Efficacy and Safety of Epicutaneous Immunotherapy for Peanut Allergy in Subjects Aged 1-4 Years With and Without Atopic Dermatitis in the EPITOPE Study

Rationale
- Atopic dermatitis (AD) is the strongest and most established risk factor for the development of food allergies, particularly in children.
- There is a high occurrence of AD in patients with peanut allergy, with a reported prevalence rate of ~60%-70%.
- It is hypothesized that patients with AD may require a different approach to immunotherapy.

Methods
- EPITOPE was a multicenter, randomized, double-blind, placebo-controlled phase 3 trial designed to evaluate the efficacy and safety of EPIT with VP250 among peanut-allergic young children aged 1 to <4 years.

Results
- **Study Design**
  - Phase 3 Global Study:
    - 362 peanut-allergic children (1 to <4 years of age) with peanut eliciting dose (ED) ≤300 mg were enrolled in the EPITOPE study.
    - Key inclusion criteria: baseline eliciting dose (ED) of ≤300 mg peanut protein,
      • 362 peanut-allergic children (1 to <4 years of age)
      • Key inclusion criteria: baseline eliciting dose (ED) of ≤300 mg peanut protein,
      • Baseline AD was common among study participants, as is often seen with the peanut-allergic population.

- **SCORAD**
  - The primary efficacy endpoint was the percent difference in AD severity in response to EPIT with VP250 and placebo after 12 months, as defined in Table 1.

- **TEAEs**
  - No SAEs were reported in the EPITOPE study.
  - Serious treatment-emergent adverse events (TEAEs) assessed as related to VP250 did not occur in any participant with AD and in one (2%) participant without AD.
  - Treatment-related TEAEs leading to permanent study discontinuation occurred in 6 (3.1%) participants with AD and 2 (4.2%) participants without AD.

- **SAEs**
  - The phase 3 EPITOPE study (NCT03211247) demonstrated that 12 months of daily EPIT with VP250 was statistically superior to placebo in desensitizing peanut-allergic young children aged 1 to <4 years with peanut allergy, with a reported prevalence rate of ~60%-70%.

Table 1: Definitive of Treatment Responder (Primary Efficacy Endpoint)

<table>
<thead>
<tr>
<th></th>
<th>ED of 12 Month</th>
<th>Ongoing Medical History of Eczema</th>
<th>Percentage of Responders (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCORAD Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>With AD</td>
<td>Without AD</td>
</tr>
<tr>
<td>ED &gt;1000 mg</td>
<td>95.5%</td>
<td>94.8%</td>
<td>94.9%</td>
</tr>
<tr>
<td>ED ≤1000 mg</td>
<td>86.9%</td>
<td>86.2%</td>
<td>86.1%</td>
</tr>
</tbody>
</table>

interaction effect between baseline AD and randomized treatment was not significant (P=0.42).

Table 2: Overall Summary of TEAEs by Ongoing Medical History of Eczema/AD

<table>
<thead>
<tr>
<th>Adverse Event Category, n (%)</th>
<th>Ongoing Medical History of Eczema/AD</th>
<th>Placebo, n=194</th>
<th>VP250, n=50</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any local AEs</td>
<td>No AD</td>
<td>36 (18.6%)</td>
<td>12 (24%)</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>With AD</td>
<td>19 (9.8%)</td>
<td>3 (6%)</td>
<td>0.38</td>
</tr>
<tr>
<td>Any SAEs</td>
<td>No AD</td>
<td>15 (7.7%)</td>
<td>2 (4%)</td>
<td>0.31</td>
</tr>
<tr>
<td></td>
<td>With AD</td>
<td>4 (2.0%)</td>
<td>0</td>
<td>0.12</td>
</tr>
</tbody>
</table>

CONCLUSIONS
- Twelve months of EPIT treatment with VP250 resulted in a significant response compared to placebo, irrespective of the ongoing AD status of study entry (Figure 2).
  - Consistent with these data, a previous subgroup analysis of peanut-allergic children aged 4-11 years demonstrated that the responder rate in those receiving VP250 was greater compared to placebo, regardless of whether participants had other atopic conditions.
  - Baseline AD was common among study participants, as is often seen with the peanut-allergic pediatric population.
  - Safety and tolerability profiles were similar in peanut-allergic young children randomized to VP250 or placebo, with no unexpected safety signals observed.

REFERENCES

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