Efficacy and Safety of Roflumilast Foam 0.3% in Patients With Seborrheic Dermatitis in a Phase 3 Trial: Assessment of Pruritus

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INTRODUCTION

Seborrheic dermatitis (SD) is a chronic inflammatory skin condition that negatively impacts quality of life, particularly in patients with more severe disease1–9 in a major complaint among patients with SD. Topical treatments include antifungals, steroids, immunomodulators, and dandruff shampoos,10 but efficacious and well-tolerated products are needed, especially those that improve itch.

METHODS

This phase 3, randomized, parallel-group, double-blind, vehicle-controlled trial (NCT03782228) was conducted in patients ≥18 years old with at least moderate SD affecting scalp and/or non-scalp areas. Eligible patients had clinical diagnosis of SD of ≥3 months duration, Investigator Global Assessment (IGA) score ≥3 (at least moderate severity), and affecting ≥20% of the body surface area (BSA) at baseline.

Patients were randomized 2:1 to apply once-daily roflumilast foam 0.3% (n=304) or vehicle (n=152) for 8 weeks. The primary efficacy endpoint was IGA Success (Complete/Almost Clear [score 0–1] plus ≥2 grade improvement) at Week 8. Secondary endpoints included Worst Itch Numeric Rating Scale (WI-NRS), which was completed daily by patients.

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 55.1%, P<0.0001) and IGA clear (50.6% vs 27.7%, P<0.0001) (Figure 2). Only 1 patient had a serious AE, and it was considered unrelated to treatment. No other serious AEs were reported. The most common TEAEs (>1% in any group) were nausea (1.6%) and headache (1.0% for vehicle). Most common SAEs (>1% in any group) were Upper respiratory infection (1.3% for vehicle), Keratoacanthoma, not in application site, deemed unrelated. Reasons for discontinuation in the roflumilast-treated group included diarrhea/hematochezia/abdominal pain in 4 patients, and pruritus, rash, facial rash, and application-site irritation in 6 patients. 16 patients discontinued treatment due to AEs.

CONCLUSIONS

• Roflumilast foam was well tolerated (Figure 6).
• 29.8% of roflumilast-treated and 30.1% of vehicle-treated patients had no evidence of irritation on the investigator’s rating of local tolerability.
• 45.4% of patients had reported "no sensation" or "light, tingling, or itching sensations" that are likely bothersome on the patient-rated assessment of local tolerability.

REFERENCES


Figure 1. Study Design

Figure 2. Patients Achieving IGA Success and IGA Clear

Figure 3. Percentage of Patients Achieving WI-NRS Success

Figure 4. LS Percent Change in Daily WI-NRS Scores

Figure 5. Changes in SD in Patients Treated With Roflumilast Foam 0.3%

Table 1. Baseline Demographics and Disease Characteristics

Table 2. Overall AEs