Onset of Treatment Effectiveness With 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

Seborrhoeic keratoses (SKs) are benign cutaneous lesions affecting approximately 64 million individuals in the US. Current treatment options for SKs require surgical or ablative procedures, including liquid nitrogen cryotherapy, shave removal, cautery, chemical peels, and laser treatments. The efficacy, safety, and tolerability profiles of these therapies are not well established, and some of these procedures can lead to adverse cosmetic effects.

The US Food and Drug Administration has approved a proprietary stabilized hydrogen peroxide topical solution 40% (w/w) for the treatment of raised SKs.

The objective of the present study is to describe the onset of efficacy of HP40 and of a proprietary hydrogen peroxide topical solution 45% (w/w) (HP45) compared with vehicle in a Phase 2 study of the efficacy and safety of these formulations for treatment of SKs on the trunk, extremities, and face.

MATERIALS AND METHODS

Study Design

This was a Phase 2, multinational, randomized, double-blind, vehicle-controlled, parallel-group study (NCT01694613).

The study consisted of 8 study visits over a maximum of 127 days, with target lesions treated at visits 2, 4, 6, and 7.

Screening Visit 2 Visit 4 Visit 6 Visit 7 Visit 8

Patient selection was based on the primary inclusion criteria of ≥1 target lesion on the face and ≥1 target lesion on the trunk or extremities.

Study Assessments

- Lesion severity (tumor effectiveness parameter) was assessed by the PLAscoring system (described in Table 1).
- Efficacy was analyzed in the per-protocol population using a pairwise comparison between groups based on the mean per-patient percentage of target lesions clear (PLA = 0).
- Safety assessments included treatment-emergent adverse events (TEAEs).

RESULTS

Study Patients

Eligible patients were ≥18 years of age with a diagnosis of 4 or more clinically stable SK target lesions on the trunk, extremities, and face (≥1 target lesion on the face and ≥1 target lesion on the trunk or extremities) and were neither pregnant nor breastfeeding.

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Efficacy

- A total of 240 patients were included in the per-protocol population (HP40, n=101; HP45, n=92; vehicle, n=47).
- The mean per-patient percentage of target lesions clear at visit 8 (primary efficacy variable) was significantly greater among patients treated with HP40 (46%) and HP45 (37%) vs vehicle (3.7%; P<0.001 for both comparisons).

Safety

- TEAEs were reported in 17.5%, 26.0%, and 22.0% of patients in the HP40, HP45, and vehicle groups, respectively.
- Most common TEAEs (≥2 patients per group) were nasopharyngitis, upper respiratory infection, rash, and pyrexia.

REFERENCES


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DISCLOSURES

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership, expert testimony, grants or patents received or pending, or royalties.

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