Tapinarof Cream 1% Once Daily for the Treatment of Extensive Atopic Dermatitis in Adolescents and Children: 4-Week Maximal-Use Trial

Amy Paller,1 Adelaide A. Hebert,2 John E. Ester,3 Philip M. Brown,2 David S. Rubenstein,2 Stephen C. Piscitelli4

1Northwestern University Feinberg School of Medicine, Chicago, IL, USA; 2McGowan School of Medicine and Children’s Memorial Hermann Hospital; UTHealth McGovern, Houston, TX, USA; 3Dermavant Sciences, Inc., Morrisville, NC, USA

INTRODUCTION

Atopic dermatitis (AD) is a chronic, inflammatory skin disease, characterized by intense pruritus and eczematous lesions. AD can substantially impact patients’ sleep and quality of life.5

There is a need for efficacious, non-steroidal topical AD therapy, with restrictions to duration, extent of use, and application sites.

Tapinarof (VTAMA), Dermavant Sciences, Inc. (USA) is a first-in-class, non-steroidal, topical aryl hydrocarbon receptor (AhR) antagonist approved by the Food and Drug Administration for the treatment of plaque psoriasis in adults, and under investigation for the treatment of plaque psoriasis in children under 2 years of age and for AD in adults and children down to 2 years of age.

Tapinarof cream 1% once daily (QD) demonstrated significant efficacy versus vehicle and was well tolerated in adults with mild to severe plaque psoriasis in two 12-week, phase 3 trials, PASI90 (NCT03268535) and PASI90-2 (NCT03295390).1

OBJECTIVES

To present the 4-week, maximal-use AD trial design and patient baseline characteristics

METHODS

Adolescents and children with AD

METHODS

Trial Design

1. In this phase 2a, multicenter, open-label trial (NCT5934586), adolescents and children with extensive AD will receive tapinarof cream 1% QD for 27 days (Figure 2). Patients or caregivers will be instructed to apply a thin layer of tapinarof cream, sufficient to cover each lesion before bedtime.

2. Tapinarof PK will be assessed Day 1 (Baseline) and 28

The screening blood sample will be used for baseline pre-dose PK assessment of the patient or caregiver.

Key inclusion and exclusion criteria are shown in Table 1

Eligible patients completing the trial have the option to enroll in an open-label, long-term extension trial (NCT53421574) to receive up to an additional 48 weeks of tapinarof treatment.

Table 2. Baseline Demographics and Disease Characteristics

<table>
<thead>
<tr>
<th>Age group</th>
<th>Number (n)</th>
<th>Mean age (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>2–12 years</td>
<td>36</td>
<td>8.9 (4.9)</td>
<td>2–12</td>
</tr>
<tr>
<td>12–17 years</td>
<td>12</td>
<td>15.8 (1.8)</td>
<td>12–17</td>
</tr>
<tr>
<td>17–19 years</td>
<td>0</td>
<td></td>
<td></td>
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<tr>
<td>19–21 years</td>
<td>0</td>
<td></td>
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</tr>
</tbody>
</table>

RESULTS

Baseline Patient Demographics and Disease Characteristics

Patient demographics and disease characteristics are shown in Table 2.

Patients' baseline demographics and disease characteristics are shown in Table 2.

Equal proportions of patients (33.3\% [12/36]) were young children (2–6 years), children (7–11 years), and adolescents (12–17 years)

Most patients (77.8\%) across the three groups had a vIGA-AD score of 3 (moderate)

Demonstrated overall mean (SD) vIGA-AD score was 7.5 (4.8), with a range of 1–9 indicating moderate to severe AD

Overall mean (SD) vIGA-AD score was 8.6 (5.8), with a range of 0–26% to 0–26% of body surface area affected

CONCLUSIONS

In this phase 2a trial, tapinarof cream 1% QD demonstrated significant efficacy versus vehicle and was well tolerated in adolescents and adults with moderate to severe AD

Tapinarof cream 1% QD has shown minimal systemic absorption in adults with AD or psoriasis, with extensive ESIA affected up to 46%.

In addition, this maximal-use PK trial assessed the safety, tolerability, PK, and efficacy of tapinarof cream 1% QD in adolescents and children down to 2 years of age with extensive, moderate to severe AD

In adolescents and children, tapinarof cream 1% QD was well tolerated in children down to 2 years of age in three phase 3 clinical trials (ADORING 1 [NCT05104698], ADORING 2 [NCT52005268], and ADORING 3 [NCT32677775]).

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