Effect of roflumilast foam 0.3% on quality of life in patients with seborrheic dermatitis: patient-reported outcomes from the STRATUM Phase III trial

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INTRODUCTION

- STRATUM is a Phase III clinical trial that evaluated the safety and efficacy of roflumilast foam 0.3% in patients with moderate-to-severe seborrheic dermatitis (SD) (**Table 1**)[1]
- Patient-reported outcomes evaluated in the trial included the Dermatology Life Quality Index (DLQI), a validated measure used to assess quality of life (QOL) in patients with skin disease. The DLQI comprises 10 items relating to patients' perceptions of QOL impact and has a score range of 0–30, with higher scores indicating greater QOL effects (**Table 2**)[2]
- Reductions in DLQI score are associated with a higher QOL, with a score of 0 or 1 indicating no effect at all.[1] Furthermore, literature supports a difference of 4 to denote clinically meaningful improvements in DLQI score for inflammatory skin diseases[3]
- This analysis aimed to evaluate the effects of roflumilast foam 0.3% on patient-reported QOL in patients with SD from the STRATUM trial

METHODS

- This analysis evaluated DLQI data collected from STRATUM patients aged ≥ 17 years with moderate-to-severe SD. Patients received roflumilast foam 0.3% or vehicle foam once daily for 8 weeks
- PRO endpoints included percentage change from baseline in DLQI score, achievement of a minimal clinically important difference (MID; defined as at least a 4-point reduction in baseline DLQI score for patients with a baseline score of > 4), and achievement of a DLQI score of 0 or 1 in patients with a baseline score > 1, for roflumilast versus vehicle at Weeks 2, 4, and 8
- The Cochran–Mantel–Haenszel test was used to assess differences in the proportion of patients achieving binary endpoints between treatment arms. Differences in change from baseline DLQI scores were assessed using analysis of covariance (ANCOVA)

Table 1. STRATUM study design[1]

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

Eligibility criteria
- Adults and adolescents (≥ 9 years of age) who had a clinical diagnosis of SD 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

The DLQI was assessed in participants patients aged ≥ 17 years (n = 430)

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

[a] Weekly average.
Key: BSA, body surface area; IGA, Investigator Global Assessment; SD, seborrheic dermatitis; WI-NRS, Worst Itch Numeric Rating Scale.

Table 2. Dermatology Life Quality Index (DLQI)[2]

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick one box for each question.

☐ Very much ☐ A lot ☐ A little ☐ Not at all

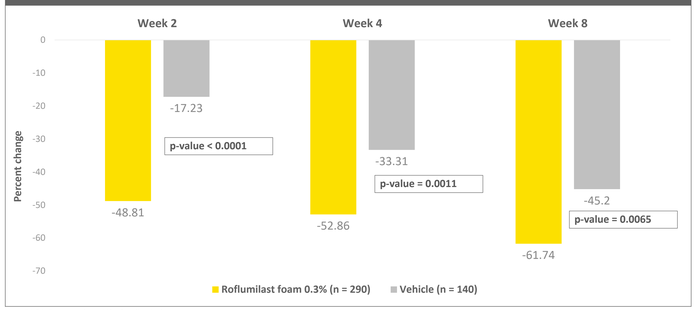
Q1. How itchy, sore, painful, or stinging has your skin been?
Q2. How embarrassed or self-conscious have you been because of your skin?
Q3. How much has your skin interfered with you going shopping or looking after your home or garden?
Q4. How much has your skin influenced the clothes you wear?
Q5. How much has your skin affected any social or leisure activities?
Q6. How much has your skin made it difficult for you to do any sports?
Q7. How much has your skin been a problem at work or studying?
Q8. How much has your skin created problems with your partner or any of your close friends or relatives?
Q9. How much has your skin caused any sexual difficulties?
Q10. How much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?

The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more QOL is impaired.

- 0–1 = **no effect**
- 2–5 = **small effect**
- 6–10 = **moderate effect**
- 11–20 = **very large effect**
- 21–30 = **extremely large effect**

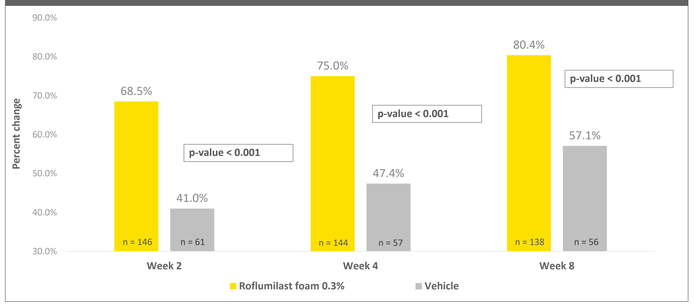
Note: "Not relevant" may be selected for the following questions: Q3, Q4, Q5, Q6, Q7, Q8, Q9, Q10.
Key: ADL – activities of daily living; DLQI – Dermatology Life Quality Index; QOL – quality of life.

Figure 1. Percentage change in baseline DLQI score by treatment group



Key: DLQI, Dermatology Life Quality Index.

Figure 2. Patients achieving an MID in DLQI score by treatment group

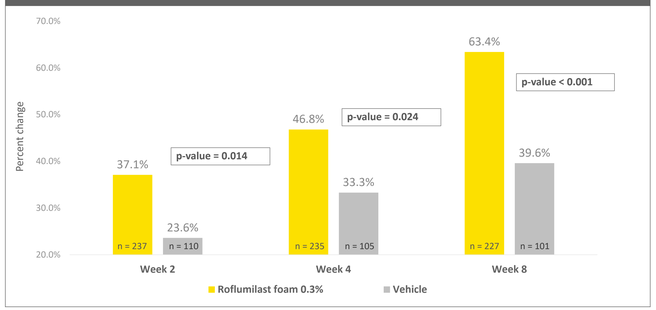


Key: DLQI, Dermatology Life Quality Index; MID, minimally important difference.

RESULTS

- A total of 430 patients were included in the analysis (140 for vehicle; 290 for roflumilast)
- At each time point, percentage change from baseline DLQI score (standard deviation) was significantly larger for roflumilast-treated patients relative to vehicle (Week 2: -48.81 [8.24] vs -17.23 [8.94]; p < 0.0001; Week 4: -52.86 [6.64] vs -33.81 [7.24]; p = 0.0011; Week 8: -61.74 [7.23] vs -45.20 [7.82]; p = 0.0065) (**Figure 1**)
- Compared with vehicle, treatment with roflumilast significantly increased the odds of achieving an MID in DLQI score from baseline at Weeks 2, 4, or 8 (odds ratio [OR]: 3.18; 95% confidence interval [CI]: 2.19, 4.62; p < 0.0001) (**Figure 2**)
- Roflumilast significantly increased the odds of achieving a DLQI score of 0 or 1 compared with vehicle at Weeks 2, 4, or 8 (OR: 2.07; 95% CI: 1.56, 2.75; p < 0.0001) (**Figure 3**)

Figure 3. Patients achieving a DLQI score of 0 or 1 by treatment group



Key: DLQI, Dermatology Life Quality Index; MID, minimally important difference; QOL, quality of life.

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%
- The DLQI is not specific to SD and may not reflect the full impact of SD on patient QOL
- This analysis excluded participants from STRATUM aged 9 to < 17 years. Therefore, results would need to be confirmed in younger patients

CONCLUSIONS

- As early as Week 2, treatment with roflumilast foam 0.3% demonstrated a significantly larger improvement in DLQI scores compared with vehicle, with improvements maintained through Week 8
- Relative to vehicle, the roflumilast foam 0.3% group had a significantly higher likelihood of achieving meaningful improvements in QOL and reaching DLQI scores indicative of no disease impact on QOL
- The rapid and sustained impact of roflumilast foam 0.3% on PROs should be considered by providers and healthcare decision-makers when assessing treatment options for SD

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.

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