Poster
#379

Long-Term Safety Results of Epicutaneous Immunotherapy (EPIT) With Viaskin Peanut in Peanut-Allergic Children Aged 4 Through 11 Years in the Phase 3 PEOPLE Study

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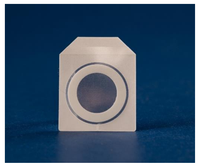
RATIONALE

- Viaskin, a patch-based technology platform, is currently being investigated for the treatment of peanut allergy. This novel approach to EPIT involves the administration of a peanut patch (VP250) containing 250 µg peanut protein to intact skin to induce desensitization (**Figure 1**)[1-5]
  - The safety and efficacy of 12 months of EPIT with VP250 have been previously established in phase 3 randomized clinical trials[1,5]

Figure 1: Viaskin Peanut Patch



- Maintenance treatment for allergen-specific immunotherapy has historically ranged from 3 to 5 years[6]; thus, it is important to characterize the long-term efficacy and safety of VP250[2]
- Interim 3-year results from PEOPLE (PEPITES Open-Label Extension) demonstrated[2]:
  - In the per-protocol population, defined as individuals who completed 3 years of VP250 treatment, 51.8% vs 40.4% (difference: 11.3%; 95% CI: 2.8, 19.6) reached an eliciting dose (ED) ≥1000 mg peanut protein at Month 36 vs Month 12 double-blind, placebo-controlled food challenge (DBPCFC), respectively
  - Daily VP250 was well tolerated; application-site reactions decreased in frequency and severity over time, and treatment adherence over 3 years was high (98.1%)

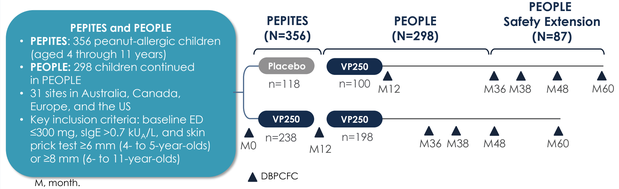
OBJECTIVE

- The aim of this analysis was to assess long-term safety of EPIT with VP250 during the PEOPLE extension safety period (Years 4 and 5 of treatment)

METHODS

- PEOPLE was an open-label trial designed to evaluate long-term efficacy and safety among children who previously participated in PEPITES (**Figure 2**)
  - Participants were aged 4 through 11 years at study entry
- In PEPITES, 356 peanut-allergic children aged 4 through 11 years were randomized 2:1 to VP250 or placebo for 12 months

Figure 2: Study Design Diagram



M, month.

- In PEOPLE, 298 participants (93.0% of PEPITES completers) received VP250 daily for up to either an additional 48 months if they were in the active treatment arm of PEPITES (VP250+VP250) or 60 months if they were in the placebo arm of PEPITES (placebo+VP250), for up to 60 months of active treatment in all participants
- Safety outcomes included duration and severity of treatment-emergent adverse events (TEAEs) and serious TEAEs
  - Adverse events (AEs) were assessed by investigators, with serious AEs defined according to the International Council for Harmonisation Good Clinical Practice
  - Skin reactions were graded by the site investigator from 0 to 4, according to the European Academy of Allergy and Clinical Immunology and the Global Allergy and Asthma Excellence Network, where grade 0 is no skin reaction and grade 4 is erythema and vesicles
  - Site investigators assessed the causality/relationship between the study drug and AE, including anaphylaxis, according to the causality criteria

RESULTS

- Of the 217 participants who completed PEOPLE Year 3, 87 (40%) participants continued treatment in the PEOPLE extension period of Years 4 and 5 (n=40 placebo+VP250, n=47 VP250+VP250); the safety data from these 87 participants over the 5-year study are included in this analysis (PEOPLE Extension Safety Population); 130 participants either elected not to continue or were ineligible
  - Mean age at the extension enrollment was 11.1 years (range 8-16), and 56.3% of participants were male
- Overall mean treatment compliance remained high at 5 years at 93.1%
- Over 5 years, all participants in the PEOPLE Extension Safety Population experienced a TEAE, with the majority considered mild or moderate in severity; most TEAEs were local application-site reactions (**Table 1**)
  - There was 1 serious treatment-related AE, which occurred in Year 1 of active treatment, and there were no permanent study discontinuations due to TEAEs
  - Treatment-related TEAEs leading to epinephrine use occurred in 1/87 (1.1%) participants (Year 1 only)
- Treatment-related anaphylactic reactions occurred in 2/87 (2.3%) participants (Years 1 and 2 only)

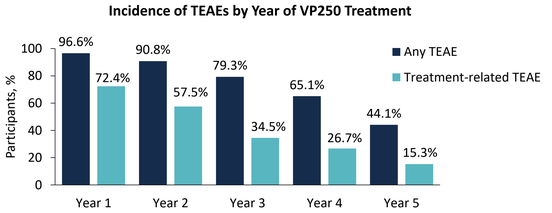
Table 1: TEAEs Over 5 Years of Active Treatment in the PEOPLE Extension Safety Population

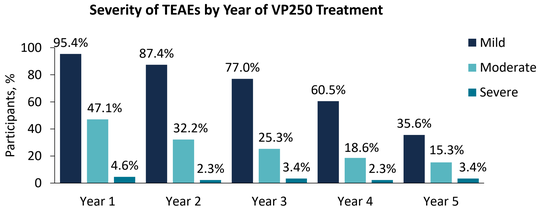
Category, n (%)	Year 1[a] (n=87)	Year 2[a] (n=87)	Year 3[a] (n=87)	Year 4[a] (n=86)	Year 5[a] (n=59)
Any TEAEs	84 (96.6)	79 (90.8)	69 (79.3)	56 (65.1)	26 (44.1)
TEAEs considered related to VP250	63 (72.4)	50 (57.5)	30 (34.5)	23 (26.7)	9 (15.3)
TEAEs by severity					
Mild TEAEs	83 (95.4)	76 (87.4)	67 (77.0)	52 (60.5)	21 (35.6)
Moderate TEAEs	41 (47.1)	28 (32.2)	22 (25.3)	16 (18.6)	9 (15.3)
Severe TEAEs	4 (4.6)	2 (2.3)	3 (3.4)	2 (2.3)	2 (3.4)
Severe TEAEs considered related to VP250	3 (3.4)	2 (2.3)	1 (1.1)	1 (1.2)	0
Serious TEAEs	2 (2.3)	0	2 (2.3)	2 (2.3)	2 (3.4)
Considered related to VP250	1 (1.1)	0	0	0	0
TEAEs leading to permanent VP250 discontinuation	0	0	0	0	0
TEAEs leading to death	0	0	0	0	0
VP250-induced local TEAEs	63 (72.4)	44 (50.6)	30 (34.5)	22 (25.6)	9 (15.3)
Severe VP250-induced local TEAEs	3 (3.4)	2 (2.3)	1 (1.1)	1 (1.2)	0
TEAEs leading to epinephrine intake	4 (4.6)	4 (4.6)	6 (6.9)	2 (2.3)	1 (1.7)
Considered related to VP250	1 (1.1)	0	0	0	0
TEAE leading to topical corticosteroid	47 (54.0)	34 (39.1)	17 (19.5)	16 (18.6)	4 (6.8)
TEAE leading to systemic or inhaled corticosteroid intake	20 (23.0)	12 (13.8)	8 (9.2)	9 (10.5)	1 (1.7)

[a] At each year, percentages are based on the number of participants in the extension safety population who applied at least 1 patch during this year.

- Approximately 93% of participants experienced a TEAE considered related to VP250
  - Treatment-related TEAEs decreased over time: 63/87 (72.4%) in Year 1 to 9/59 (15.3%) in Year 5, as did the severity (**Figure 3**)
  - The most commonly reported TEAEs related to VP250 were administration-site conditions, which decreased in frequency and severity over time

Figure 3: Incidence and Severity of TEAEs Over Time in PEOPLE Extension Safety Population (N=87)





CONCLUSIONS

- 87 participants entered the PEOPLE safety extension period
- Trends over 5 years showed a decrease in the frequency and severity of TEAEs
- Of this cohort, no participant reported treatment-related epinephrine use after Year 1 of PEOPLE (no use in Year 4 or 5)
- These data suggest that long-term VP250 treatment in children with peanut allergy has a favorable safety and tolerability profile, resulting in high treatment compliance, which may facilitate its use over multiple years of treatment

Viaskin is an investigational agent, and it has not yet been approved by the US FDA or any other regulatory authority.

References: 1. Fleischer DM et al. *JAMA*. 2019;321(10):946-955. 2. Fleischer DM et al. *J Allergy Clin Immunol*. 2020;146(4):863-874. 3. Pongracic JA et al. *J Allergy Clin Immunol Pract*. 2022;10(7):1864-1873.e10. 4. Wang J, Sampson HA. *Pediatr Allergy Immunol*. 2018;29(4):341-349. 5. Greenhawt M et al. *N Engl J Med*. 2023;388(19):1755-1766. 6. Moote W et al. *Allergy Asthma Clin Immunol*. 2018;14(suppl 2):53.

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