Safety of Hydrogen Peroxide Topical Solution 40% and 45% (w/w) in Patients With Seborrheic Keratoses on the Trunk, Extremities, and Face: Results of a Phase 2, Randomized, Double-Blind, Vehicle-Controlled, Parallel-Group Study

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INTRODUCTION

Seborrheic keratoses (SKs) are benign epithelial skin lesions that affect approximately 64 million individuals in the United States, and are characterized by an erythematous, hyperkeratotic, and sometimes thickened appearance.1-3 Evolving treatment options often involve invasive procedures that may lead to adverse cosmetic effects such as pigment changes, scarring, and infection.4-6 The US Food and Drug Administration has approved a proprietary, stabilized hydrogen peroxide topical solution 40% (w/w) (HP40) for the treatment of raised SKs7-8 The objective of this presentation is to describe the safety findings of a Phase 2 study designed to evaluate the efficacy and safety of HP40 compared with a proprietary hydrogen peroxide topical solution 4% (w/w) (HP4) and vehicle in patients with SKs on the trunk, extremities, and face.

MATERIALS AND METHODS

Study Design

Patients (N=193), multi-center, randomized, double-blind, vehicle-controlled, parallel-group study with 3 treatment groups (NCT03146981)

The duration of study participation was a maximum of 124 days per patient, comprising 4 study visits, with target lesions treated at 2 treatment visits (visits 2 and 4).

- During screening (visit 1), eligible SK target lesions located on the trunk, extremities, and face were identified. For each patient, 1 target lesion must have been on the face and 1 must have been on the trunk or extremity.
- At visit 2, patients were randomized in a 1:2:2 ratio to receive vehicle, 4% hydrogen peroxide topical solution (HP4), or 40% hydrogen peroxide topical solution (HP40) and vehicle retreatment criteria

RESULTS

Study Patients

- A total of 252 patients were enrolled in the ITT population and randomized to treatment with HP4 (n=65), HP40 (n=100), or vehicle (n=87).
- Baseline demographics and clinical characteristics were similar across groups.
- 4 serious TEAEs occurred across the 3 groups; these were not considered related to treatment (Table 2).

Study Assessments

- Lesion severity (primary effectiveness parameter) was assessed using the PLA Scoring System.

Conclusions

- Most patient- and investigator-reported LSRs that occurred during treatment with HP40 and HP4 were well tolerated and associated with a favorable safety profile.

Only minimal changes in skin pigmentation were observed at the end of the study compared with earlier time points.

References


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Figure 2. Frequencies of LSRs by Visit, Intensity, and Treatment Condition: (A) Patient-Reported LSRs and (B) Investigator-Reported LSRs

Table 1. PLA Scoring

Table 2. Baseline Demographics and Clinical Characteristics, Intent-to-Treat Population

Table 3. Overall Summary of Safety

Table 4. Summary of Treatment-Related TEAEs

Table 5. Summary of SAEs

Table 6. TEAEs by preferred term

Table 7. SAEs by severity

Table 8. Patient-Reported LSRs

Table 9. Investigator-Reported LSRs

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