Clinical efficacy and patient-reported impacts of roflumilast foam 0.3% in seborrheic dermatitis: An analysis of STRATUM data for patients unresponsive or intolerant to topical corticosteroids

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SYNOPSIS

- Seborrheic dermatitis (SD) is a chronic, inflammatory, dermatologic condition that causes flaking scales and persistent itching.[1] Treatment options include topical corticosteroids (TCS), which present challenges such as limited efficacy and adverse effects[1]
- In the Phase 3 STRATUM trial, roflumilast foam 0.3% demonstrated efficacy and tolerability in the treatment of moderate-to-severe SD (**Table 1**)[2]
- This subgroup analysis supports that roflumilast foam 0.3% provides meaningful efficacy and quality-of-life (QOL) improvements in patients with SD who report an inadequate response, intolerance, or contraindication to TCS prior to enrollment in STRATUM

OBJECTIVE

- The aim of this subgroup analysis was to assess the efficacy and patient-reported QOL effects of roflumilast foam 0.3% versus vehicle in patients with moderate-to-severe SD who reported an inadequate response, intolerance, or contraindication to TCS prior to enrollment in STRATUM

METHODS

- Patients aged ≥ 9 years with at least moderate SD (Investigator Global Assessment [IGA] ≥ 3) who reported a previous inadequate response, intolerance, or contraindication to TCS were randomized 2:1 to roflumilast foam 0.3% or vehicle for 8 weeks
- Efficacy was assessed using a 5-point physician-evaluated IGA – a common clinical endpoint used in dermatology trials. The primary efficacy endpoint was IGA success (Clear or Almost Clear with at least a 2-grade improvement) at Week 8
- QOL was evaluated in patients aged ≥ 17 years using the Dermatology Life Quality Index (DLQI) – a validated patient-reported questionnaire (score range of 0–30), with higher scores indicating greater QOL effects. Endpoints included percentage change from baseline in DLQI score, achievement of a minimal important difference (MID; defined as at least a 4-point reduction in baseline DLQI score), and achievement of a DLQI score of 0 or 1 (indicating no disease effect at all) by treatment group at Weeks 2, 4, and 8
- Differences in change from baseline DLQI scores were assessed using the Kruskal-Wallis test. The Cochran–Mantel–Haenszel test was used to assess differences in the proportion of patients achieving binary endpoints between treatment groups

RESULTS

- 189 patients at baseline were included in the subgroup analysis (129 roflumilast foam 0.3%; 60 vehicle). At Week 8, 78.8% of roflumilast foam 0.3% patients achieved IGA success versus 48.3% of vehicle patients (odds ratio [OR]: 3.45; 95% confidence interval [CI]: 1.62, 7.36; p < 0.001) (**Figure 1**)
- At all time points, percentage change from baseline in DLQI score was significantly greater for roflumilast foam 0.3%-treated patients relative to vehicle (**Figure 2**)
- Treatment with roflumilast foam 0.3% significantly increased the odds of achieving an MID in DLQI score from baseline to Weeks 2, 4, and 8 compared with vehicle (OR: 6.97; 95% CI: 3.97, 12.24; p < 0.001) (**Figure 3**)
- Relative to vehicle, the odds of achieving a DLQI score of 0 or 1 from baseline to Weeks 2, 4, and 8 was significantly higher for patients treated with roflumilast foam 0.3% (OR: 2.46; 95% CI: 1.58, 3.81; p < 0.001) (**Figure 4**)

Table 1. STRATUM study design[2]

Phase 3, parallel group, double-blind, vehicle-controlled study (N = 457)

Eligibility criteria
- Adults and adolescents (≥ 9 years of age) who had a clinical diagnosis of seborrheic dermatitis for at least 3 months
- Stable disease for at least 4 weeks before the baseline assessment
- IGA score of at least 3 on a 5-point scale
- Involvement of up to 20% BSA

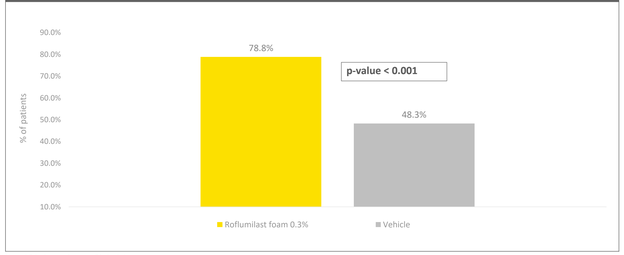
Randomize 2:1 → Roflumilast foam 0.3% / Vehicle foam QD

8 weeks dosing
Visits: Weeks 2, 4, 8

Baseline patient characteristics		
Age, mean (SD): 42.7 (17.03)	Male, n (%): 228 (49.9)	BSA (%), mean (SD): 2.92 (2.24)
IGA 3, n (%): 428 (93.7)	IGA 4, n (%): 29 (6.3)	WI-NRS, mean (SD): 4.95 (2.32)[a]

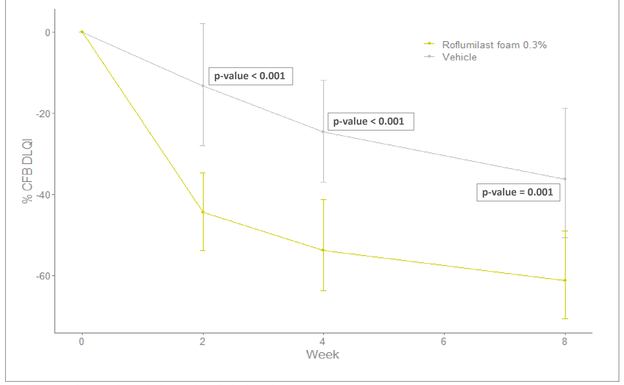
Key: BSA, body surface area; IGA, Investigator Global Assessment; QD, once daily; SD, standard deviation; WI-NRS, Worst Itch Numeric Rating Scale.

Figure 1. Patients achieving IGA success by treatment group at Week 8



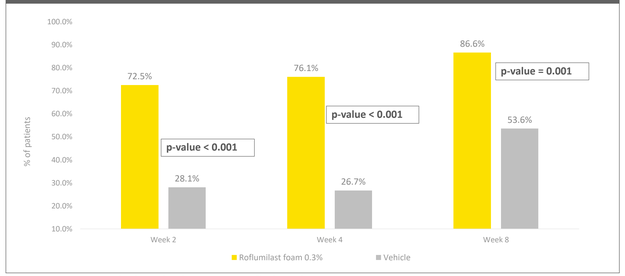
Key: IGA, Investigator Global Assessment.

Figure 2. Percentage change in baseline DLQI score by treatment group



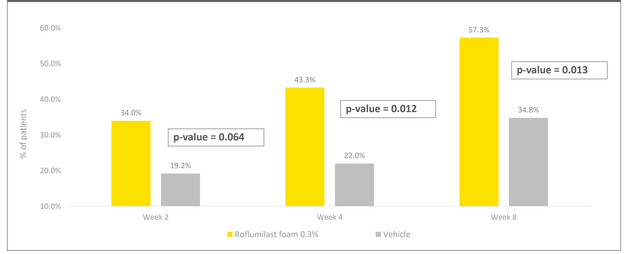
Key: CFB, change from baseline; DLQI, Dermatology Life Quality Index.

Figure 3. Patients achieving an MID in DLQI score by treatment group



Note: Patients were required to have a baseline DLQI score >4 for this analysis.
Key: DLQI, Dermatology Life Quality Index; MID, minimally important difference.

Figure 4. Patients achieving a DLQI score of 0 or 1 by treatment group



Key: DLQI, Dermatology Life Quality Index.

LIMITATIONS

- The limited follow-up period of 8 weeks in STRATUM may not allow for the assessment of long-term QOL impacts associated with roflumilast foam 0.3%
- Although the DLQI is a commonly used endpoint in dermatology clinical trials, it is not specific to SD and may not reflect the full impact of SD
- Patients with IGA scores below 3 were not included in the analysis; therefore, conclusions may not be applicable to those with SD classified as Mild (2)
- QOL was not assessed in participants from STRATUM aged 9 to < 17 years. QOL results may need to be confirmed in younger patients

CONCLUSIONS

- Patients with SD and an inadequate response, intolerance, or contraindication to TCS had approximately 3.5 times greater odds of achieving IGA success with roflumilast foam 0.3% treatment compared with vehicle
- Roflumilast foam 0.3% was associated with a rapid and significant improvement in DLQI scores relative to vehicle in this patient population. Furthermore, roflumilast foam 0.3%-treated patients had six times greater odds of achieving a clinically meaningful difference in DLQI score and twice likely to achieve a score of 0 or 1
- Roflumilast foam 0.3% may offer important benefits for patients with SD when treatment with TCS is unsuccessful or contraindicated. This should be considered by providers and healthcare decision-makers when assessing treatment options for these patients

DISCLOSURES

This study was funded by Arcutis Biotherapeutics, Inc. DC and BS are employees of Arcutis Biotherapeutics, Inc. JL, BB, CH, RB, and TW are employees of Lumanity, Inc., a consulting company that provides paid consulting services to Arcutis Biotherapeutics, Inc. MZ is an employee of DOCS Dermatology.

REFERENCES

1. Dall'Oglio F, et al. *Clin Cosmet Investig Dermatol*. 2022 Aug 6;15:1537-1548. 2. Arcutis Biotherapeutics, Inc.. Data on file, 2023.