Long-Term Efficacy and Safety of Hydrogen Peroxide Topical Solution, 45% (w/w) in Patients With Common Warts: Posttreatment Results From the Phase 2 WART 203 Trial

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INTRODUCTION

Verruca vulgaris (common warts) is a cutaneous manifestation of the human papillomavirus that impacts as many as 20% of children and 10% of adults globally. Current treatments for common warts include chemotherapy, cryotherapy, burning, and, in more difficult cases, laser treatments, chemical peels, or destruction by carbon dioxide lasers. No prescription therapies are approved by the US Food and Drug Administration for the treatment of common warts.

A proprietary, stabilized, high-concentration hydrogen peroxide topical solution, 45% (w/w) [HP45] is currently in clinical development for the treatment of common warts.

A Phase 1/2 clinical trial was designed to evaluate the efficacy and safety of HP45 in patients with common warts 12 weeks after completion of treatment.

MATERIALS AND METHODS

Study Design

The Phase 2 WART-203 trial (NCT03739826) was a randomized, double-blind, vehicle-controlled, multicenter study designed to evaluate the efficacy and safety of HP45 administration vs vehicle for 8 weeks in patients with common warts. Patients were required to complete a total of 13 study visits: screening, randomization and first treatment, then 7 more weekly treatments, prior to efficacy assessments at week 8, 8, additional follow-up evaluations at weeks 12 and 16, and follow-up visit at the end of study evaluation at week 20 (Figure 1).

RESULTS

Patients

Of the 159 patients enrolled and treated, 157 patients were included in the per-protocol population, and 151 patients completed posttreatment week 20 (HP45; n=76; vehicle, n=75) and were included in the long-term analysis.

Baseline demographics and clinical characteristics of study patients are summarized in Table 2.

Table 2. Baseline Demographics and Clinical Characteristics of Study Patients (N=159)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HP45</th>
<th>Vehicle</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>52.2±16.8</td>
<td>50.2±16.5</td>
<td>0.3029</td>
</tr>
<tr>
<td>Sex, male/female</td>
<td>78/38</td>
<td>77/39</td>
<td>0.2789</td>
</tr>
<tr>
<td>Fitzpatrick skin type</td>
<td>45.6%</td>
<td>44.8%</td>
<td>0.5966</td>
</tr>
<tr>
<td>History of treatment for common warts</td>
<td>1.3%</td>
<td>1.9%</td>
<td>0.5667</td>
</tr>
<tr>
<td>No. of treated warts per patient</td>
<td>5.1±1.7</td>
<td>5.1±1.6</td>
<td>0.8994</td>
</tr>
<tr>
<td>PWA score of 2 or 3, %</td>
<td>30.1%</td>
<td>30.1%</td>
<td>0.9985</td>
</tr>
</tbody>
</table>

Conclusions

The 20-week results represent an increase in the proportion of patients with clearance of the target wart from week 0 after treatment was completed (please see the AAD 2019 photog by Tyring et al. Efficacy and Safety of Hydrogen Peroxide Topical Solution, 45% (w/w) for Treatment of Common Warts: 8-Week Results From the Phase 2 WART-203 Trial). A statistically significantly greater proportion of patients treated with HP45 maintained all treated warts clear at week 20 (53.3% vs vehicle; p<0.001; Figure 2). A statistically significantly greater proportion of patients treated with HP45 maintained all treated warts clear or near clear at week 20 (49.1% vs vehicle; p<0.001) (Table 3).

Efficacy and Safety Analyses

Efficacy analyses were conducted in the per-protocol population, defined as patients who completed the study, minus 0.5 treatment visits, completed the 8- and 20-week (end of study) assessments, and had no documented protocol violations.

Endpoints were based on PWA scores (Table 1), used to record the severity of each target and nontarget wart at each time point. The Physician Wart Assessment™ (PWA) is a validated, validated outcome measure to assess the severity of target and nontarget warts.

Figure 2. Mean Score and Mean Change From Baseline PWA Scores at Week 20, Per-Protocol Population (N=157)

The mean per-patient percentage of “treated warts clear” at week 20 was significantly greater for HP45 (49.1%) vs vehicle (30.1%, p<0.001). Figure 3.

Figure 3. Percentages of Target Warts or All Treated Warts Clear or Almost Clear at Week 20, Per-Protocol Population (N=157)

The mean per-patient percentage change from baseline in PWA score at week 20 was statistically significantly greater with HP45 (−43.8%) vs vehicle (−17.7%; p<0.001) (Figure 4A).

REFERENCES


CONCLUSIONS

1. Safety and clinical efficacy findings observed at 8 weeks of treatment with HP45 were maintained for 12 weeks following treatment cessation in patients with common warts.

2. All assessments based on target warts and all treated warts showed statistically significant improvement at week 20 with HP45 treatment compared with vehicle.

Safety of 159 patients in the safety analysis, 47 patients reported 76 TEAEs most were mild or moderate in severity (Table 5). The most common treatment-related TEAE in the HP45 group was application site pain (2.5% vs 2.5%; p=0.5667). No serious adverse events were reported. No patients discontinued treatment due to TEAEs.

Table 3. Summary of Adverse Events, Safety Population (N=159)

<table>
<thead>
<tr>
<th>AE Category</th>
<th>HP45 (n=75)</th>
<th>Vehicle (n=76)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All TEAEs</td>
<td>83 (70.3%)</td>
<td>64 (59.7%)</td>
<td>0.1581</td>
</tr>
<tr>
<td>Application site pain</td>
<td>2 (2.6%)</td>
<td>3 (3.9%)</td>
<td>0.9000</td>
</tr>
<tr>
<td>Application site reaction</td>
<td>2 (2.6%)</td>
<td>2 (2.6%)</td>
<td>0.9999</td>
</tr>
<tr>
<td>Other</td>
<td>77 (80.7%)</td>
<td>62 (75.0%)</td>
<td>0.3485</td>
</tr>
</tbody>
</table>

Acknowledgments

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Disclosure

SRT has conducted clinical studies sponsored by Aclaris; SRT has been an employee and consultant for Aclaris, and a competitor of Aclaris; and was sponsored by and is consultant for Aclaris; NR is a competitor of Aclaris; RT is an employee of Aclaris and may own stock or stock options in that company.