Efficacy and Tolerability of Roflumilast Cream 0.3% in Patients With Chronic Plaque Psoriasis Involvement on the Face, Intertriginous, and Pooled Results from Phase 3 Trials (DERMIS-1 and DERMIS-2)

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INTRODUCTION

- Patients with psoriasis involving special areas, such as the face, intertriginous, and genital areas, may have a disproportionately greater negative impact on their quality of life than patients without psoriasis involvement in those areas.
- Chronic use of current topical treatment options in these areas is limited due to risk of local skin effects or limitations on duration of use.
- Roflumilast is a selective and highly potent phosphodiesterase 4 (PDE4) inhibitor with greater affinity for PDE4B than aripiprazole or risperidone and approximately 2-500-fold more potent based on in vitro assays.
- Topical roflumilast is being investigated as a once-daily, nonsteroidal treatment for long-term management of various dermatologic conditions, including atopic dermatitis, seborrheic dermatitis, and chronic plaque psoriasis (approved by the US Food and Drug Administration July 29, 2022).

METHODS

- DERMIS-1 and DERMIS-2 were 2 identical, phase 3, randomized, double-blind, vehicle-controlled, 8-week studies of once-daily roflumilast cream 0.3% in patients (22 years of age) with psoriasis body surface area (IBA) affected: 2%-20%.
- The primary efficacy endpoint was Investigator Global Assessment (IGA) Success at Week 8, which was defined as achievement of Clear or Almost Clear IGA status plus ≥2 points improvement from baseline.

RESULTS

- Baseline disease characteristics and demographics were similar across treatment groups (Table 1).
- Significantly more roflumilast-treated patients achieved the primary endpoint, IGA Success at Week 8 (Figure 2).
- Across the subgroups at Week 8, a greater percentage of patients in the roflumilast group achieved IGA Success compared with that of the vehicle group.
- More patients in the roflumilast group also had an IGA status of Clear or Almost Clear across subgroups at Week 8 (Figure 3).
- More roflumilast-treated patients who had a baseline score ≥4 on the Worst Numeric Rating Scale (WI NRS) had a 4-point improvement at Week 8 across subgroups (Figure 4).
- The least square mean percent change from baseline in Psoriasis Symptom Diary (PSD) scores was greater after roflumilast treatment than with vehicle treatment across subgroups (Figure 5).

SAFETY

- In patients with involvement in 5A, local tolerability was highly favorable as reported by patient and investigator assessment of irritation, burning, and stinging (Figure 6).
- ≥97.6% of patients had no evidence of irritation at Week 8 on investigator-rated assessments.
- ≥97.2% reported no warm/hotting sensation or mild sensation at Week 8 on patient-rated assessments.

CONCLUSIONS

- Roflumilast cream 0.3% provided improvement across multiple efficacy endpoints versus vehicle cream while demonstrating favorable safety and tolerability in patients with chronic plaque psoriasis involving intertriginous, and/or face, and/or genital areas in 2 phase 3 trials.
- The local tolerability profile as assessed by both patients and investigators was favorable.
- The subgroup analysis of the pooled results of the phase 3 DERMIS-1 and DERMIS-2 trials showed that once-daily roflumilast cream 0.3% demonstrated efficacy and tolerability in patients with psoriasis involvement in difficult-to-treat areas.

REFERENCES