Psoriasis is a chronic, immune-mediated disease characterized by scaly, erythematous, and pruritic plaques that can be painful, disfiguring, and severely impact quality of life.

There is a need for efficacious and well-tolerated topical therapies for plaque psoriasis without restrictions on duration, site, and extent of use, or concerns due to long-term adverse effects or local intolerance. However, no topicals with novel mechanisms have been US Food and Drug Administration (FDA)-approved in over 20 years.

Tapinarof is a first-in-class, non-steroidal, topical therapeutic aryl hydrocarbon receptor modulator (TAMAR) in development for the treatment of psoriasis and atopic dermatitis.

PSOARING 1 (NCT03956335) and PSOARING 2 (NCT03983990) were two pivotal phase 3 trials designed to assess the efficacy and safety of tapinarof cream 1% once daily (QD) in patients with mild-to-severe plaque psoriasis.

Primary efficacy endpoints and safety results from the two pivotal trials have been previously reported, demonstrating highly statistically significant efficacy and good tolerability of tapinarof cream 1% QD versus vehicle QD at 12 weeks.

### RESULTS

#### Study Design

In two identically designed, phase 3, multicenter (US and Canada), double-blind, vehicle-controlled randomized trials, patients with mild-to-severe plaque psoriasis were randomized 2:1 to tapinarof cream 1% QD or vehicle QD for 12 weeks (Figure 1).

Following the double-blind period, patients could enroll in an open-label, long-term extension trial or complete a follow-up visit 4 weeks after the end of treatment (Week 16).

![Figure 1. Study Design](image)

*Adult patients with stable plaque psoriasis

- **Aged 18–75 years**
- **PGA score ≥4**
- **BSA ≥3%–<20%**

**Vehicle QD (n=172)**

**Tapinarof 1% QD (n=340)**

**Tapinarof 1% QD (n=343)**

**Double-blind treatment (12 weeks)**

**Week 12**

**PGA 3 – Moderate**

**PGA 4 – Severe**

**PGA 5 – Very Severe**

**BSA**

*Proportion of patients, %

- **BSA affected, %**
  - 3 – Moderate
  - 4 – Severe

**TAPINAROF**

**Vehicle QD**

**Week 12**

**Mean age, years (SD)**

**Male, n (%)**

**Weight, kg (SD)**

**BMI, kg/m**

**Tapinarof 1% QD (n=340)**

**Vehicle QD (n=172)**

**Mean %BSA affected was 7.9 (4.8) and 7.6 (4.3) in PSOARING 1 and 2, respectively.**

### Primary Endpoint: PGA Response

As previously reported, PGA response rates were highly statistically significant in the tapinarof group versus the vehicle group in both PSOARING 1 and 2: 35.4% vs 6.0% and 40.2% vs 6.3% (both P<0.0001), respectively.

### Table 1. Baseline Patient Demographics and Disease Characteristics

<table>
<thead>
<tr>
<th>Measure</th>
<th>PSOARING 1</th>
<th>PSOAGING 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (SD)</td>
<td>50.0 (13.7)</td>
<td>50.0 (13.7)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>213 (62.6)</td>
<td>186 (54.8)</td>
</tr>
<tr>
<td>Weight, kg (SD)</td>
<td>917.2 (24.6)</td>
<td>923.6 (24.3)</td>
</tr>
<tr>
<td>BMI, kg/m² (SD)</td>
<td>31.4 (10.6)</td>
<td>31.8 (17.7)</td>
</tr>
<tr>
<td>PGA, n (%)</td>
<td>2 – Mild</td>
<td>179 (55.9)</td>
</tr>
<tr>
<td>3 – Moderate</td>
<td>70 (21.0)</td>
<td></td>
</tr>
<tr>
<td>4 – Severe</td>
<td>8 (2.4)</td>
<td></td>
</tr>
<tr>
<td>PASI, mean (SD)</td>
<td>8.7 (4.1)</td>
<td>9.1 (3.7)</td>
</tr>
<tr>
<td>EBB, mean (SD)</td>
<td>7.8 (4.1)</td>
<td>7.3 (4.1)</td>
</tr>
</tbody>
</table>

### Conclusions

Tapinarof cream 1% QD significantly improved all measures of disease activity and showed rapid, clear, and consistent separation versus vehicle as early as the first clinical assessment at Week 2.

These findings are consistent with the superior clinical efficacy and good tolerability profile of tapinarof cream reported previously.

Early improvements continued throughout the trials and did not reach maximal effect by Week 12, as confirmed by results from a long-term extension trial.

Tapinarof cream 1% QD has the potential to be the first topical, non-steroidal psoriasis treatment with a novel mechanism of action in over 20 years.

### References