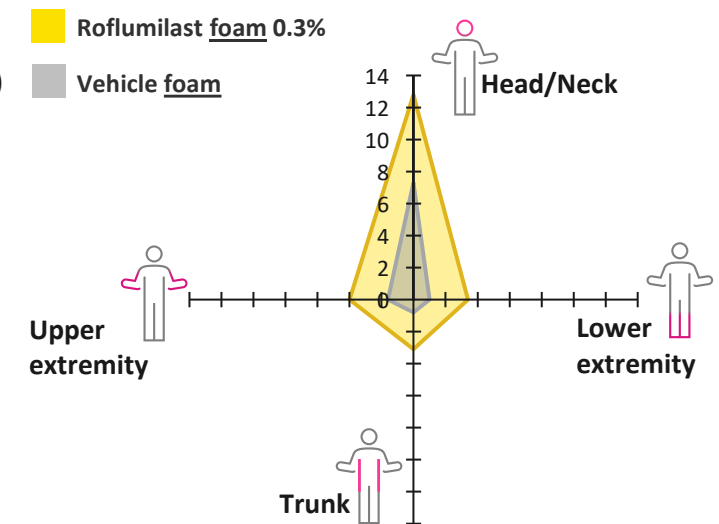
Week	ROF	VEH
2	2.1	0.7
4	3.2	1.1
8	4.1	1.4



ARRECTOR (psoriasis of the scalp and body)

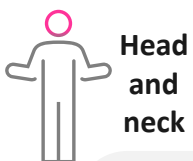
Mean improvement in total score over time

Week	ROF	VEH
2	2.4	0.9
4	3.6	1.5
8	4.4	1.7



Improvements in Mean PASI Scores at Week 8

Head and Neck



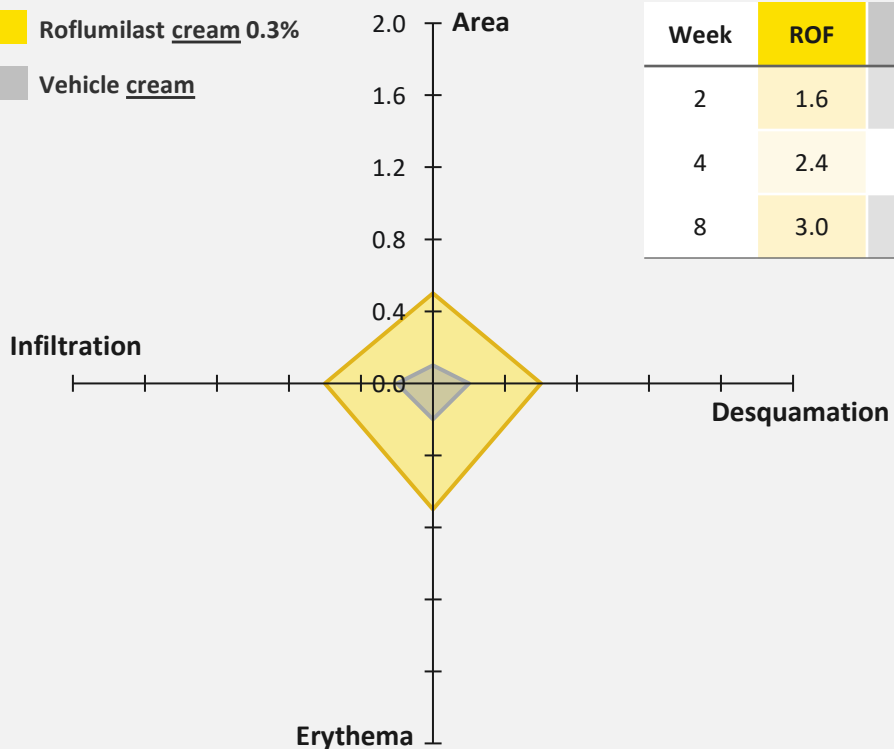
Signs and symptoms of psoriasis in the head and neck improved with roflumilast cream and foam versus vehicle starting at week 2 and continued to improve through week 8

DERMIS-1/2 (plaque psoriasis)

Mean improvement in component scores at week 8

Mean improvement in total head/neck scores over time

- Roflumilast cream 0.3%
- Vehicle cream



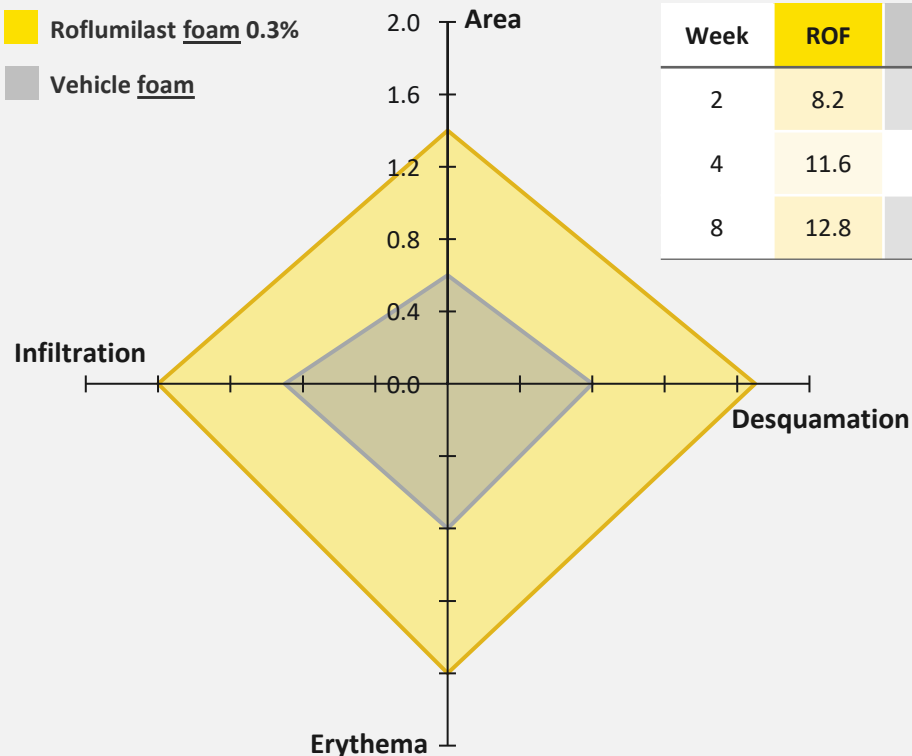
Week	ROF	VEH
2	1.6	0.4
4	2.4	0.9
8	3.0	1.1

ARRECTOR (psoriasis of the scalp and body)

Mean improvement in component scores at week 8

Mean improvement in total head/neck scores over time


- Roflumilast foam 0.3%
- Vehicle foam



Week	ROF	VEH
2	8.2	5.1
4	11.6	6.1
8	12.8	7.3

Improvements in Mean PASI Scores at Week 8

Trunk and Upper and Lower Extremities

 Roflumilast cream/foam 0.3%

 Vehicle cream/foam

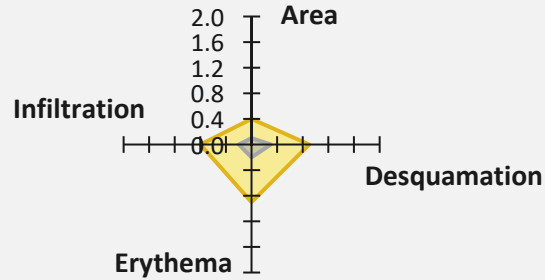
DERMIS-1/2 (plaque psoriasis)

Mean improvement in component scores at week 8

Mean improvement in total body region score over time



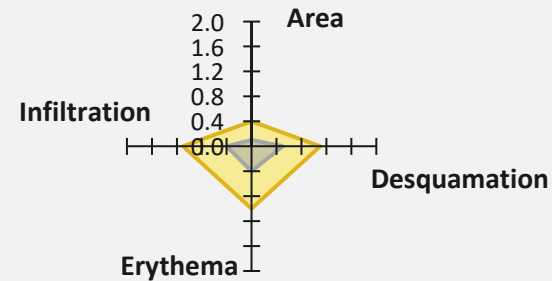
Trunk



Week	ROF cream	VEH cream
2	1.7	0.5
4	2.5	0.9
8	3.3	1.1



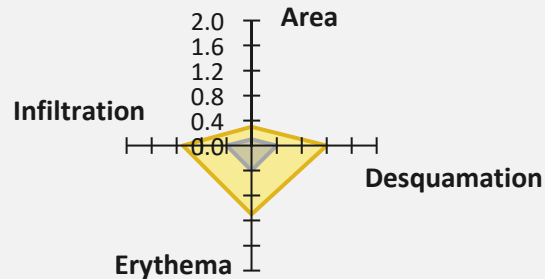
Upper extremities



Week	ROF cream	VEH cream
2	2.5	0.7
4	3.8	1.3
8	4.9	1.7



Lower extremities

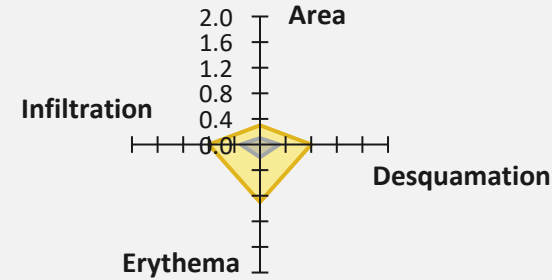


Week	ROF cream	VEH cream
2	2.3	0.9
4	3.5	1.3
8	4.6	1.6

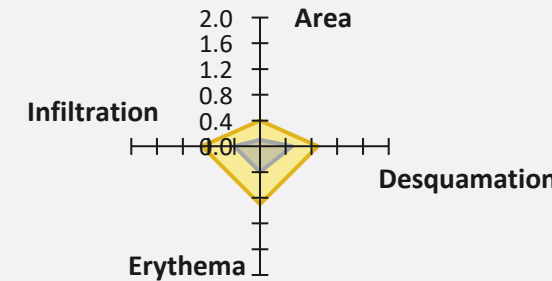
ARRECTOR (psoriasis of the scalp and body)

Mean improvement in component scores at week 8

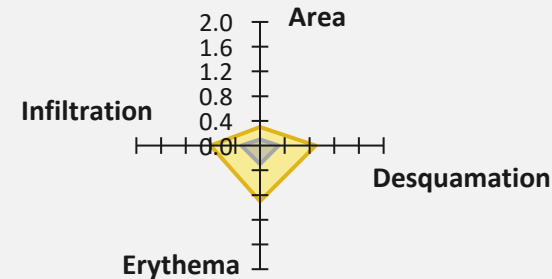
Mean improvement in total body region score over time



Week	ROF foam	VEH foam
2	1.5	0.5
4	2.5	0.7
8	3.1	0.8



Week	ROF foam	VEH foam
2	2.0	0.8
4	3.3	1.4
8	4.0	1.6



Week	ROF foam	VEH foam
2	1.7	0.4
4	2.6	0.9
8	3.4	1.0

Conclusions

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Once-daily roflumilast cream 0.3% and roflumilast foam 0.3% improved psoriasis symptom severity, reducing PASI total and component scores more than vehicle cream and foam

- Improvements in total and component scores were observed at the 2-week assessment and continued to improve through 8 weeks of treatment

Mean improvements in psoriasis were reported with roflumilast cream and foam across body regions: head and neck, trunk, and upper and lower extremities

- Improvements in the head and neck region had notable increases in mean total score with roflumilast, specifically for patients from the ARRECTOR study (roflumilast foam 0.3%: 12.8; vehicle foam: 7.3), who were to have $\geq 10\%$ scalp involvement at enrollment
- Improvements by region were observed for total and component (total area, desquamation, erythema, and infiltration) scores

These results show that both roflumilast cream 0.3% and foam 0.3% provide consistent benefit across body regions affected by psoriasis, offering a treatment alternative to commonly used topical corticosteroids

PASI, Psoriasis Area and Severity Index.

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