Effect of Fitzpatrick Skin Type on Efficacy of Calcipotriene Plus Betamethasone Dipropionate Topical Suspension in Treatment of Psoriasis Vulgaris

Bagel J¹, Ganslandt C², Levi E³, Stein Gold L⁴

¹Director, Psoriasis Treatment Center of Central NJ, East Windsor, NJ
²Senior Medical Adviser, LEO Pharma A/S, Ballerup, Denmark
³Scientific Advisor, LEO Pharma Inc., Parsippany, NJ
⁴Director of Dermatology Clinical Research, Division of Dermatology, Henry Ford Health System, West Bloomfield, MI
Introduction

• Approximately twice as many Caucasians as African Americans develop psoriasis (2.5% vs 1.3%, respectively)\(^1\)
• Fitzpatrick skin type classification is a recognized tool for dermatologic research based on the color of skin
• A topical suspension containing calcipotriene plus betamethasone dipropionate has recently been studied for the treatment of psoriasis vulgaris on the body in a randomized, vehicle-controlled, double-blind, 4-arm, multicenter study (NCT01188928)\(^2\)
• A subanalysis of the study examined the effect of Fitzpatrick skin type on efficacy of the 2-compound suspension

Methods

Inclusion Criteria

• Men/women ≥18 years of age
• Clinical diagnosis of stable plaque psoriasis vulgaris ≥6 months involving ≥10% of the trunk and/or limbs
• Amenable to treatment with a maximum of 100 g of topical medication per week
• Investigator’s Global Assessment (IGA) of disease severity of mild to moderate plaque psoriasis vulgaris on the body
Exclusion Criteria

• Use of phototherapy or systemic or topical treatment(s) with a possible effect on psoriasis vulgaris for defined periods (2 weeks to 4 months, depending on treatment) prior to randomization

• Diagnosis of guttate, erythrodermic, exfoliative, or pustular psoriasis

• Skin conditions affecting the treatment area for which treatment with a corticosteroid-containing medication should be avoided

• Disorders of calcium metabolism associated with hypercalcemia

• Severe renal or hepatic disorders
**Study Design**

- Randomized to 1 of 4 treatment groups in a 5:5:1:1 ratio
- Treatments were used once daily for up to 8 weeks

<table>
<thead>
<tr>
<th>Group</th>
<th>Treatment</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50 mcg/g calcipotriene + 0.5 mg/g betamethasone (as dipropionate)</td>
<td>C/BD</td>
</tr>
<tr>
<td>2</td>
<td>0.5 mg/g betamethasone (as dipropionate)</td>
<td>BD</td>
</tr>
<tr>
<td>3</td>
<td>50 mcg/g calcipotriene</td>
<td>C</td>
</tr>
<tr>
<td>4</td>
<td>Vehicle</td>
<td>V</td>
</tr>
</tbody>
</table>
Assessments

• The primary response criterion was the percentage of subjects at Weeks 4 and 8 achieving “controlled disease”
  – Controlled disease was defined as “clear” or “almost clear” disease with at least a 2-step improvement based on IGA
  – Subjects with mild disease at baseline were required to achieve “clear” disease for treatment to be considered a success

• The secondary response criterion was the percentage change in Psoriasis Area and Severity Index (PASI) score assessed at Weeks 4 and 8

• In this subanalysis, subjects were classified according to Fitzpatrick skin type and grouped as either skin type I-III or IV-VI
Results

• 1152 subjects were randomized

<table>
<thead>
<tr>
<th></th>
<th>C/BD</th>
<th>BD</th>
<th>C</th>
<th>V</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>482</td>
<td>479</td>
<td>96</td>
<td>95</td>
</tr>
</tbody>
</table>

• Baseline characteristics were comparable across all treatment groups (including age, gender, race, and ethnicity)
  – The majority of subjects recorded skin types II (white; always burns easily; tans minimally), III (white; burns moderately; tans) or IV (white; burns minimally; always tans well)
  – 89.1% White
  – 6.2% African American, and other races comprised the rest of the subjects
  – 14.7% Hispanic/Latino ethnicity
  – Mean PASI 7.9
Figure 1. Fitzpatrick Skin Type Distribution at Baseline Among All Randomized Subjects*

*1152 subjects were randomized to 1 of 4 treatment groups
Figure 2. Controlled Disease With Calcipotriene and Betamethasone Dipropionate at Weeks 4 and 8

• Subanalysis of C/BD treatment by skin type showed no difference in the rate of controlled disease at Weeks 4 and 8.

Fitzpatrick skin types I-III vs IV-VI at Week 4; \( P = .71 \)
Fitzpatrick skin types I-III vs IV-VI at Week 8; \( P = .87 \)
Figure 3. Mean Percent Change in PASI With Calcipotriene and Betamethasone Dipropionate at Weeks 4 and 8

• Subanalysis of C/BD treatment by skin type showed no difference in the percentage change in PASI score from baseline to Week 4 and Week 8.

Fitzpatrick skin types I-III vs IV-VI at Week 4; \( P = 0.93 \)
Fitzpatrick skin types I-III vs IV-VI at Week 8; \( P = 0.53 \)
Conclusions

• No difference in efficacy response to treatment with calcipotriene plus betamethasone dipropionate topical suspension was found between patients with Fitzpatrick skin types I-III and those with skin types IV-VI