Halobetasol Propionate 0.01% / Tazarotene 0.045% Lotion for the Treatment of Plaque Psoriasis in Patients with Mild Scaling and Mild Plaque Elevation

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SYNOPSIS

• Combining tazarotene (TAZ) with a potent-to-superpotent topical corticosteroid, such as halobetasol propionate (HP), is recommended for the treatment of patients with mild-to-moderate psoriasis.1,2

• The HP + TAZ combination may provide synergistic efficacy, increase the duration of remission, and reduce side effects of each drug when used alone.3

• A once-daily, fixed-combination HP 0.01% / TAZ 0.045% lotion (Duobrii, Ortho Dermatologics) was developed utilizing polymers and emulsion technology, which allows for rapid and uniform distribution of HP and TAZ, humectants, and moisturizers on the skin.4

• In two phase 3, double-blind studies (NCT02462070, NCT02462122), adult participants were randomized 2:1 to HP/TAZ or vehicle once daily for 8 weeks, with a 4-week posttreatment follow-up.5,6

• Participants were required to have an Investigator’s Global Assessment (IGA) score of 3 (mild) or 4 (severe) and a body surface area (BSA) of ≥10% to ≤20% at baseline.

• In these studies, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (CeraVe, NY) were provided as needed for optimal moisturizing/steaming of the skin.

• Efficacy measures included treatment success (percentage of participants with ≥2-grade reductions from baseline in IGA severity at week 8), change in affected BSA, and percentage of participants with ≥2-grade improvements from baseline (success) in erythema, plaque elevation, and scaling.

OBJECTIVE

To evaluate efficacy and safety of HP 0.01% / TAZ 0.045% lotion in patients with either mild scaling or mild plaque elevation at baseline.

METHODS

• In two phase 3, double-blind studies (NCT03462070, NCT03462122), adult participants were randomized 2:1 to HP/TAZ or vehicle once daily for 8 weeks, with a 4-week posttreatment follow-up.5,6

• Participants were required to have an Investigator’s Global Assessment (IGA) score of 3 (mild) or 4 (severe) and a body surface area (BSA) of ≥10% to ≤20% at baseline.

• In these studies, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (CeraVe, NY) were provided as needed for optimal moisturizing/steaming of the skin.

• Efficacy measures included treatment success (percentage of participants with ≥2-grade reductions in IGA score and a score of 0/1 [clear] or 2/3 [almost clear]), change in affected BSA, and percentage of participants with ≥2-grade improvements from baseline (success) in erythema, plaque elevation, and scaling.

• Treatment-emergent adverse events (TEAEs) were evaluated.

• Pooling, post hoc analyses were performed in subsets of patients with either mild scaling (score of 2) or mild plaque elevation (score of 2) at baseline.

RESULTS

Demographics and Baseline Characteristics

- Of 418 study participants in the overall population, 58 had mild scaling at baseline and 44 had mild plaque elevation at baseline.

- Participant demographics and characteristics were generally similar across the groups, though there was a higher proportion of males in the mild scaling group and more participants in the mild plaque elevation group had moderate IGA at baseline (Table 1).

Efficacy

- Compared with vehicle, HP/TAZ-treated participants in the mild scaling group had significantly greater reductions from baseline in IGA score and a score of 0 [clear] or 1 [almost clear]), change in affected BSA, and scaling compared with vehicle.

- In the mild plaque elevation group, those treated with HP/TAZ demonstrated significantly greater improvements in signs of psoriasis at week 8 versus vehicle (Figure 2).

- A numerically higher treatment success rate was observed with HP/TAZ versus vehicle at week 8 in the mild plaque elevation group, with significance reached 4 weeks posttreatment (Figure 2).

- Lack of statistical separation of HP/TAZ from vehicle for treatment success and BSA reduction was significantly attributed to the small population and/or favorable response to the vehicle formulation.

CLINICAL COMMENTARY

- Unlike real-world use, participants in this study were required to continue administration of HP/TAZ for 8 continuous weeks—even if they had clearance of active psoriasis—which may have contributed to reduced levels of iteration in the mild plaque groups versus the overall population.

- Treatment-emergent irritation may potentially be addressed in the clinic by:

  - Recommending that patients temporarily interrupt drug use (eg, drug holiday) and resume application of the lotion once irritation signs/symptoms have subsided.

  - Encouraging the use of moisturizers before resuming treatment.

CONCLUSIONS

- In two pooled phase 3 studies, HP 0.01% / TAZ 0.045% lotion was efficacious and well tolerated following 8 weeks of treatment among participants with mild plaque elevation and mild scaling.

- Rates of contact dermatitis were higher in the HP/TAZ-treated mild scaling and plaque elevation subgroups versus the overall population (Table 2).

<table>
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<tr>
<th>Study Visit (Weeks)</th>
<th>Mild Scaling</th>
<th>Mild Plaque Elevation</th>
<th>Overall Population</th>
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<td>HP/TAZ Lotion</td>
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<td>HP/TAZ Lotion</td>
<td>Vehicle</td>
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<tr>
<td>Study ITT</td>
<td>Any TEAEs, n (%)</td>
<td>Treatment-related TEAEs, n (%)</td>
<td>Any TEAEs, n (%)</td>
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May hold stock and/or stock options in its parent company.

ACKNOWLEDGEMENTS

Medical writing support was provided by Preaceutt Medical Communications Group (Chicago, IL) with financial support from Ortho Dermatologics, Ortho Dermatologics is a division of Bausch Health US, LLC. Presented at Winter Clinical 2021 • January 16-24, 2021 • Virtual