**INTRODUCTION**

- Roflumilast cream (ARQ-151), a phosphodiesterase-4 (PDE-4) inhibitor, is under investigation as a once-daily topical treatment for plaque psoriasis.
- In a randomized, double-blind, placebo-controlled study of adults with chronic plaque psoriasis, roflumilast cream administered once daily was superior to placebo cream.

**OBJECTIVE**

To assess the effect of roflumilast cream on various PRO related to itch.

**METHODS**

- Design: parallel, randomized, double-blind, vehicle-controlled phase 2b study.
- Location: 3 sites in the United States.
- **eligibility**

**EXCLUSION**

- Pregnant or breastfeeding women.
- Inability to give informed consent.
- History of moderate to severe chronic plaque psoriasis requiring an effective systemic or biologic therapy.
- History of moderate to severe chronic plaque psoriasis requiring an effective systemic or biologic therapy.
- **expected outcomes**

**ENDPOINTS**

- **Primary**
  - IGA “clear” or “almost clear” at Week 6
  - Improvement in Itch-Related Sleep Loss NRS assessed intensity of sleep loss

- **Secondary**
  - Improvement in severity of itch based on Item 1 of the PSD.
  - Improvement in severity of itch based on Item 2 of the PSD.
  - Improvement in burden of itch based on Item 2 of the PSD.

**RESULTS**

- **baseline characteristics**

**Table 1. Baseline Characteristics**

<table>
<thead>
<tr>
<th>Age, years (mean)</th>
<th>Sex, male (n, %)</th>
<th>Race, n (%), White</th>
<th>Treatment, n (%)</th>
<th>Psoriasis-affected BSA, % (mean score)</th>
<th>PASI, mean score (SD)&lt;br&gt;</th>
<th>WI-NRS, mean score* (SD)&lt;br&gt;</th>
<th>PSD Item 2, Itch Burden,*&lt;br&gt;</th>
<th>LS Mean Change in WI-NRS Score&lt;br&gt;</th>
<th>Baseline&lt;br&gt;</th>
<th>Week 2&lt;br&gt;</th>
<th>Week 6&lt;br&gt;</th>
<th>Week 12&lt;br&gt;</th>
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</thead>
<tbody>
<tr>
<td>51.7 (14.1)</td>
<td>56 (51.4)</td>
<td>244 (73.9)</td>
<td>0.3% (n=109)</td>
<td>7.7 (3.6)</td>
<td>5.2 (3.0)</td>
<td>6.3 (4.0)</td>
<td>5.9 (3.6)</td>
<td>−0.3 (3.0)</td>
<td>−0.7 (3.0)</td>
<td>−0.5 (3.3)</td>
<td>−0.2 (3.1)</td>
<td>−0.4 (3.2)</td>
</tr>
<tr>
<td>54.4 (14.2)</td>
<td>62 (54.9)</td>
<td>201 (60.8)</td>
<td>0.15% (n=113)</td>
<td>8.0 (3.9)</td>
<td>5.5 (3.2)</td>
<td>6.3 (4.0)</td>
<td>6.2 (3.7)</td>
<td>−0.7 (3.3)</td>
<td>−0.9 (3.1)</td>
<td>−0.8 (3.6)</td>
<td>−0.7 (3.5)</td>
<td>−0.7 (3.3)</td>
</tr>
<tr>
<td>55.5 (13.5)</td>
<td>67 (61.5)</td>
<td>208 (63.1)</td>
<td>Vehicle (n=113)</td>
<td>7.6 (3.1)</td>
<td>5.5 (3.2)</td>
<td>6.2 (4.0)</td>
<td>6.1 (3.6)</td>
<td>−0.4 (3.1)</td>
<td>−0.7 (3.1)</td>
<td>−0.6 (3.3)</td>
<td>−0.5 (3.0)</td>
<td>−0.6 (3.1)</td>
</tr>
</tbody>
</table>

**Figure 1. Study Design**

**Figure 2. WI-NRS Score “What was the worst level of itch over the past 24 hours?”**

- The graph shows the mean WI-NRS score at baseline and Week 2 for the three treatment groups. The score is represented on a scale from 0 (no itch) to 10 (itch as bad as you can imagine).

**Figure 3. Proportion of Patients With a WI-NRS Score ≥6 at Baseline Who Achieved a Baseline WI-NRS Score ≤3 at Week 2**

- The figure illustrates the proportion of patients achieving a decrease in WI-NRS score from baseline to Week 2, with each group depicted in a different color.

**Figure 4. PSD NRS Item 2 Score”How intense was your itch-related sleep loss over the past 24 hours?”**

- The graph presents the mean NRS score for Item 2 of the PSD at baseline and Week 2 for the three treatment groups, illustrating the reduction in itch-related sleep loss.

**Figure 5. Itch-Related Sleep Loss NRS Score: “How intense was your itch-related sleep loss over the past 24 hours?”**

- The figure shows the mean NRS score for the Itch-Related Sleep Loss measure at baseline and Week 2 for the three treatment groups, highlighting the improvement in sleep loss.

**Figure 6. Itch-Related Sleep Loss NRS Score:**

- The graph compares the Itch-Related Sleep Loss NRS scores among the three treatment groups (Vehicle, Roflumilast 0.3%, Roflumilast 0.15%) at baseline and Week 2.

**Discussion**

- Robust improvements in severity of itch based on Item 1 of the PSD were observed for both roflumilast 0.3% and 0.15% at Weeks 2 through 12 (P < 0.012 vs vehicle).

**CONCLUSIONS**

- Roflumilast and roflumilast 0.15% were superior to vehicle in achieving “clear” or “almost clear” skin at Week 6 and Week 12.

**REFERENCES**