Efficacy and Safety of Long-Term Epicutaneous Immunotherapy in Peanut-Allergic Children Aged 4 Through 7 Years in the Phase 3 PEOPLE Trial

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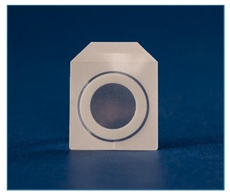
Rationale

- Peanut allergy (PA) is the most common food allergy, affecting 2.2% of US children younger than 17 years[1,2]
- Evidence is accumulating to suggest that allergic responses may be more modifiable in younger children than in older children. As such, prioritizing treatments that target younger age groups is important[3-5]
- VIASKIN®, a patch-based technology platform, is currently being investigated for the treatment of PA **(Figure 1)**. This novel approach to epicutaneous immunotherapy (EPIT) involves the administration of a peanut patch containing 250 µg peanut protein (VP250) to intact skin to induce desensitization[6-10]
- In the previously reported phase 3 PEPITES study (NCT02636699), daily EPIT with VP250 was statistically superior to placebo in desensitizing peanut-allergic children aged 4 through 11 years,[6] with greater responder rates in younger children aged 4 through 7 years[11]

Figure 1. VP250 Patch



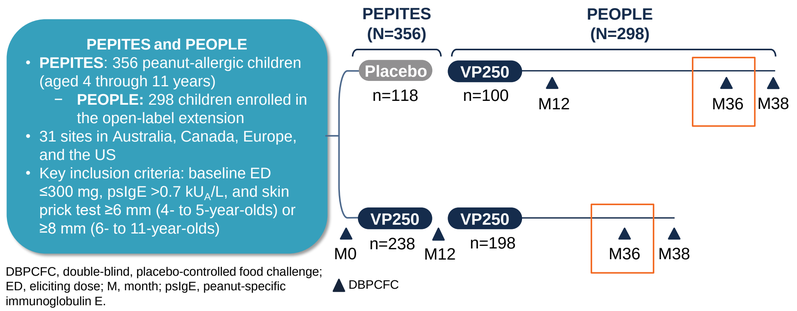
Objective

- To characterize the long-term efficacy and safety of daily EPIT with VP250 for PA in the subgroup of children aged 4 through 7 years in PEOPLE

Methods

- In PEPITES, peanut-allergic children aged 4 through 11 years were randomized 2:1 to VP250 or placebo for 12 months
- After 12 months of VP250 or placebo, PEPITES participants who completed the trial were eligible to enroll in PEOPLE for up to 36 months of active treatment **(Figure 2)**

Figure 2. Study Design Diagram



DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; M, month; psIgE, peanut-specific immunoglobulin E.

- Double-blind, placebo-controlled food challenges (DBPCFCs) were performed at Month (M) 12 and M36
- The eliciting dose (ED) was the dose at which allergic reaction signs or symptoms met the prespecified stopping criteria and ended the DBPCFC
- In PEPITES, the primary measure of treatment effect was the difference in response rates between active and placebo treatment groups
- Safety was assessed throughout the study according to frequency, severity, and relatedness of adverse events (AEs)
- A post hoc analysis among participants aged 4 through 7 years at study entry was completed

Key Points

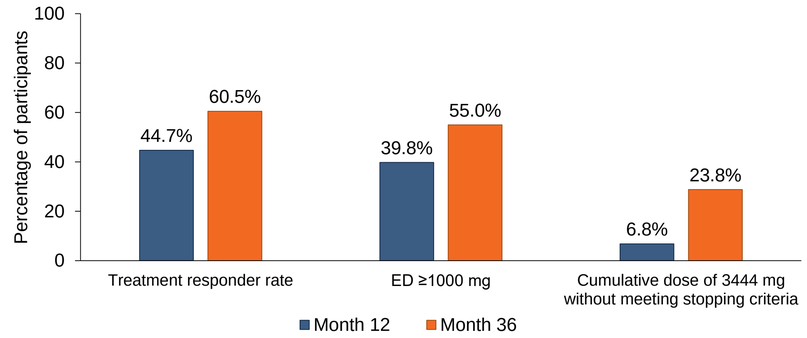
- Among children aged 4 through 7 years at PEPITES entry, treatment with VP250 showed continued increases in treatment effect with a consistently favorable safety profile out to 36 months
  - Among participants initially randomized to placebo, a treatment benefit was observed after 36 months, though lower in magnitude compared to those initially randomized to VP250; similar to previous studies, this may indicate that earlier treatment initiation provides greater treatment benefit
- These findings are consistent with recent results from EPITOPE and its open-label extension that demonstrated an increased treatment effect over multiple years of VP250 treatment in toddlers aged 1 through 3 years[4]
- These data support the potential of VP250 as a long-term treatment option for peanut-allergic children, if approved

RESULTS

Efficacy

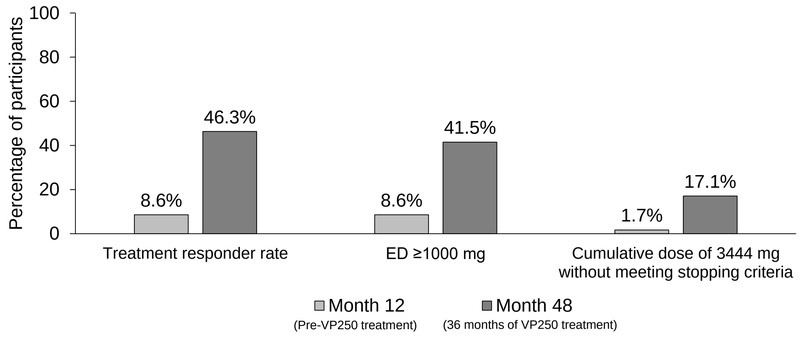
- Of PEOPLE participants (N=298), 161 (54%) were aged 4-7 years at treatment initiation in PEPITES
- Among participants who were randomized to active treatment in PEPITES (VP250+VP250, n=103), increases in treatment effect were observed from M12 to M36 of VP250 treatment **(Figure 3)**
  - The percentage of treatment responders increased from 44.7% at M12 to 60.5% at M36
  - The proportion of participants achieving an ED ≥1000 mg increased from 39.8% at M12 to 55.0% at M36
  - The proportion of participants consuming a cumulative dose of 3444 mg (equivalent to 12-14 peanuts) without meeting stopping criteria increased from 6.8% at M12 to 23.8% at M36

Figure 3. VP250 Efficacy Over Time in the VP250+VP250 Group



- Among participants initially randomized to placebo (placebo+VP250, n=58), a treatment benefit was observed after 36 months, similar to the VP250+VP250 group, though it was lower in magnitude **(Figure 4)**

Figure 4. Efficacy of 3 Years of VP250 in the Placebo+VP250 Group



Safety

- The safety profile in the subgroup of children aged 4 through 7 years was consistent with that observed in the overall 4- through 11-year-old population in PEOPLE **(Table 1)**
  - All participants experienced treatment-emergent adverse events (TEAEs), which were mostly mild to moderate in severity
- TEAEs considered related to VP250 were reported in 90.3% of participants in the VP250+VP250 group and in 94.8% of the placebo+VP250 group and mainly consisted of local application-site reactions
- Serious TEAEs considered related to VP250 were reported in 1 participant (VP250+VP250)

Table 1. Safety Profile in Children Aged 4 Through 7 Years

AE category, n (%)	VP250+VP250 (N=103)	Placebo+VP250 (N=58)
TEAEs	103 (100)	58 (100)
Mild	103 (100)	57 (98.3)
Moderate	76 (73.8)	40 (69.0)
Severe	5 (4.9)	10 (17.2)
Treatment-related TEAEs	93 (90.3)	55 (94.8)
Serious TEAEs	11 (10.7)	1 (1.7)
Treatment-related	1 (1.0)	0
TEAEs leading to permanent study treatment discontinuation	3 (2.9)	1 (1.7)
Treatment-related local TEAEs	93 (90.3)	54 (93.1)
Severe treatment-related local TEAEs	2 (1.9)	9 (15.5)
Anaphylactic reaction	18 (17.5)	5 (8.6)
Treatment-related	5 (4.9)	0
TEAEs leading to epinephrine use	19 (18.4)	10 (17.2)
Treatment-related TEAEs leading to epinephrine use	3 (2.9)	0
TEAEs leading to topical corticosteroid use	83 (80.6)	49 (84.5)
TEAEs leading to systemic or inhaled corticosteroid use	46 (44.7)	25 (43.1)

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