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, which present challenges such as limited efficacy and adverse effects.1
- 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 MID (2).
- QOL was not assessed in participants from STRATUM aged 9 to < 17 years. QOL results may need to be confirmed in younger patients.

METHODS
- Patients aged ≥ 9 years with at least moderate SD (Investigator Global Assessment [IGA] ≥ 3) who reported an inadequate response, intolerance, or contraindication to TCS were randomized 2:1 to roflumilast foam 0.3% versus 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), which presents challenges such as limited efficacy and adverse impacts.2

RESULTS
- 129 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]: 2.46; 95% confidence interval [CI]: 1.58, 3.81; p < 0.001) (Figure 1).
- Treatment with roflumilast foam 0.3% significantly increased the odds of achieving an MID in DLQI score from baseline to Week 2, 4, and 8 compared with vehicle (OR: 6.97; 95% CI: 3.97, 12.24; p < 0.001) (Figure 2).
- 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).

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% 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.

DESERVICES
- The authors report owning shares in Arcutis Biopharma, Inc. SD and MM are employees of Arcutis Biopharma, Inc. SD, MM, CB, and TW are employees of Lumanity, Inc., a consulting company that provides paid consulting services to Arcutis Biopharma, Inc. SD and MM are employees of the DOCS Medical Research.

REFERENCES