POS-10

Efficacy and Safety of Roflumilast Foam 0.3% for Seborrheic Dermatitis: STRATUM Age and Sex Subgroups

Adelaide A. Hebert,[1] Shehla Admani,[2] Jeannette Jakus,[3] Melinda J. Gooderham,[4] David Krupa,[5] Jennifer C. Jaworski,[5] Diane Hanna[5]

[1]UTHealth McGovern Medical School, Houston, TX; [2]Stanford University School of Medicine, Stanford, CA; [3]SUNY Downstate Health Sciences University, Brooklyn, NY; [4]SKiN Centre for Dermatology, Probity Medical Research and Queen's University, Peterborough, ON; [5]Arcutis Biotherapeutics, Inc., Westlake Village, CA

ABBREVIATIONS

AE, adverse event; BSA, body surface area affected; HCP, health care provider; IGA, Investigator Global Assessment; ITT, intent to treat; PDE4, phosphodiesterase 4; QD, once daily; SAE, serious AE; SD, seborrheic dermatitis; TCS, topical corticosteroids; TEAE, treatment-emergent AE; WI-NRS, Worst Itch-Numeric Rating Scale; y, year.

REFERENCES

1. Chovatiya R, et al. *Adv Ther*. 2024;41:4433–4445. 2. Jackson JM, et al. *J Am Acad Dermatol*. 2024;90:597–604. 3. Ungar B, et al. *J Am Acad Dermatol*. 2025;92(6):1277–1287. 4. Desai S, et al. *J Drugs Dermatol*. 2022;21:1373–1374. 5. Chovatiya R, et al. *J Dermatolog Treat*. 2025;36(1):2476576. 6. Burshtein J, et al. *Dermatol Online J*. 2025;31(1). doi: 10.5070/D331164978. 7. Chang CH and Chovatiya R. *Arch Dermatol Res*. 2024;316(4):100. 8. Draelos ZD, et al. *J Drugs Dermatol*. 2024;23:834–840. 9. Blauvelt A, et al. *J Am Acad Dermatol*. 2024;90:986–993. 10. ZORYVE® (roflumilast) foam. Prescribing information. Arcutis Biotherapeutics, Inc.; May 2025.

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DISCLOSURES

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INTRODUCTION

- SD is a chronic inflammatory skin disease that negatively impacts patient quality of life, with pruritus being the most bothersome symptom[1]
  - Outside of infancy, SD may occur in adolescents or adults, regardless of gender[2]
- Recent assessment of the molecular profile of SD in adult patients has demonstrated that SD has a unique immunological and molecular profile, with distinct barrier disruption, confirming that *Malassezia* spp. function as a commensal organism[3]
- Historically, prescription treatment options for SD include topical antifungals and TCS, often used in combination; some HCPs may prescribe topical calcineurin inhibitors (off label)[2,4]
  - Less than 25% of patients with SD are satisfied with their treatment, with lack of efficacy and complicated application regimens being key issues[5]
  - TCS are not approved for long-term use, and lower-potency formulations are required in thin-skinned/sensitive areas because of an increased risk of cutaneous and systemic AEs[6]
  - A recent synthesis of data clarifies the role of *Malassezia* in the pathogenesis of SD, and discusses the demonstrated efficacy of topical anti-inflammatory agents (eg, PDE4 inhibitors) used as monotherapies for SD[7]
- Roflumilast foam 0.3% is a topical PDE4 inhibitor that does not contain ethanol, isopropyl alcohol, propylene glycol, polyethylene glycol, formaldehyde-releasing agents, or fragrances that can irritate the skin, damage hair, or lead to contact sensitization[8]
  - In the phase 3 STRATUM trial (NCT04973228), efficacy, safety, and tolerability of roflumilast foam 0.3% versus vehicle foam were demonstrated in patients aged ≥9 years with at least moderate SD, leading to its approval in this indication[9,10]
- Outcomes from subpopulation analysis of the STRATUM trial, based on age and sex, are described here

METHODS

Study Design

- STRATUM was a phase 3, randomized, parallel-group, vehicle-controlled, double-blind trial conducted in patients aged ≥9 years with at least moderate SD affecting scalp and/or non-scalp areas
  - Eligible patients had a clinical diagnosis of SD for ≥3 months, at least moderate IGA (≥3), and BSA ≤20%
- Patients were randomized 2:1 to apply roflumilast foam 0.3% or vehicle foam once daily for 8 weeks
- This analysis includes patient subgroups based on sex and age group (9–17 years, 18–64 years, and ≥65 years)

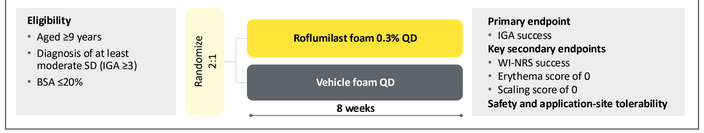
Outcomes in This Analysis (at Week 8)

- IGA success, defined as clear (0) or almost clear (1) plus ≥2-grade improvement from baseline
- IGA 0
- WI-NRS success, defined as ≥4-point improvement among patients with baseline score ≥4
- Erythema and scaling scores of 0 (none)
- Safety and application-site tolerability

RESULTS

- The 304 and 153 patients randomized to receive roflumilast foam 0.3% and vehicle foam, respectively, were equally distributed by sex and 32 (7.0%) were aged 9–17 years
  - The majority of patients were White (77.9%) and not Hispanic or Latino (78.8%)
- Overall, greater proportions of patients in the roflumilast group versus vehicle group achieved week-8 IGA success (79.5% vs 58.0%; *P*<0.0001), IGA 0 (50.6% vs 27.7%; *P*<0.0001), and WI-NRS 0/1 (60.1% vs 41.4%; *P*=0.0052)
  - Outcomes within the sex and age subgroups were similar to those observed in the overall population
- Higher proportions of patients who received roflumilast versus vehicle achieved erythema (57.8% vs 32.0%) and scaling (58.1% vs 36.5%) scores of 0 in the overall population (both *P*<0.0001), within the sex subgroups (each *P*<0.03; data not shown), and in the following age subgroups, respectively
  - 9–17 years: 52.9% vs 33.3%; 41.2% vs 26.7%
  - 18–64 years: 57.0% vs 32.7% (*P*<0.0001); 58.2% vs 38.6% (*P*=0.001)
  - ≥65 years: 64.8% vs 26.3%; 64.5% vs 31.6%
- Roflumilast foam 0.3% was well tolerated; treatment-related AEs were reported for 2.6% of patients and application-site pain was reported for 1 patient (0.3%)
  - No evidence of application-site irritation was reported by investigators for ≥98.9% of patients in the roflumilast group across time points
  - A hot, tingling/stinging sensation that caused definite discomfort was reported by ≤1.3% of patients treated with roflumilast across time points, including after the first application

Study Design

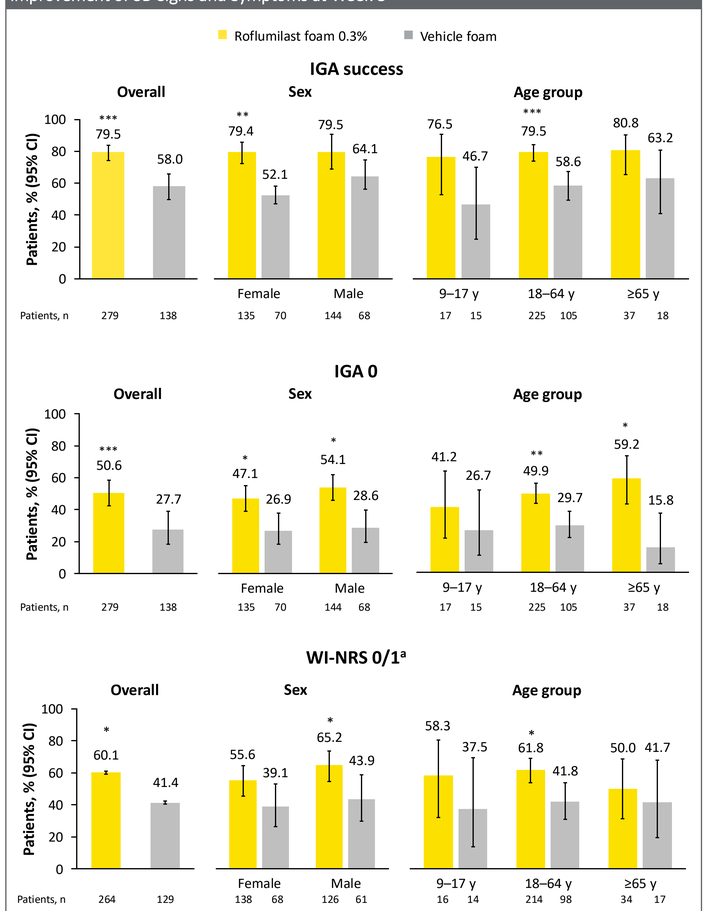


Demographics and Baseline Disease Characteristics

		Roflumilast foam 0.3% (n=304)	Vehicle foam (n=153)
Age, years	Mean (SD) [range]	43.2 (16.8) [9–87]	41.8 (17.5) [9–83]
	9–17, n (%)	17 (5.6)	15 (9.8)
	18–64, n (%)	249 (81.9)	119 (77.8)
	≥65, n (%)	38 (12.5)	19 (12.4)
Female at birth, n (%)		151 (49.7)	78 (51.0)
IGA, n (%)	Moderate (3)	287 (94.4)	141 (92.2)
	Severe (4)	17 (5.6)	12 (7.8)
Weekly WI-NRS, mean (SD) [range]		5.1 (2.34) [0.0–10.0]	4.7 (2.29) [0.0–9.4]
BSA, %, mean (SD) [range]		2.9 (2.03) [0.3–15.0]	3.0 (2.57) [0.2–20.0]

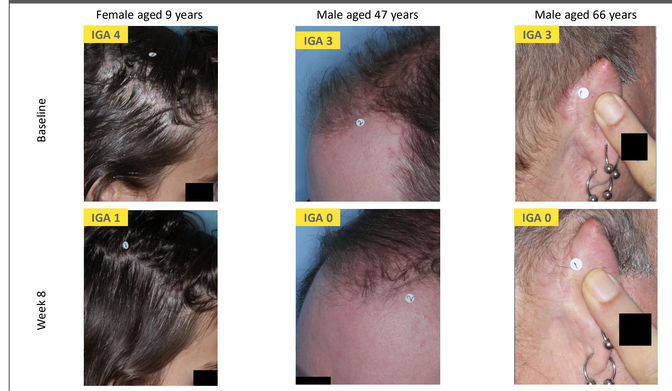
ITT population.

Improvement of SD Signs and Symptoms at Week 8



ITT population; multiple imputation data for IGA; observed data for WI-NRS. *P≤0.05; **P≤0.001; ***P≤0.0001. [a]In patients with WI-NRS ≥2 at baseline.

Improvement With Roflumilast Foam 0.3%



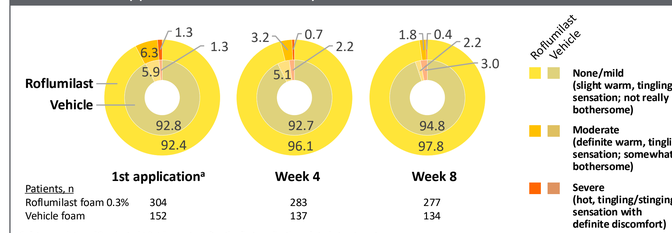
IGA is a global measure. White dots are stickers used for reference by HCP in photos.

Summary of Adverse Events

Patients, n (%)		Roflumilast foam 0.3% (n=304)	Vehicle foam (n=153)
Patients with any TEAE		70 (23.0)	33 (21.6)
Patients with any treatment-related AE		8 (2.6)	5 (3.3)
Patients with any treatment-emergent SAE		1 (0.3)	0
Patients with any TEAE leading to study/study treatment discontinuation		2 (0.7)	3 (2.0)
Death		0	0
Most frequently[a] reported TEAEs	COVID-19	11 (3.6)	5 (3.3)
	Nausea	5 (1.6)	0
	Urinary tract infection	4 (1.3)	3 (2.0)
	Nasopharyngitis	4 (1.3)	1 (0.7)

Safety population. [a]Events reported for >1% of the overall population.

Patient-rated Application-site Tolerability



Safety population. [a]Conducted 10–15 minutes after the first application of study treatment.

CONCLUSIONS

SD symptoms improved across various efficacy outcomes with once-daily application of roflumilast foam 0.3%, regardless of sex or age subgroup.

- Over 8 weeks, outcomes in sex and age subgroups were similar to those observed for the overall population
- Higher proportions of patients achieved erythema/scaling scores of 0 with roflumilast compared with vehicle

Roflumilast foam 0.3% was well tolerated.

- Application-site pain was reported for 1 patient in the roflumilast group
- Patients reported low rates of a hot, tingling/stinging sensation that caused definite discomfort across time points, including after the first application (≤1.3% in the roflumilast group)

These outcomes, and the favorable safety and application-site tolerability profile of roflumilast foam 0.3%, support its use as a monotherapy treatment for patients aged ≥9 years with SD.