INTRODUCTION

Seborrheic keratoses (SKs) are benign cutaneous lesions affecting approximately 44 million individuals in the United States. Current treatment options for SKs require surgical or ablative procedures, including liquid nitrogen cryotherapy, shave removal, curettage, 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.

Until recently, a safe, effective, noninvasive, and cosmetically acceptable treatment was not available for the successful removal of SK lesions.

Materials and Methods

Study Design

A Phase 2, multicenter, randomized, double-blind, vehicle-controlled, parallel-group study (NCT03140089) was designed to include 3 treatment groups (vehicle, HP40, HP45).

The study comprised 6 visits spanning over a maximum of 127 days, with target lesions treated at 2 treatment visits (Figure 1). During screening visit 1, ≥ 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 on the trunk or extremities. At visit 2, patients were randomized in a 1:2:2 ratio to receive vehicle, HP40, or HP45, respectively, and received the first treatment.

After a follow-up examination on day 8 (visit 3), target lesion assessments and retreatment occurred during visits 4, 5, 6, and 7, followed by a final target lesion assessment at end-of-study visit 8 (day 106).

The per-patient population included all eligible patients who received all study treatments, completed visit 8, had ≥1 target lesions assessed by the validated Physician Lesion Assessment™ (PLA), and did not have a protocol violation during the study.

RESULTS

Study Patients

Eligible patients were ≥18 years of age with a diagnosis of 4 typical, 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).

Target lesions were required to be discrete with a clinically typical appearance (PLA ≥ 1 grade ≥ 2); length and width ≤ 15 mm, thickness ≤ 2 mm; and not be obstructed or within 5 mm of the orbita rim.

Study Assessments

Lesion severity (primary effectiveness parameter) was assessed using the PLA (Table 1).

Efficacy was analyzed in the per-protocol population using a pairwise comparison between groups based on the mean per-patient percentages of target lesions clear (PLA = 0) at day 106 (Figure 2).

Safety assessments included treatment-emergent adverse events (TEAEs) (Table 2).

Study Patients

A total of 240 patients were enrolled in the per-protocol population (101 HP40, 101 HP45, 38 vehicle); 101 patients were treated with HP40 or HP45: 83 patients with HP40 (n = 47) and 55 patients with HP45 (n = 47).

Baseline demographics and clinical characteristics were similar across groups (Table 2).

Efficacy

A total of 240 patients were enrolled in the per-protocol population (HP40, n = 101; HP45, n = 100; vehicle, n = 47).

The mean per-patient percentage of all target lesions clear at visit 8 (primary efficacy variable) was significantly greater among patients treated with HP40 (40.5%) and HP45 (57.9%) vs vehicle (1.5%; P < 0.0001; Figure 3).

No significant differences were observed for comparisons of HP40 vs HP45.

Figure 2. Mean Per-Patient Percentages of All Target Lesions Clear at Visit 8 by Treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Mean Per-Patient Percentage Clear (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vehicle</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>HP40</td>
<td>40.5 (43.3%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>HP45</td>
<td>57.9 (55.8%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Figure 3. Mean Per-Patient Percentages of Target Lesions Clear (PLA = 0) on the Face at Visit 8 by Treatment

The mean per-patient percentage of target lesions clear on the trunk at visit 8 was significantly greater for comparisons of HP40 (43.1%) and HP45 (53.8%) vs vehicle (1.4%; P < 0.0001; Figure 4).

A significant difference was also observed in mean per-patient percentage target lesions clear on the trunk at visit 8 for HP40 (43.1%) vs HP45 (53.3%; P < 0.02).

Figure 4. Mean Per-Patient Percentages of Target Lesions Clear (PLA = 0) on the Trunk at Visit 8 by Treatment

Mean per-patient percentage of target lesions clear on the extremities at visit 8 was significantly greater for comparisons of HP40 (39.8%) and HP45 (53.8%) vs vehicle (1.2%; P < 0.0001; Figure 5).

A significant difference was also observed in mean per-patient percentage target lesions clear on the extremities at visit 8 for HP40 (39.8%) vs HP45 (53.8%; P < 0.02).

Figure 5. Mean Per-Patient Percentages of Target Lesions Clear (PLA = 0) on the Extremities at Visit 8 by Treatment

Safety

The most common TEAEs reported in the HP40 and HP45 treatment groups (n = 2 patients in either group) were nasopharyngitis, bronchitis, drug eruption, headache, and hypertension.

4 serious TEAEs occurred across the 3 groups: HP40: syncope, deep vein thrombosis; HP45: pancreatic carcinoma, vehicular fatality; none were related to study medication.

Please see AAD 2019 Poster by Dubois et al, Safety of Hydrogen Peroxide Topical Solution 40% and 45% (w/w) in Patients With Seborrheic Keratoses on the Trunk, Extremities, and Face, for a more complete, detailed description of safety findings from this study.

Acknowledgments

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Disclosures

At the time of submission, Dr. Bahler was an employee of Aclaris Therapeutics, Inc., and may own stock/stock options in that company. Dr. Alster is an inventor on a U.S. patent and was an employee of Aclaris Therapeutics, Inc., and may own stock/stock options in that company.