Roflumilast Cream (ARQ-151) Improved Itch Severity and Itch-Related Sleep Loss in Adults With Chronic Plaque Psoriasis in a Phase 2b Study

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INTRODUCTION

- Roflumilast cream (ARQ-151), a phosphodiesterase 4 (PDE4) inhibitor, is under investigation as a once-daily topical treatment for plaque psoriasis.
- In a randomized, double-blind, phase 2b trial of 335 adults with chronic plaque psoriasis, roflumilast cream administered once daily was superior to vehicle for the primary end point.
- Primary end point: a ≥4-point change in Itch Burden (PSD Item 2) from baseline based on Investigator Global Assessment (IQA) at 6 weeks

OBJECTIVE

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

METHODS

- Design: parallel, randomized, double-blind, vehicle-controlled phase 2b study
- Location: 30 sites in the United States and Canada

RESULTS

- Baseline characteristics are presented in Table 1.
- Baseline characteristics are presented in Table 2.

CONCLUSIONS

- Treatment-emergent AEs were uncommon in this study and were similar across treatment groups (Table 2).
- More patients discontinued the study due to an AE in the vehicle group than in the roflumilast groups.
- Severity of application site pain was low and similar to vehicle
- 97% of AEs were rated mild or moderate

Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Age (years), mean (SD)</th>
<th>Roflumilast 0.15% (n=113)</th>
<th>Roflumilast 0.3% (n=109)</th>
<th>Placebo (n=109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>57 (11)</td>
<td>56 (11)</td>
<td>58 (11)</td>
<td></td>
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</tbody>
</table>

Table 2. Summary of AEs

<table>
<thead>
<tr>
<th>AEs</th>
<th>Roflumilast 0.15% (n=113)</th>
<th>Roflumilast 0.3% (n=109)</th>
<th>Placebo (n=109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most common (≥2%)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Nasopharyngitis</td>
<td>2 (1.8)</td>
<td>3 (2.7)</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>7 (6.4)</td>
<td>3 (2.7)</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>5 (4.5)</td>
<td>3 (2.7)</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>Headache</td>
<td>5 (4.5)</td>
<td>4 (3.7)</td>
<td>4 (3.7)</td>
</tr>
<tr>
<td>Itch-related sleep loss NRS</td>
<td>1 (1.8)</td>
<td>1 (0.9)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Sensory measurement disorder</td>
<td>2 (1.8)</td>
<td>3 (2.7)</td>
<td>4 (3.7)</td>
</tr>
</tbody>
</table>

REFERENCES


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DISCLOSURES

ARS, AK, and OAD are employees of Arcutis Biotherapeutics, Inc. and hold stock/stock options in the company. ARS, AK, and OAD received personal fees, consulting fees, and other fees from Arcutis Biotherapeutics, Inc. and outside companies related to the results presented in this poster. MPO, JMO, and NMM are employees of Arcutis Biotherapeutics, Inc. and hold stock/stock options in the company. MPO, JMO, and NMM received personal fees, consulting fees, and other fees from Arcutis Biotherapeutics, Inc. and outside companies related to the results presented in this poster.