Once-Daily Roflumilast Foam 0.3% for Scalp and Body Psoriasis: A Randomized, Double-blind, Vehicle-Controlled Phase 2b Study

Leon H. Kirck,1 Angela Moore,2 Neal Bhatia,3 Alim R. Devani,4 Zoe D. Dragois,5 Janet DuBois,6 Melinda J. Goodherder,7 Steven E. Kemper,8 Edward Lain,9 Mark Lee,10 Dedee F. Murrell,11 Kim A. Papp,12 David R. M. Pariser,13 Rodney Sinclair,14 Matthew Zirwas,15 Patrick Burnett,16 Robert C. Higham,16 Lynn Navale,16 David R. Berk,16

1Kaiser School of Medicine at Mount Sinai, NY; 2Indiana Medical Center, Indianapolis, IN; 3Physicians Skin Care, PLLC, Louisville, KY; 4And Skin Sciences, PLLC, Louisville, KY, USA; 5Arbogast Research, Atlanta, TX, USA; 6Baylor University Medical Center, Dallas, TX, USA; 7University of California, San Diego, CA, USA; 8Dermatological Surgery Clinical Study, Frisco, TX, USA; 9Dermatology Research Institute, Skin Health & Wellness Centre and Probity Medical Research, Calgary, AB, Canada; 10Dermatology Consulting, High Point, NC, USA; 11DermResearch, Inc., Austin, TX, USA; 12SkinCentre for Dermatology, Probity Medical Research and Queens University, Peterborough, ON; 13Pfizer, Bursley Mills, South Africa; 14American Academy of Dermatology, Austin, TX, USA; 15SkinResearch, Brisbane, Australia; 16Probity Medical Research and F. Perry Medical Research, Inc., OH, Canada; 17Eastern Virginia Medical School and Virginia Dermatology Research, Inc., Norfolk, VA, USA; 18S2c Dermatology, East Melbourne, Australia; 19Dermatologists of the Central States, Probity Medical Research, and Ohio University, Athens, OH, USA; 20Arcutis Biopharmaceuticals, Inc., Westlake Village, CA, USA

INTRODUCTION

• In patients with psoriasis, about 80% have scalp psoriasis (S-PsO)1
  – S-PsO is often associated with itch, the most burdensome symptom of psoriasis2
• Itching, flaking, and appearance of plaques on the scalp can cause social embarrassment and adversely impact quality of life3
  – Treatment of S-PsO is difficult because the hair may limit efficacy of creams and ointments and reduce treatment adherence4
• Roflumilast is a potent, nonsteroidal, phosphodiesterase-4 inhibitor being investigated as a topical treatment for various dermatologic conditions
  – Roflumilast foam (0.3%) is an emollient, water-based, moisturizing foam that can be used on the scalp or body
• Roflumilast cream met the primary and secondary endpoints and was well-tolerated in a phase 2b randomized, double-blind, vehicle-controlled trial in adults with psoriasis3

We investigated roflumilast foam for S-PsO and body PsO in a phase 2, randomized, double-blind, vehicle-controlled 8-week study (Figure 1)

Figure 1. Study Design

Table 2. Baseline Disease Characteristics (ITT Population)

<table>
<thead>
<tr>
<th>n (%)</th>
<th>Roflumilast Foam 0.3% (n=200)1</th>
<th>Vehicle Foam (n=104)</th>
<th>Overall (n=304)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISA, mean %</td>
<td>8.0</td>
<td>7.6</td>
<td>7.9</td>
</tr>
<tr>
<td>Baseline S-IGA</td>
<td>2 – Mild</td>
<td>38 (19)</td>
<td>14 (13.5)</td>
</tr>
<tr>
<td></td>
<td>3 – Moderate</td>
<td>151 (75.5)</td>
<td>80 (76.9)</td>
</tr>
<tr>
<td></td>
<td>4 – Severe</td>
<td>29 (14.5)</td>
<td>10 (9.6)</td>
</tr>
<tr>
<td>Baseline B-IGA</td>
<td>2 – Mild</td>
<td>60 (34.5)</td>
<td>39 (37.5)</td>
</tr>
<tr>
<td></td>
<td>3 – Moderate</td>
<td>119 (62.8)</td>
<td>60 (57.2)</td>
</tr>
<tr>
<td></td>
<td>4 – Severe</td>
<td>5 (3.0)</td>
<td>5 (4.8)</td>
</tr>
<tr>
<td>PSI-SI, mean (SD)</td>
<td>22.4 (12.5)</td>
<td>20.9 (11.7)</td>
<td>21.9 (12.3)</td>
</tr>
<tr>
<td>SI-NRS, 24 h, n (%)</td>
<td>6.4 (2.4)</td>
<td>6.6 (2.3)</td>
<td>6.5 (2.3)</td>
</tr>
<tr>
<td>SI-NRS, ≥4, n (%)</td>
<td>173 (86.5)</td>
<td>96 (92.3)</td>
<td>269 (88.5)</td>
</tr>
</tbody>
</table>

1Reason for discontinuation: patients were classifying baseline values due to fluctuation outside of the data-capture window and were not evaluable. ISA, study foroum on PsA, Study Investigator Global Assessment; PSI–Paronychia Area Severity Index; PSI-SI, Psoriasis Scalp Severity Index; SD, standard deviation; S-IGA, Scalp investigator Global Assessment; B-IGA, Body investigator Global Assessment.

Roflumilast foam significantly increased the percentage of patients with S-IGA Success at Week 8 (primary endpoint; Figure 2)

Figure 2. Percentage of Patients Achieving S-IGA Success

• Significantly more patients treated with roflumilast foam had B-IGA Success as early as Week 2 (Figure 3)

Figure 3. Percentage of Patients Achieving B-IGA Success

CONCLUSIONS

• Patients with scalp psoriasis need topical treatments that provide effective control of psoriasis with low incidence of side effects
• In this phase 2b study, once-daily roflumilast foam significantly improved both scalp and body psoriasis, apparent as early as 2 weeks after treatment initiation
• Roflumilast foam provided a robust and rapid reduction in itch that was maintained throughout the study
• Roflumilast foam was well-tolerated with low rates of treatment-emergent AEs, application-site AEs, and discontinuations due to AE
• Rates of these events were similar to vehicle
• Favorable safety profile and encouraging efficacy results warrant further investigation of once-daily roflumilast foam as a potential novel therapy for the treatment of scalp and body psoriasis

REFERENCES


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DISCLOSURES

LH, AM, MM, AR, DD, ZS, GS, US, EJ, WJ, WR, KE, DWM, DDK, AM, and NZ are investigators and/or consultants for Arcutis Biopharmaceuticals, Inc. and received payments/fees/paying for travel/honouraria, shipping, speaking fees, or salary from Arcutis Biopharmaceuticals, Inc. or any or some employees of Arcutis Biopharmaceuticals, Inc. Additional disclosures provided on request.