EPOPEX (EPITOPE Open-label Extension), Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers After 3 Years of Treatment

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Rationale

- There are few options for peanut allergy treatment beyond avoidance,[1-3] and patients, caregivers and physicians continue to express a desire for additional approaches
- VIASKIN®, a patch-based technology platform, is currently being investigated for the treatment of peanut allergy. This novel approach to epicutaneous immunotherapy (EPIT) involves the administration of a peanut patch (VP250) containing 250 µg peanut protein to intact skin to induce desensitization[4-8]
- In the previously reported phase 3 EPITOPE study (NCT03211247), 67% in the VP250 group vs 33.5% in the placebo group were treatment responders after 12 months (difference: 33.4%; 95% CI: 22.4, 44.5 [*P*<0.001])[8]
- Eligible participants could enroll in the open-label extension (OLE) study, EPOPEX, to receive up to 36 months of treatment with VP250
  - Previous results demonstrated continued increases in treatment effect after 24 months of VP250 and no new safety signals[9]

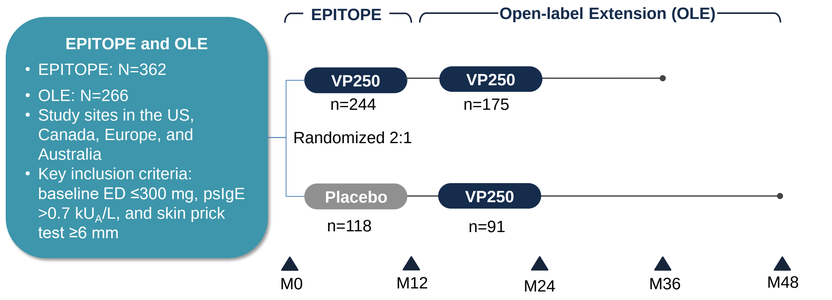
Objective

- To assess the efficacy and safety of up to 36 months of treatment with VP250 in peanut-allergic children

Methods

- After 12 months of VP250 or placebo, EPITOPE participants who completed the trial were eligible to enroll in the OLE for up to 36 total months of treatment with VP250 (**Figure 1**)

Figure 1. Study Design Diagram



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

- Annual double-blind, placebo-controlled food challenges (DBPCFCs) were conducted per the PRACTALL guidelines[10] using a standardized, blinded food matrix and were ended when signs or symptoms sufficiently met prespecified stopping criteria
- The eliciting dose (ED) was the dose at which allergic reaction signs or symptoms met the prespecified stopping criteria and ended the DBPCFC
- Key efficacy outcomes measured in the OLE were percentage of participants reaching an ED ≥1000 mg and ≥2000 mg, percentage of treatment responders, and percentage of participants not meeting stopping criteria at highest dose (2000 mg) during DBPCFC
  - Treatment responders were defined as having an ED ≥300 mg (if baseline ED ≤10 mg) or ED ≥1000 mg at Month (M) 36 (if baseline ED >10 to ≤300 mg)
- Safety outcomes were assessed by treatment-emergent adverse event (TEAE) rates, including anaphylaxis

References: 1. Xolair (omalizumab). Package insert. Genentech, Inc; 2024. Accessed January 6, 2025. https://www.gene.com/download/pdf/xolair_prescribing.pdf 2. Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp]. Package insert. Aimmune Therapeutics, Inc; 2024. Accessed January 6, 2025. https://www.palforzia.com/palforzia-pi.pdf 3. Capucilli P, et al. *Ann Allergy Asthma Immunol.* 2020;124(5):459-465. 4. Fleischer DM, et al. *JAMA.* 2019;321(10):946-955. 5. Fleischer DM, et al. *J Allergy Clin Immunol.* 2020;146(4):863-874. 6. Pongracic JA, et al. *J Allergy Clin Immunol Pract.* 2022;10(7):1864-1873.e10. 7. Wang J, Sampson HA. *Pediatr Allergy Immunol.* 2018;29(4):341-349. 8. Greenhawt M, et al. *N Engl J Med.* 2023;388(19):1755-1766. 9. Greenhawt M, et al. EPOPEX, efficacy and safety of epicutaneous immunotherapy in peanut-allergic toddlers: 1-year open-label extension to EPITOPE. Presented at: American College of Allergy, Asthma, and Immunology; November 11, 2023; Anaheim, CA. 10. Sampson HA, et al. *J Allergy Clin Immunol.* 2014;134(5):1016-1025.e43.

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

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Key Points

- 36 months of VP250 in peanut-allergic children aged 1 through 3 years resulted in continued accumulation of treatment benefit without any new safety signals
- After 3 years of VP250, approximately two-thirds of participants completed the DBPCFC (12-14 peanut kernels) without meeting stopping criteria
- In placebo-treated EPITOPE participants, 24 months of VP250 showed increased treatment benefit compared to 12 months; this effect was consistent with the VP250+VP250 group, though lower in magnitude, possibly due to initiating treatment one year later and smaller n numbers
- Safety results were consistent with previous VP250 trials, with mainly local application-site reactions that decreased in frequency and severity over time as well as low rates of treatment-related anaphylaxis[5,8]

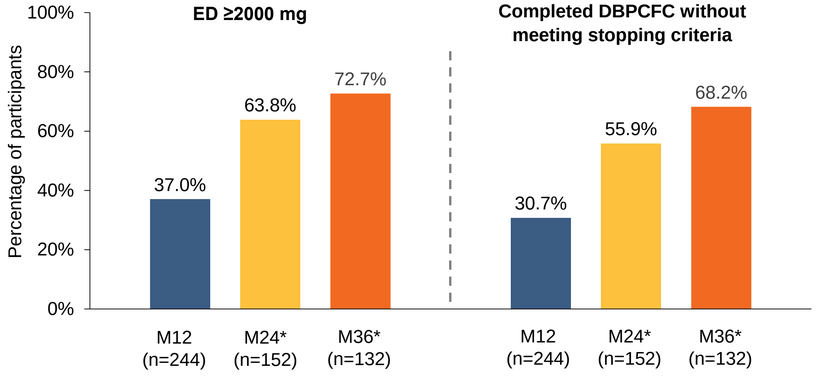
Results

- 266 EPITOPE participants enrolled in the OLE; 149 in the VP250+VP250 group completed the 36-month DBPCFC and 62 in the Placebo+VP250 group completed the 24-month DBPCFC

Efficacy: VP250+VP250 Group (36 Months of Active Treatment)

- After 36 months of VP250, increases compared to M12 were seen for all efficacy endpoints
  - 83.5% of participants reached an ED ≥1000 mg (3-4 peanut kernels)
  - 72.7% of participants reached an ED ≥2000 mg (6-8 peanut kernels) (**Figure 2**)
  - 84.4% of participants were treatment responders
  - 68.2% of participants completed the DBPCFC without meeting stopping criteria (12-14 peanut kernels) (**Figure 2**)

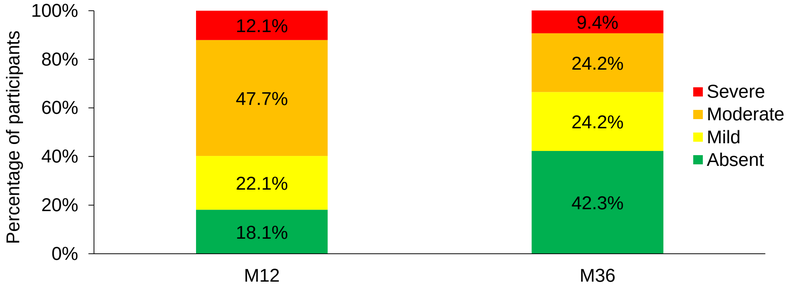
Figure 2. VP250+VP250 Efficacy Over Time



*Number of participants with non-missing food challenge endpoint.

- Continued reductions in DBPCFC reaction severity occurred, with 66.5% having no or mild symptoms at M36 vs 40.2% at M12 in the VP250+VP250 participants (**Figure 3**)

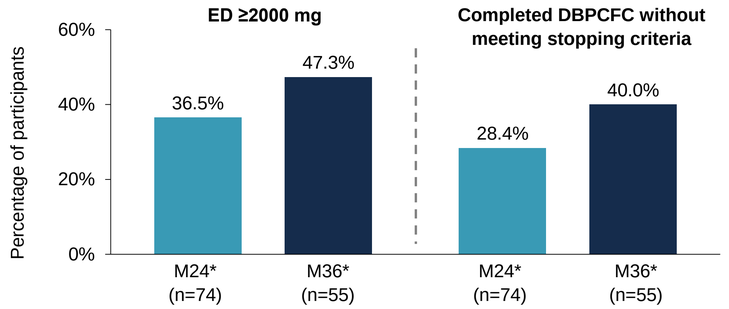
Figure 3. Maximum Severity of DBPCFC Symptoms (VP250+VP250)



Efficacy: Placebo+VP250 Group (24 Months of Active Treatment)

- In the Placebo+VP250 group, a second year of VP250 treatment resulted in increases in the percentage of participants who reached an ED ≥1000 mg, reached an ED ≥2000 mg (**Figure 4**), completed the DBPCFC without reaching stopping criteria (**Figure 4**), and treatment responders
  - The results observed are consistent with gains in efficacy seen in the VP250+VP250 group after 24 months of treatment, though lower in magnitude

Figure 4. Placebo+VP250 Efficacy Over Time



*Number of participants with non-missing food challenge endpoint.

Safety

- No treatment-related anaphylaxis or serious treatment-related TEAEs occurred during the third year (**Table 1**)
- The frequency and severity of local treatment-related TEAEs decreased over each year of VP250 treatment (**Table 1**)

Table 1. Safety Profile

Adverse event category, n (%)	VP250+VP250 Year 1 (EPITOPE) (N=175)	VP250+VP250 Year 2 (N=175)	VP250+VP250 Year 3 (N=165)	Placebo+VP250 Year 1 (N=91)	Placebo+VP250 Year 2 (N=78)
TEAEs	175 (100%)	172 (98.3%)	145 (87.9%)	90 (98.9%)	71 (91.0%)
Treatment-related TEAEs	175 (100%)	161 (92.0%)	113 (68.5%)	88 (96.7%)	51 (65.4%)
Serious TEAEs	17 (9.7%)	7 (4.0%)	3 (1.8%)	2 (2.2%)	1 (1.3%)
Treatment-related serious TEAEs	1 (0.6%)	0	0	1 (1.1%)	0
TEAEs leading to permanent study treatment discontinuation	0	1 (0.6%)	0	1 (1.1%)	0
Treatment-related local TEAEs	175 (100%)	161 (92.0%)	111 (67.3%)	86 (94.5%)	50 (64.1%)
Severe treatment-related local TEAEs	37 (21.1%)	10 (5.7%)	3 (1.8%)	15 (16.5%)	1 (1.3%)
Treatment-emergent local AESIs	40 (22.9%)	26 (14.9%)	14 (8.5%)	2 (2.2%)	2 (2.6%)
Anaphylactic reaction	11 (6.3%)	11 (6.3%)	4 (2.4%)	7 (7.7%)	1 (1.3%)
Treatment-related anaphylactic reaction	3 (1.7%)	0	0	1 (1.1%)	0
TEAEs leading to epinephrine use	16 (9.1%)	10 (5.7%)	10 (6.1%)	8 (8.8%)	2 (2.6%)
Treatment-related TEAEs leading to epinephrine use	2 (1.1%)	0	0	0	0

AESI, adverse event of special interest; TEAE, treatment-emergent adverse event.