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*Bausch Health US, LLC is an affiliate of Bausch Health Companies Inc. Ortho Dermatologics is a division of Bausch Health US, LLC.

SYNOPSIS
- Topical corticosteroids are the mainstay of psoriasis treatment, particularly for mild disease, though topical treatments as part of combination therapy are often necessary.
- However, treatment of local skin reactions is crucial, especially with potent topical corticosteroids.
- Recent phase 3 clinical data have demonstrated efficacy and tolerability of a fixed combination halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ) Dual®.

OBJECTIVE
- To investigate adverse effects and local skin reactions over the long-term use of HP/TAZ lotion.

METHODS
- This was a 1-year multicenter, open-label study (NCT02462083) in patients with moderate-to-severe plaque psoriasis (baseline IGA was moderate (3; 86.5%) or severe (4; 13.5%); median baseline age was 51.9 years (range: 19 to 87 years); 65.6% were male and 86.0% were white.
- Patients were treated with HP/TAZ once-daily if they had not achieved treatment success a for 4 weeks, then treated with HP/TAZ twice-daily if they had not achieved treatment success b for 4 weeks, and continued the study and were subsequently managed in 4-week cycles, if they had not achieved treatment success c for 4 weeks.
- Maximum continuous exposure was 24 weeks.

RESULTS
- Participants and Exposure
- A total of 59 participants were included in the safety population.
- Mean age was 51.9 years (range: 19 to 87 years); 65.6% were male and 86% were white.
- Baseline IGA was moderate (3; 86.5%) or severe (4; 13.5%); median affected body surface area was 5%.

TEAEs by severity, n (%)

<table>
<thead>
<tr>
<th>TEAE</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>147</td>
<td>10.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Pain</td>
<td>16</td>
<td>13.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Infection</td>
<td>1</td>
<td>0.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Atrophy</td>
<td>10</td>
<td>8.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Telangiectasias</td>
<td>6</td>
<td>4.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Folliculitis</td>
<td>7</td>
<td>5.5%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

- Most local skin reactions were transient and resolved prior to end of dosing.
- Incidence of other local skin reactions are shown in Table 1.
- The most common TEAEs related to study drug were application site pain, application site reaction, mild itching, and mild application site reaction.

TREATMENT-EMERGENT ADVERSE EVENTS
- Over half of participants experienced treatment-emergent adverse events (TEAEs) during the long-term study, primarily during the first 12 weeks (Table 1).
- Most TEAEs were mild or moderate.
- None of the serious adverse events (SAEs) were related to treatment.

TABLE 1. Treatment-Emergent Adverse Event Summary

<table>
<thead>
<tr>
<th>TEAE</th>
<th>No. of Participants</th>
<th>No. (%)</th>
<th>No. (%)</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
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</tr>
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</table>

- Incidence peaked at 2.3% for skin atrophy (week 8), 2.7% for folliculitis (week 8), and 1.5% for striae and telangiectasias (week 28).
- Local skin reactions most frequently reported at baseline: AEs for application site folliculitis (14 participants [2.5%]) and application site reaction (3 participants [0.7%]).
- Most local skin reactions were transient and resolved prior to end of dosing.

CONCLUSIONS
- No clinically meaningful trends in local skin reactions were observed following long-term use of HP/TAZ lotion.

Skin Reactions
- Select local skin reactions showed marked improvements in severity of itching, dryness, and burning/stinging over the study course; greatest improvement was for itching (Figure 4).
- Incidence of treatment-emergent Grade 3 skin reactions was 22.2% for itching, 4.8% for dryness, and 9.5% for burning/stinging.
- Incidence of other local skin reactions is shown in Figure 3.

- Percentage of participants reporting itching, dryness, and burning/stinging over the study course; greatest improvement was for itching (Figure 4).
- Incidence of treatment-emergent Grade 3 skin reactions was 22.2% for itching, 4.8% for dryness, and 9.5% for burning/stinging.
- Incidence of other local skin reactions is shown in Figure 3.

REFERENCES

AUTHOR DISCLOSURES
- Mark Lebwohl is a consultant of Bausch Health Companies Inc.
- Jeffrey Sugarman is a consultant for the following companies: Amgen, AbbVie, Almirall, Altera Therapeutics, AstraZeneca, Bausch Health, Biogen, Celgene, Galderma, Gilead, Genentech, Janssen, Merck for Health Care LLC, Merck Sharp & Dohme, Novartis, Ortho Dermatologics, Pfizer, Roche, Sanofi, and UCB.
- David Pariser is a consultant for the following companies: Acadia Pharmaceuticals, Amgen, Almirall, Allergan, Biofrontera, Biogen, Biotest, Galderma, Genentech, Gilead Sciences, Janssen, Merck for Health Care LLC, Merck Sharp & Dohme, Novartis, Ortho Dermatologics, Pfizer, Sanofi, and UCB.
- Jerry Bagel is a consultant for the following companies: Amgen, Almirall, AstraZeneca, Bausch Health Companies Inc., Biogen, Galderma, Genentech, Gilead Sciences, Janssen, Merck for Health Care LLC, Merck Sharp & Dohme, Novartis, Ortho Dermatologics, Pfizer, Sanofi, and UCB.
- Cynthia Trickett is a consultant for the following companies: Amgen, Almirall, Allergan, Biogen, Biotest, Galderma, Genentech, Gilead Sciences, Janssen, Merck for Health Care LLC, Merck Sharp & Dohme, Novartis, Ortho Dermatologics, Pfizer, Sanofi, and UCB.
- Abby Jacobson has received honoraria from Bausch Health Companies Inc., Biogen, Galderma, Genentech, Gilead Sciences, Janssen, Merck for Health Care LLC, Merck Sharp & Dohme, Novartis, Ortho Dermatologics, Pfizer, Sanofi, and UCB.
- Robert Israel is a consultant for the following companies: Amgen, Almirall, Allergan, Biogen, Biotest, Galderma, Genentech, Gilead Sciences, Janssen, Merck for Health Care LLC, Merck Sharp & Dohme, Novartis, Ortho Dermatologics, Pfizer, Sanofi, and UCB.
- Abby Jacobson is a consultant for the following companies: Amgen, Almirall, Allergan, Biogen, Biotest, Galderma, Genentech, Gilead Sciences, Janssen, Merck for Health Care LLC, Merck Sharp & Dohme, Novartis, Ortho Dermatologics, Pfizer, Sanofi, and UCB.

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