Rapid and Early Onset of Itch Relief with Tapinarof Cream 1% Once Daily in Two Pivotal Phase 3 Trials in Adults and Children Down to Two Years of Age with Atopic Dermatitis

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INTRODUCTION

Pruritus is the most bothersome symptom for patients with atopic dermatitis (AD), and has a significant negative impact on health-related quality of life.1

Pruritus can negatively affect physical activity, school attendance and learning, sleep, and psychological well-being.2

Relief from AD symptoms, such as pruritus, has significant efficacy in disease management.3

Table 1. Baseline Demographics and Disease Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>ADORING 1 (n=429)</th>
<th>ADORING 2 (n=420)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>15.6 (16.5)</td>
<td>16.4 (16.2)</td>
</tr>
<tr>
<td>Sex, % males</td>
<td>54.1</td>
<td>51.9</td>
</tr>
<tr>
<td>VIGA-ADTM score &lt; 3</td>
<td>78.2%</td>
<td>81.6%</td>
</tr>
<tr>
<td>EASI score ≥ 15</td>
<td>83.1</td>
<td>82.6</td>
</tr>
<tr>
<td>BSA 5%–35%</td>
<td>66.2%</td>
<td>68.6%</td>
</tr>
<tr>
<td>% of patients with AD duration</td>
<td>4.2</td>
<td>5.8</td>
</tr>
</tbody>
</table>

Table 2. Itch Response over Time (Days)

<table>
<thead>
<tr>
<th>Variable</th>
<th>ADORING 1 (n=429)</th>
<th>ADORING 2 (n=420)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean daily PP-NRS</td>
<td>–3.0 (2.8)</td>
<td>–1.2 (2.2)</td>
</tr>
<tr>
<td>Mean peak PP-NRS</td>
<td>–2.0</td>
<td>–2.2</td>
</tr>
<tr>
<td>Mean change in PP-NRS score</td>
<td>–2.1</td>
<td>–2.4</td>
</tr>
</tbody>
</table>

RESULTS

Baseline Patient Demographics and Disease Characteristics

The analyses included 429 tapinarof-treated and 227 vehicle-treated patients (Table 1). Mean baseline PP-NRS scores were similar across treatment groups in ADORING 1 and 2.

Safety

No serious AEs or discontinuations were reported. The most common AEs in the tapinarof and vehicle groups were pruritus (48.1% vs 35.7%) and AD symptom flare (21.1% vs 15.6%). There were no new or unexpected AEs attributable to tapinarof.

MATERIALS AND METHODS

Trial Design

In the ADORING 1 and 2 phase 3 trials, patients with AD were randomized 2:1 to tapinarof cream 1% or vehicle QD for 8 weeks (Figure 1). Following the double-blind period, patients could enter an open-label, long-term extension trial (ADORING 3) or complete a follow-up visit 1 week after the end of the double-blind period (Figure 1).

Figure 1. ADORING 1 and 2 Trial Design

Patients with atopic dermatitis

- Age ≥ 12 years
- VIGA-ADTM score ≥ 3†
- BSA 5–35%
- Pruritus affecting the back of the leg at baseline. At Week 4, the primary endpoint (vIGA-ADTM score of 0 or almost clear (0) and ≥2-grade improvement) was achieved

Objective

To evaluate the safety and tolerability of tapinarof cream 1% in adult and adolescent patients with moderate-to-severe AD

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- To assess the safety and tolerability of tapinarof cream 1% in adult and adolescent patients with moderate-to-severe AD

Patient who Achieved the Primary Endpoint at 4 Weeks

The patient who achieved the primary endpoint at 4 weeks was a 25-year-old male with AD duration of 12 years. He was randomized to the vehicle group in ADORING 1 and then to the tapinarof group in ADORING 2.

Patient who Achieved the Primary Endpoint at 8 Weeks

The patient who achieved the primary endpoint at 8 weeks was a 19-year-old female with AD duration of 5 years. She was randomized to the tapinarof group in both ADORING 1 and 2.

REFERENCES


CONCLUSIONS

Tapinarof cream 1% demonstrated rapid itch relief from 24 hours after initial application, with improvements increasing through week 8 and across all visits in itch relief over 8 weeks with AD. Significant improvements in pruritus versus vehicle were seen as early as Week 1 and continued through Week 8. The minimal clinically important difference of 2-point reduction in mean PP-NRS score was not reached in either study through Week 8 in both trials.

Figure 2. Rapid and Significant Relief of Itch in the Tapinarof Cream 1% Group (n=270)

Figure 3. Rapid and Significant Relief of Itch in the Tapinarof Cream 1% Group (n=270)

Figure 4. Achievement of Primary Endpoint and Complete Resolution of Itch by Week 4 in a 7-Year-Old Patient with AD Treated with Tapinarof Cream 1% QD

ACKNOWLEDGMENTS

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PATIENTS

- To achieve the primary endpoint at 4 weeks in adult and adolescent AD patients

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