**INTRODUCTION**

Seborrheic dermatitis (SD) is a common, chronic inflammatory skin disease that affects patients of all ages, with a global prevalence of approximately 5%.

Treatment is via topical therapies, including antifungal agents and corticosteroids, which have limitations (side effects and/or inability to use on both hair/no-hair-bearing areas).

Roflumilast is a selective phosphodiesterase 4 (PDE4) inhibitor with greater affinity for PDE4D than apremilast and crisaborole (25- to >30-fold more potent in vitro assays).

Topical roflumilast is being investigated as a once-daily, nonsteroidal treatment for long-term management of psoriasis (FDA-allowed July 2022), atopic dermatitis, and SD.

Efficacy, safety, and tolerability of roflumilast foam have been demonstrated in a phase 2a trial in SD and a subsequent open-label safety trial (NCT04091646/NCT04445987).

Here, we report the results of a phase 3 trial (NCT04973228) of roflumilast foam 0.3% in patients with SD.

**METHODS**

This phase 3 randomized, parallel-group, double-blind, vehicle-controlled trial was conducted in patients 18 years old with at least moderate SD affecting scalp and/or non-scalp areas (Figure 1).

The primary efficacy endpoint was Investigator Global Assessment (IGA) Success (IGA of Clear or Almost Clear plus ≥2-grade improvement from baseline) at Week 8.

**RESULTS**

Baseline patient demographics and disease characteristics were similar between the groups (Table 1).

Overall, significantly more roflumilast-treated patients than vehicle-treated patients achieved the primary efficacy end-point of IGA Success (Figure 2) and IGA status of Clear (Figure 3) at Week 8:

- Percentages of patients achieving IGA Success and IGA Clear at Weeks 2, 4, and 4 were greater with roflumilast.

Significantly greater percentages of roflumilast than vehicle-treated patients achieved secondary end-points of:

- WI-NRS Success at Weeks 2, 4, and 8 (Figure 4)
- Overall Assessment of Erythema score of 0 (Figure 5) at Week 8
- Overall Assessment of Scaling score of 0 (Figure 5) at Week 8

Local tolerability was favorable in investigator- and patient-rated assessments (Figure 6).

Overall incidence of treatment-emergent adverse events (TEAEs), serious adverse events, and TEAEs leading to discontinuation were low, with similar rates between roflumilast and vehicle (Table 2).

**DISCUSSIONS**

Once-daily, nonsteroidal roflumilast foam 0.3% provided improved efficacy across multiple efficacy endpoints versus vehicle in patients with SD in a phase 3 trial.

- 80% of patients achieved IGA Success and >50% achieved complete clearance by Week 8.
- >60% of patients achieved an itch response at Week 8, with significant improvements at the 2- and 4-week assessments.

Local tolerability was generally favorable as reported by patient and investigator assessments of irritation, burning, and stinging, consistent with safety profiles in prior trials.

**REFERENCES**


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**DISCLOSURES**


Roflumilast foam is a novel, once-daily, nonsteroidal treatment for SD that is currently under development for patients with moderate-to-severe SD. This study was supported by Arcutis Biotherapeutics, Inc. All authors disclosed no relevant conflicts of interest.