**INTRODUCTION**

- Seborrheic dermatitis (SD) is a chronic inflammatory skin condition that negatively impacts quality of life, particularly in patients with more severe disease.
- It is a major complaint among patients with SD.
- Topical treatments include antifungals, steroids, immunomodulators, and dandruff shampoos, but efficacious and safe options are needed, especially those that improve itch.
- Roflumilast is a selective, potent, phosphodiesterase 4 inhibitor being investigated as a once-daily treatment for SD.

**METHODS**

- This phase 3, randomized, parallel-group, double-blind, vehicle-controlled trial (NCT04973228) was conducted in patients ≥9 years old with at least moderate SD affecting scalp and/or non-scalp areas.
- Eligible patients had clinical diagnosis of SD of ≥3-month duration, Investigator Global Assessment (IGA) score ≥3 (at least moderate severity), and affecting ≥20% of the body surface area (BSA, Figure 1).
- Patients were randomized 2:1 to apply once-daily roflumilast foam 0.3% (n=304) or vehicle (n=153) for 8 weeks.
- The primary efficacy endpoint was IGA Success (Completely Clear/Almost Clear [score 0–1] plus ≥2 grade improvement at Week 8).
- Secondary efficacy endpoints included Worst Itch Numeric Rating Scale (WI-NRS), which was completed daily by patients.
- Safety and local tolerability were also evaluated.

**RESULTS**

- Demographics and baseline characteristics were similar in the treatment groups (Table 1).
- Overall, significantly more roflumilast-treated patients than vehicle-treated patients achieved IGA success (79.5% vs 58.0%; P=0.0001) and IGA status of Clear (60.6% vs 27.7%; P=0.0001) at Week 8 (Figure 2).
- Significantly greater percentages of roflumilast than vehicle-treated patients had ≥4-point improvement on WI-NRS at Weeks 2 (32.7% vs 15.5%; P=0.0005), 4 (47.6% vs 29.1%; P=0.0003), and 8 (62.8% vs 40.6%; P=0.0001) (Figure 3).
- Greater improvement in itch was observed among roflumilast-treated patients as early as 48 hours after the first application (mean percent change from baseline: -27.87% vs -13.11%; nominal P=0.0004; Figure 4).
- Changes in SD in patients treated with roflumilast foam 0.3% are shown in Figure 5.

**Safety**

- Rates of adverse events (AEs) with roflumilast foam and vehicle were low (Table 2).
- Few treatment-related AEs were reported.
- Very few AEs led to study discontinuation, with similar rates of discontinuation between roflumilast and vehicle groups.
- Overall, significantly more roflumilast-treated patients than vehicle-treated patients achieved IGA Success at Week 8 (Figure 2).

**CONCLUSIONS**

- Once-daily, non-scalp roflumilast foam 0.3% provided improvement across multiple efficacy endpoints, including itch improvement, 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 itch response at Week 8, with significant improvements at the 2- and 4-week assessments.
- Greater improvement in daily itch scores was observed among roflumilast-treated patients as early as 48 hours after the first dose.
- Local tolerability was highly favorable on investigator- and patient-rated assessments and was consistent with safety profiles in prior trials.

**REFERENCES**


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