Once-Daily Roflumilast Foam 0.3% Improves Severity and Burden of Itch in Patients With Scalp and Body Psoriasis in a Randomized, Double-blind, Vehicle-Controlled Phase 2b Study

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INTRODUCTION

• In patients with psoriasis, about 80% have scalp involvement.
• Scalp involvement is often associated with itch
• The bioecologic burden of scalp psoriasis is significant
• Fingernail and tinea capitis are common associated conditions
• Treatment of scalp psoriasis is difficult because of variable severity, extent, and location
• Roflumilast cream was previously developed for the treatment of severe chronic obstructive pulmonary disease
• Treatment failure with scalp psoriasis has been associated with treatment adherence

METHODS

• This was a double-blind, vehicle-controlled trial (Figure 1).
• Eligible patients were adults and adolescents ≥12 years old with scalp involvement for at least 6 months
• Patients were randomized 2:1 to roflumilast or matching vehicle foam
• At the primary efficacy endpoint, the α was partitioned to test secondary endpoints.
• For continuous measures, an ANOVA was performed on the change from baseline
• Per-protocol analysis included all patients who completed the study

RESULTS

• A total of 304 patients were randomized to roflumilast foam 0.3% (n=200) or vehicle foam (n=104; intent-to-treat [ITT] population; n=198)
• Roflumilast foam (n=96)

• Vehicles foam (n=104)

Primary Efficacy Endpoint: Scalp Investigator Global Assessment (S-IGA)

• Significant improvements were observed in S-IGA success for both roflumilast foam (40.7%) and vehicle foam (24.7%)
• Roflumilast foam was non-inferior to vehicle foam

Secondary Efficacy Endpoints

• Improvement in the Investigator Global Assessment of Scalp (I-IGA)
• Improvement in the Investigator Global Assessment of Body (B-IGA)
• Improvement in the Dermatology Life Quality Index (DLQI)
• Improvement in the Psoriasis Symptom Diary (PSD)
• Improvement in the Psoriasis Scalp Severity Index (PSSI)
• Improvement in the SI-NRS

Conclusions

• Roflumilast foam significantly improves scalp and body psoriasis at week 8
• Roflumilast foam is well-tolerated and has a favorable adverse event profile

Table 1. Patient Disposition

<table>
<thead>
<tr>
<th>Group</th>
<th>Randomized (n=304)</th>
<th>Intent-to-treat (n=200)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roflumilast foam</td>
<td>200</td>
<td>165</td>
</tr>
<tr>
<td>Vehicle foam</td>
<td>104</td>
<td>39</td>
</tr>
</tbody>
</table>

Table 2. Baseline Disease Characteristics (ITT Population)

<table>
<thead>
<tr>
<th>Group</th>
<th>Roflumilast foam 0.3% (n=165)</th>
<th>Vehicle foam (n=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SI-NRS, mean (SD)</td>
<td>6.7 (2.48)</td>
<td>6.8 (2.3)</td>
</tr>
<tr>
<td>B-IGA Success</td>
<td>80%</td>
<td>50%</td>
</tr>
<tr>
<td>Psoriasis Symptom Diary</td>
<td>3.1%</td>
<td>5.6%</td>
</tr>
<tr>
<td>PSSI, mean (SD)</td>
<td>8 (2.45)</td>
<td>8.2 (2.4)</td>
</tr>
<tr>
<td>DLQI, mean (SD)</td>
<td>6.6 (5.18)</td>
<td>6.8 (4.66)</td>
</tr>
</tbody>
</table>

Figure 2. Percentages of Patients Achieving S-IGA Success (A) and B-IGA Success (B)

Figure 3. Mean % CfB (95% CI)

Figure 5. LS Mean Change From Baseline in DLQI

Table 3. Adverse Events

<table>
<thead>
<tr>
<th>Group</th>
<th>Roflumilast foam 0.3% (n=198)</th>
<th>Vehicle foam (n=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEAEs, n (%)</td>
<td>46 (23.2)</td>
<td>20 (10.5)</td>
</tr>
<tr>
<td>Patients with any TEAE</td>
<td>46 (23.2)</td>
<td>20 (10.5)</td>
</tr>
<tr>
<td>Patients with any serious AE</td>
<td>11.5%</td>
<td>3.1%</td>
</tr>
<tr>
<td>Patients who discontinued study due to AE</td>
<td>5.6%</td>
<td>2.6%</td>
</tr>
</tbody>
</table>

CONCLUSIONS

• Patients with scalp psoriasis need topical treatments that provide effective control of psoriasis with low incidence of side effects
• In this large study, once-daily roflumilast foam significantly improved both scalp and body psoriasis, supported by improvements in measures of itch and IGA
• Scalp and body itch abated by week 2 with further reduction throughout the study
• Roflumilast foam was well-tolerated with low rates of treatment-emergent AEs, application-site AEs, and discontinuation due to AE
• Rates of adverse events were similar to vehicle
• Favorable safety profile and encouraging efficacy results warrant further investigations in non-inferiority randomized trials and as a potential novel therapy for the treatment of scalp and body psoriasis

REFERENCES


ACKNOWLEDGEMENTS

• This study was supported by Arcutis Biotherapeutics, Inc.
• Abridged results presented by Dr. Javier Alonso-Llamazares at the International Society of Dermatology Meeting, 2021.
• All authors contributed to the study design, data collection, data analysis, and manuscript preparation.

DISCLOSURES

• All authors declare no relevant conflicts of interest.
• Dr. Papp and Dr. Saavedra are on the advisory board for Arcutis Biotherapeutics, Inc.

Presented at the 2021 Fall Clinical Dermatology Conference, Las Vegas, NV, USA, October 21-24, 2021