Safety of Hydrogen Peroxide Topical Solution, 40% (w/w) in Patients With Skin of Color and Seborrheic Keratoses: Pooled Analysis of Two Phase 3, Randomized, Double-Blind, Vehicle-Controlled, Parallel-Group Studies

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SYNOPSIS
- Seborrheic keratoses (SKs) are benign yet aesthetically bothersome cutaneous lesions found mainly on the trunk, head, and neck.1
- Hydrogen peroxide topical solution 40% (w/w) (HP40) is the first topical treatment approved by the US Food and Drug Administration for adults with raised SKs.2,3
  - Limited information is currently available regarding HP40 treatment in patients with skin of color.
- Two randomized, double-blind, vehicle-controlled, parallel-group Phase 3 studies were conducted to investigate the safety and efficacy of HP40 compared with vehicle for the treatment of SKs.
  - At visit 1 of both trials, investigators determined the Fitzpatrick Skin Type of all eligible study patients.

OBJECTIVE
- We conducted a post hoc, pooled analysis of data from the two Phase 3 pivotal clinical trials to evaluate the safety and tolerability of HP40 treatment in patients with skin of color, defined as having Fitzpatrick Skin Types IV, V, or VI.

MATERIALS AND METHODS

Patients
- This was a pooled, post hoc analysis of data from two Phase 3, multicenter, randomized, double-blind, vehicle-controlled studies (NCT02667236, NCT02667237).
- Eligible patients were required to be ≥18 years of age and have 4 target SKs (≥1 on the face and ≥1 on the trunk or extremities).
- For the current analysis, patients were also required to have a Fitzpatrick Skin Type of IV, V, or VI.

Study Design
- Both studies were vehicle-controlled and had a parallel-group design (Figure 1).
  - Patients were randomized to receive HP40 or vehicle.
  - Treatments were administered at visit 2 (all patients) and visit 4 (if the Physician’s Lesion Assessment Tool [PLA] grade was ≥0).
    - Details of the validated PLA tool are summarized in Table 1.
  - The PLA was performed at visits 1, 2, 4, 6, 7, and 8.
  - Safety was assessed at all visits.

Safety
- Treatment-related TEAEs were reported in 12 (6.6%) patient treated with HP40 experienced a treatment-related TEAE of a postprocedural complication.
- No treatment-related adverse events were observed in the vehicle group.
- Investigator- and patient-reported LSRs (Figure 2).
  - HP40-treated patients reported an LSR of pruritus or stinging and no investigator observed atrophy, edema, erosion, scarring, ulceration, or vesicles.
  - Most investigator-observed LSRs among HP40-treated target lesions at visit 8 were mild (crusting, 3.8%; erythema, 3.2%; hypopigmentation, 1.5%; hyperpigmentation, 0.6%; scaling, 3.8%).
  - Investigators reported moderate crustation for 1 target lesion (6.6%) and moderate hyperpigmentation for 4 target lesions (2.6%).
  - No severe LSRs were reported at visit 8.

RESULTS

Patient Characteristics
- A total of 97 patients with Fitzpatrick Skin Types IV, V, or VI were included in the pooled analysis (HP40, n=39; vehicle, n=58).
- Baseline demographics were similar between the HP40 and vehicle treatment groups (Table 2).

Safety Endpoints
- Safety assessments included treatment-related treatment-emergent adverse events (TEAEs) and local skin reactions (LSRs), which were evaluated by patients and clinical trial investigators.
  - At visits 2 and 4, patients rated LSRs at 10 minutes posttreatment, and investigators rated LSRs at 20 minutes posttreatment.

Table 2. Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Vehicle (n=58)</th>
<th>HP40 (n=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>48 (82.8)</td>
<td>32 (82.1)</td>
</tr>
<tr>
<td>Age group, y</td>
<td>46 (82.9)</td>
<td>32 (82.1)</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>4 (6.9)</td>
<td>8 (20.5)</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>44 (75.9)</td>
<td>24 (61.5)</td>
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<tr>
<td>Missing data</td>
<td>10 (17.2)</td>
<td>7 (17.9)</td>
</tr>
</tbody>
</table>

Figure 2. Frequencies of LSRs That Occurred During Treatment Visits or End of Study by Visit, Intensity, and Treatment: (A) Patient-Reported LSRs; (B) Investigator-Reported LSRs

Figure 1. Study Design

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Disclosures
CH has conducted clinical trials for and participates in advisory boards for Aclaris Therapeutics, Inc. ET has conducted clinical trials for Aclaris Therapeutics. TMJ is an investigator for Aclaris Therapeutics. MB is a statistical consultant to Aclaris and owns stock in that company. JS and SDS are employees of Aclaris Therapeutics and may own stock/stock options in that company.

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REFERENCES