Impact of Age on Efficacy and Safety of Fixed-Dose Clindamycin Phosphate 1.2%/Adapalene 0.15%/Benzoyl Peroxide 3.1% Gel in Participants with Moderate-to-Severe Acne


SYNOPSIS

- Acne affects patients of all ages, but there are age-related differences in clinical presentations and efficacy and safety of acne treatments.
- Topical clindamycin phosphate 1.2%/adapalene 0.15%/benzoyl peroxide 3.1% CAB gel is the only fixed-dose, triple-combination formulation approved for the treatment of acne and is indicated for use in patients aged ≥12 years.
- In three clinical studies of participants with moderate-to-severe acne, once-daily CAB demonstrated superior efficacy to vehicle and comparable safety, with good safety and tolerability.

OBJECTIVE

- This post hoc analysis was performed to evaluate the efficacy and safety of CAB in pediatric, adolescent, and adult participants.

METHODS

- In studies 1 (NCT03101922) and two phase 3 (NCT04495402, NCT04495403) studies, participants aged 17 years with moderate-to-severe acne were randomized to once-daily CAB or vehicle, data from participants randomized to the adult group only is shown.
- Endpoints included percentage of participants achieving treatment success (defined as ≥2-grade reduction from baseline in EASI and PASI scores) and discontinuation due to treatment-related AEs. Efficacy outcome measures were assessed at weeks 2, 4, 8, and 12.
- Safety was assessed at weeks 1, 4, 8, and 12, and serious AEs were monitored throughout the study.
- Efficacy and safety endpoints were evaluated via a 0-100 scale, with higher scores indicating greater improvement from baseline.

RESULTS

- CAB Gel (n=297) showed significant improvements in treating acne inflammatory lesions in both age groups at week 12, versus 45%-62% with vehicle.
- The pooled population comprised 657 participants in two age groups: aged 9-24 years (n=293) and ≥25 years (n=364).
- There were no notable age-related trends in safety or tolerability.

TABLE 1. Baseline Demographics and Characteristics (ITT Population, Pooled Participants)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
<th>Mean Age (SD)</th>
<th>Female (%)</th>
<th>Black (%)</th>
<th>Hispanic/Latino (%)</th>
<th>Asian (%)</th>
<th>Non-Hispanic/Latino (%)</th>
<th>Caucasian (%)</th>
<th>White (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-24 yrs</td>
<td>293</td>
<td>18.7 (3.0)</td>
<td>62.6</td>
<td>20.6</td>
<td>10.9</td>
<td>6.2</td>
<td>99.8</td>
<td>3.4</td>
<td>96.6</td>
</tr>
<tr>
<td>≥25 yrs</td>
<td>364</td>
<td>25.7 (7.8)</td>
<td>63.4</td>
<td>28.5</td>
<td>8.1</td>
<td>0</td>
<td>99.9</td>
<td>4.2</td>
<td>95.8</td>
</tr>
</tbody>
</table>

TABLE 2. Treatment-Emergent Adverse Events Through Week 12 by Age

<table>
<thead>
<tr>
<th>Age Group</th>
<th>N</th>
<th>Reportable AE (%)</th>
<th>Mild (%)</th>
<th>Moderate (%)</th>
<th>Severe (%)</th>
<th>Related (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-24 yrs</td>
<td>293</td>
<td>48.6</td>
<td>42.7</td>
<td>1.7</td>
<td>3.1</td>
<td>3.6</td>
</tr>
<tr>
<td>≥25 yrs</td>
<td>364</td>
<td>55.3</td>
<td>49.0</td>
<td>4.0</td>
<td>2.0</td>
<td>3.6</td>
</tr>
</tbody>
</table>

FIGURE 1. Treatment Success Through Week 12 by Age (ITT Population, Pooled Participants)

FIGURE 2. Least Squares Mean Percent Reductions in Lesion Counts Through Week 12 by Age (ITT Population, Pooled Participants)

FIGURE 3. Acne Improvements with CAB in Participants Aged 9-24 and ≥25 Years

FIGURE 4. Cutaneous Safety and Tolerability Through Week 12 by Age (Safety Population, Pooled Participants)

CONCLUSIONS

- Fixed-dose, triple-combination CAB gel was efficacious and well tolerated in participants with moderate-to-severe acne, regardless of age.
- Approximately half of CAB-treated pediatric/adolescent and adult participants achieved clear/almost clear skin, with >70% reductions in lesion counts.
- No age-related trends in efficacy or tolerability were observed, suggesting that the innovative CAB gel (approved for use in patients aged ≥12 years) is a valuable treatment option for patients of all ages.

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REFERENCES


AUTHOR DISCLOSURES

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