Impact of roflumilast foam 0.3% on patient-reported quality of life in seborrheic dermatitis: An analysis of STRATUM data for patients unresponsive or intolerant to corticosteroids

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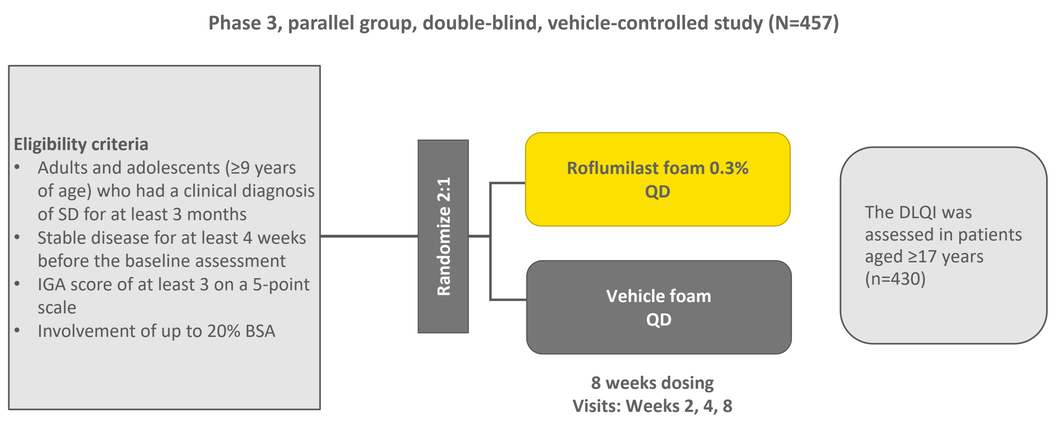
INTRODUCTION

- Seborrheic dermatitis (SD) is a chronic, inflammatory dermatologic condition that causes flaking scales and persistent itch.[1] Treatment options include topical corticosteroids (TCS), which are often prescribed because they are efficacious but whose use is limited in duration and location due to risk of adverse events[1]
- In the Phase 3 STRATUM trial, roflumilast foam 0.3% demonstrated efficacy for the treatment of moderate-to-severe SD (**Figure 1**)[2]
- 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 (**Figure 2**). Reductions in DLQI score are associated with a higher QOL, with a score of 0 or 1 indicating no effect at all.[3] Furthermore, literature supports a minimal important difference of 4 to denote clinically meaningful improvements in DLQI score for inflammatory skin diseases[4]
- The aim of this analysis was to assess the QOL impact of roflumilast foam 0.3% versus vehicle in patients with moderate-to-severe SD who reported an inadequate response, intolerance, or contraindication to TCS

METHODS

- Baseline and follow-up DLQI data from the STRATUM trial was collected for patients aged ≥17 years with moderate-to-severe SD who had an inadequate response, intolerance, or contraindication to TCS (N=181). Patients received roflumilast foam 0.3% or vehicle foam once daily for 8 weeks
- The analysis assessed the following endpoints: percentage change from baseline in DLQI score, achievement of a minimal important difference (MID; defined as a ≥4-point reduction in DLQI score from baseline in patients with a DLQI score >4 at baseline), and achievement of a DLQI score of 0 or 1, for roflumilast foam 0.3% versus vehicle 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 arms

Figure 1. STRATUM study design[2]



Baseline patient characteristics[a]		
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]

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

Figure 2. Dermatology Life Quality Index (DLQI)[3]

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.

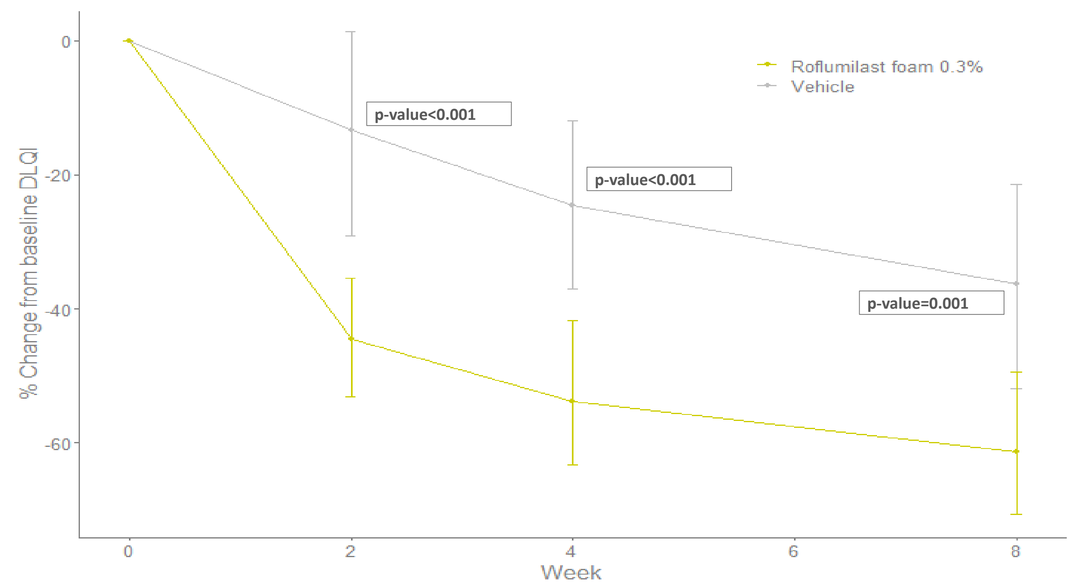
- 0–1 = **no effect**
- 2–5 = **small effect**
- 6–10 = **moderate effect**
- 11–20 = **very large effect**
- 21–30 = **extremely large effect**

Note: "Not relevant" may be selected for the following questions: Q3-Q10.
Key: ADL – activities of daily living; DLQI – Dermatology Life Quality Index; QOL – quality of life.

RESULTS

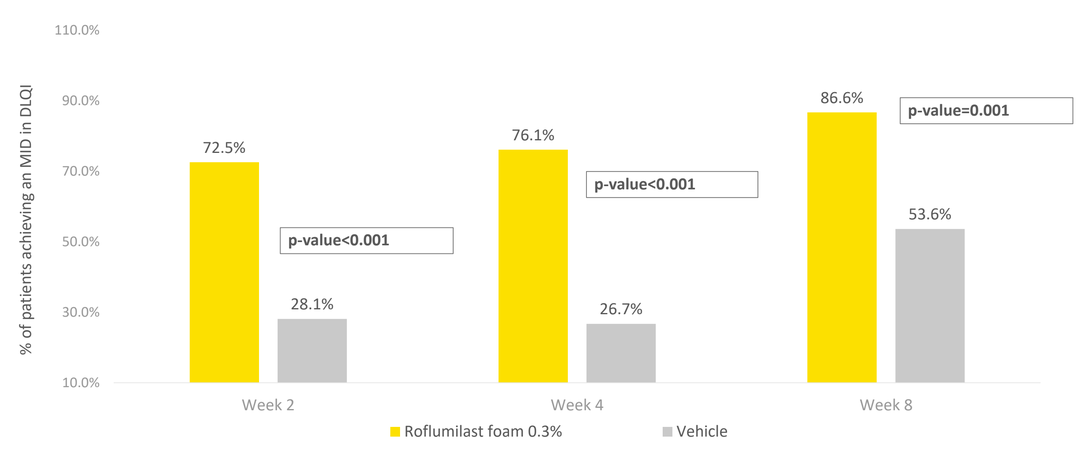
- 181 patients at baseline were included in the subgroup analysis (125 roflumilast foam 0.3%; 56 vehicle). At all time points, percent change from baseline in DLQI score was significantly greater for roflumilast foam 0.3%-treated patients relative to vehicle (**Figure 3**)
- Treatment with roflumilast 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 4**)
- 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 5**)

Figure 3. Percentage change from baseline in DLQI score by treatment group



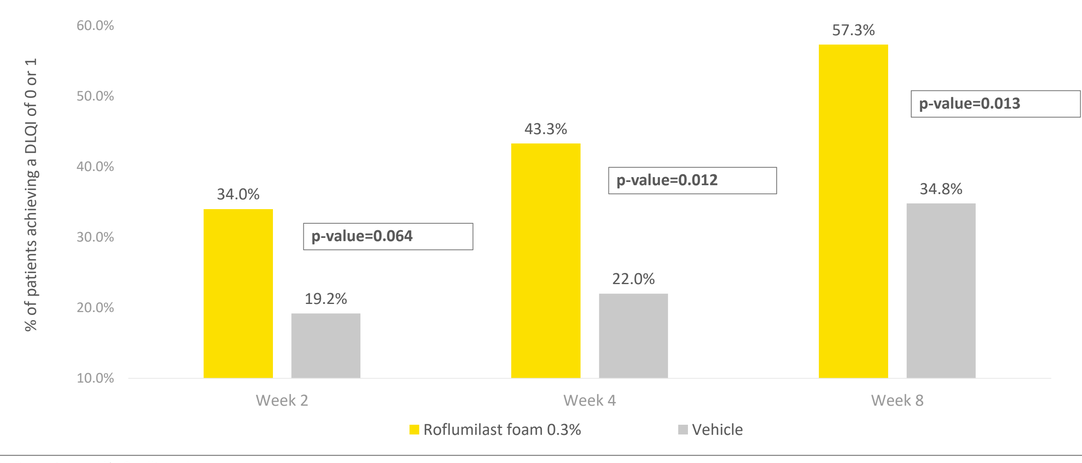
Key: DLQI, Dermatology Life Quality Index.

Figure 4. Patients achieving an MID in DLQI score by treatment group



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

Figure 5. 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%
- 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. Results may need to be confirmed in younger patients

CONCLUSIONS

- Treatment with roflumilast foam 0.3% demonstrated a rapid and significant improvement in DLQI scores relative to vehicle in patients with SD who reported an inadequate response, intolerance, or contraindication to TCS. Furthermore, roflumilast-treated patients were six times more likely to achieve a clinically meaningful difference in DLQI score and twice as likely to achieve a score of 0 or 1
- The impact of roflumilast foam 0.3% on QOL may offer important benefits for SD patients when treatment with TCS is unsuccessful or not viable. 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.

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