**Apremilast in Pediatric Patients With Moderate to Severe Plaque Psoriasis: 16-Week Efficacy and Safety Results From the Phase 3, Randomized, Double-Blind, Placebo-Controlled SPROUT Study**

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**Introduction and Objective**

- Treatment options for pediatric patients with moderate to severe plaque psoriasis are limited
- SPROUT evaluated the efficacy and safety of apremilast (APR) compared with placebo (PBO) in pediatric patients

**Study Design and Patient Population**

- **Randomization:** 2:1 was stratified by age group
  - Patients weighing ≥ 20 to < 50 kg received APR 20 mg twice daily (BID); patients weighing ≥ 50 kg received APR 30 mg BID
- **Main Inclusion Criteria:** 6–17 years of age with moderate to severe psoriasis (Psoriasis Area and Severity Index [PASI] ≥ 12, body surface area [BSA] ≥ 10%, static Physician Global Assessment [sPGA] ≥ 3) inadequately controlled or intolerant to topical therapy
- **Primary Endpoint:** sPGA response (score of 0 [clear] or 1 [almost clear] with ≥ 2-point reduction from baseline) at week 16
- **Major Secondary Endpoint:** ≥ 75% reduction from baseline in PASI score (PASI-75)
- **Analysis:** Efficacy endpoints were analyzed for the intent-to-treat population; safety was analyzed for the safety population

**Baseline Characteristics**

- There were 120 patients in the ≥ 20- to < 50-kg group and 125 in the ≥ 50-kg group

<table>
<thead>
<tr>
<th>Age (n = 245)</th>
<th>PBO (n = 82)</th>
<th>APR (n = 163)</th>
<th>Total (n = 245)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6–11, n (%)</td>
<td>34 (41.5)</td>
<td>67 (41.1)</td>
<td>101 (41.2)</td>
</tr>
<tr>
<td>12–17, n (%)</td>
<td>48 (58.5)</td>
<td>96 (58.9)</td>
<td>144 (58.8)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>43 (52.4)</td>
<td>74 (45.4)</td>
<td>117 (47.8)</td>
</tr>
<tr>
<td>Duration of plaque psoriasis, mean (SD), y</td>
<td>4.0 (3.39)</td>
<td>4.3 (3.35)</td>
<td>4.2 (3.36)</td>
</tr>
<tr>
<td>sPGA score, n (%)</td>
<td>3.2 (0.81)</td>
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</tr>
<tr>
<td>PASI score, mean (SD)</td>
<td>19.5 (7.94)</td>
<td>20.0 (8.16)</td>
<td>19.8 (8.07)</td>
</tr>
</tbody>
</table>

**Key Takeaways**

- APR significantly reduced the psoriasis severity in pediatric patients with moderate to severe plaque psoriasis inadequately controlled or intolerant to topical therapy compared with PBO
- No new safety signals were identified; AEs were consistent with the known safety profile of APR

**Additional Results**

**PASI scores and affected BSA were significantly improved in patients treated with APR at week 16**

**Safety**

- No new safety signals were identified, and adverse events (AEs) were consistent with the known APR safety profile
- Rates of treatment-emergent AEs (TEAEs) leading to drug withdrawal were low (APR: 3.1%, PBO: 1.3%)
- Reasons for withdrawal included primarily gastrointestinal disorders for APR and suicidal ideation for PBO
- The most common TEAE was diarrhea
- 70% of these events of diarrhea in the APR group resolved within 3 days during the PBO-controlled period
- For a table of overall safety and TEAEs occurring in ≥ 5% of patients, scan the QR code

**References:**