Topical corticosteroids (TCSs) are efficacious but are also associated with adverse events (AEs) that can limit their use.1,2 Atopic dermatitis (AD) is a chronic, relapsing and remitting inflammatory skin disease characterized by pruritus that can substantially impact sleep and quality of life.3–5

OBJECTIVE

The primary objective of the study was to assess the proportion of adult and pediatric patients with AD who achieved vIGA-ADTM response* at Week 8 and who had ≥2-grade improvement in EASI and ≥75% reduction in pruritus (EASI75/PP-NRS75) at Week 8 with once daily Tapinarof Cream 1% compared to vehicle QD, using an Intention-to-treat (ITT), multiple imputation analysis. The primary endpoint was highly statistically significant with Tapinarof Cream 1% QD vs Vehicle QD: 55.8% vs 22.9% (95% CI 40.4, 68.9) and 59.1% vs 33.8% (95% CI 45.9, 67.0) for ≥2-grade improvement in EASI and ≥75% reduction in pruritus (EASI75/PP-NRS75) at Week 8, respectively. The secondary endpoint was also met with statistical significance with Tapinarof Cream 1% QD vs Vehicle QD: 42.5% vs 21.2% (95% CI 27.0, 52.0) and 39.9% vs 15.7% (95% CI 25.7, 55.4) for vIGA-ADTM response at Week 8 and ≥2-grade improvement in EASI and ≥75% reduction in pruritus (EASI75/PP-NRS75) at Week 8, respectively (Table 2).

RESULTS

Table 1: Baseline Demographics and Disease Characteristics

<table>
<thead>
<tr>
<th>Group</th>
<th>Age (years)</th>
<th>Gender (male/female)</th>
<th>Race</th>
<th>BMI (kg/m²)</th>
<th>EASI</th>
<th>BSA</th>
<th>vIGA-ADTM*</th>
<th>PP-NRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vehicle QD (n=270)</td>
<td>40.3 (11.8)</td>
<td>6.8 (2.3)</td>
<td>6.5 (2.4)</td>
<td>7.7 (2.1)</td>
<td>122 (89.1)</td>
<td>22.1 (6.6)</td>
<td>0.3 (0.1)</td>
<td>6.5 (2.4)</td>
</tr>
<tr>
<td>Tapinarof Cream 1% QD (n=137)</td>
<td>46.4 (11.8)</td>
<td>10.8 (2.3)</td>
<td>7.7 (2.1)</td>
<td>12.2 (8.3)</td>
<td>19.9 (5.6)</td>
<td>23.1 (8.1)</td>
<td>0.3 (0.1)</td>
<td>7.7 (2.1)</td>
</tr>
</tbody>
</table>

CONCLUSIONS

The current results suggest that Tapinarof Cream 1% QD is highly efficacious in the treatment of AD in children (≥2 years) and adults. Tapinarof Cream 1% QD is efficacious and safe for intermittent therapy for up to 52 weeks. Tapinarof Cream 1% QD is efficacious for the treatment of AD in pediatric and adult patients across a wide range of body mass index (BMI) and EASI score values. Tapinarof Cream 1% QD achieved highly statistically significant improvements in vIGA-ADTM response at Week 8, ≥2-grade improvement in EASI and ≥75% reduction in pruritus (EASI75/PP-NRS75) at Week 8 in a broad patient population with AD.

REFERENCES