The Safety and Efficacy of Roflumilast Cream 0.15% and 0.05% in Atopic Dermatitis: Phase 2 Proof-of-Concept Study

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INTRODUCTION

- The prevalence of atopic dermatitis (AD) is high, affecting 15% to 20% of the population worldwide.1
- The majority of patients with AD are managed with topical corticosteroids (TCS), emollients, and topical calcineurin inhibitors.2
- However, the chronic nature of AD results in frequent use of AD medications, which can lead to skin atrophy, striae, and hyperpigmentation.3
- Other treatment options include tacrolimus and pimecrolimus, which have been associated with increased cost and poorer adherence.4
- Topical corticosteroids (TCS) are useful for treating acute exacerbations of AD, but their long-term use is limited due to side effects and poor adherence.5
- Roflumilast cream is in phase 3 development for plaque psoriasis.6

METHODS

- Randomized, double-blind, vehicle-controlled multicenter phase 2 study (ClinicalTrials.gov: NCT04686056).

OBJECTIVE

- To assess the short-term safety and efficacy of once-daily (QD) topical roflumilast cream in patients with mild to moderate AD.

RESULTS

- Overall, patients were recruited from 3 sites in Canada and 19 sites in the United States and assigned to roflumilast 0.15% (n=45), roflumilast 0.05% (n=46), or vehicle (n=45).
- Secondary and exploratory endpoints showed significant improvement with roflumilast cream over vehicle at Week 4 (Figure 3).
- Data presented for intent-to-treat population. CI: confidence interval; EASI: Eczema Area and Severity Index; vIGA-AD: Validated Investigator Global Assessment for Atopic Dermatitis; WI-NRS: Worst Itch Numeric Rating Scale.

CONCLUSIONS

- Efficacy of roflumilast cream continued to improve through Week 4 (Figure 4).
- Statistical significance was reached for other efficacy endpoints.
- Continued efficacy through Week 4 was observed.

REFERENCES


ACKNOWLEDGEMENTS

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DISCLOSURES

- The authors have no conflicts of interest to disclose.
- The study was presented at the 40th Annual Fall Clinical Dermatology Conference, October 29–November 1, 2020.

Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Roflumilast 0.15% (n=45)</th>
<th>Roflumilast 0.05% (n=46)</th>
<th>Vehicle (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), years</td>
<td>33 (7.3)</td>
<td>31 (6.7)</td>
<td>29 (6.4)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>White 24 (53.3)</td>
<td>32 (69.6)</td>
<td>32 (71.1)</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td>White 24 (53.3)</td>
<td>32 (69.6)</td>
<td>32 (71.1)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td>Male 22 (48.9)</td>
<td>21 (45.6)</td>
<td>18 (40.0)</td>
</tr>
<tr>
<td>Exposed skin surface area (BSA), %</td>
<td>1.5-35%</td>
<td>1.5-35%</td>
<td>1.5-35%</td>
</tr>
<tr>
<td>EASI, mean score (SD)</td>
<td>2.8 (0.4)</td>
<td>2.8 (0.4)</td>
<td>2.8 (0.4)</td>
</tr>
<tr>
<td>vIGA-AD score, mean (SD)</td>
<td>9.5 (4.1)</td>
<td>8.4 (4.1)</td>
<td>9.2 (3.9)</td>
</tr>
<tr>
<td>WI-NRS, mean score (SD)</td>
<td>3.0 (1.1)</td>
<td>2.9 (1.1)</td>
<td>2.9 (1.1)</td>
</tr>
<tr>
<td>LS Mean Change From Baseline, % (95% CI)</td>
<td>-5.0 (SEK 0.6)</td>
<td>-4.3 (SEK 0.6)</td>
<td>-4.8 (SEK 0.6)</td>
</tr>
</tbody>
</table>

Table 2. Summary of AEs

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Roflumilast 0.15% (n=45)</th>
<th>Roflumilast 0.05% (n=46)</th>
<th>Vehicle (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>vIGA-AD score of “Clear” or “Almost Clear”</td>
<td>20 (44.4)</td>
<td>21 (45.6)</td>
<td>18 (40.0)</td>
</tr>
<tr>
<td>EASI Percent Change From Baseline</td>
<td>-72.3 (95% CI)</td>
<td>-69.4 (95% CI)</td>
<td>-72.3 (95% CI)</td>
</tr>
<tr>
<td>TEAEs</td>
<td>12 (26.7)</td>
<td>10 (21.7)</td>
<td>6 (13.3)</td>
</tr>
<tr>
<td>TEAE leading to study discontinuation</td>
<td>1 (2.2)</td>
<td>1 (2.2)</td>
<td>1 (2.2)</td>
</tr>
<tr>
<td>SAEs</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 1. Study Design

Figure 2. Attitude GIC Change From Baseline at Week 4 (Primary Endpoint)

Figure 3. Secondary and Exploratory Endpoints showed significant improvement with roflumilast cream over vehicle at Week 4 (Figure 3).

Figure 4. Secondary and Exploratory Endpoints showed significant improvement with roflumilast cream over vehicle at Week 4 (Figure 3).