Real-World Protective Effects of Peanut Epicutaneous Immunotherapy in Allergic Toddlers

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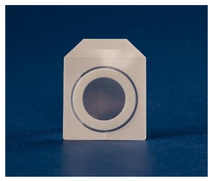
Rationale

- Allergic reactions due to accidental peanut consumption (APC) are common among peanut-allergic children, despite strict avoidance[1]
- 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 (VP) containing 250 µg peanut protein (VP250) to intact skin to induce desensitization[2-6] **(Figure 1)**
  - The safety and efficacy of 12 months VP250 have been previously investigated in phase 3 randomized clinical trials[2,3,6]
- Previous results of EPIT with VP in toddlers aged 1 through 3 years in the EPITOPE study and first year of the EPITOPE open-label extension (OLE) trial demonstrated reduced rates of allergic reactions following APC compared with placebo[6,7]

Figure 1: VP250 Patch



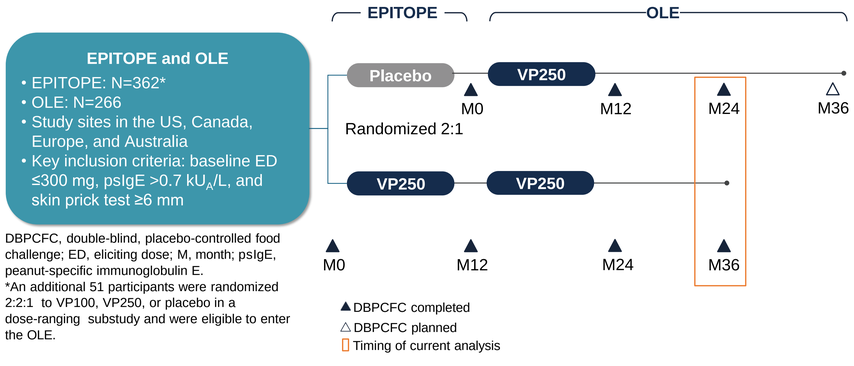
Objective

- To characterize APC in peanut-allergic children aged 1 through 3 years through Year 2 of the EPITOPE OLE trial

Methods

- EPITOPE included a dose-ranging substudy in which participants received either VP containing 100 µg peanut protein (VP100), VP250, or placebo, followed by a 12-month, randomized, double-blind, placebo-controlled (DBPC) trial to assess the efficacy and safety of VP250 in peanut-allergic toddlers aged 1 through 3 years[6] (**Figure 2**)
  - 362 participants were randomized 2:1 to 12 months of VP250 or placebo
  - Eligible participants who completed the Month 12 DBPC food challenge could enroll in the OLE for up to a total of 3 years of active treatment

Figure 2. EPITOPE and OLE Study Design



DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; M, month; psIgE, peanut-specific immunoglobulin E.
*An additional 51 participants were randomized 2:2:1 to VP100, VP250, or placebo in a dose-ranging substudy and were eligible to enter the OLE.

- Data on APCs occurring during EPITOPE and the OLE were collected prospectively and analyzed longitudinally
- The associations between efficacy outcome and rate of APC events and related allergic reactions were analyzed by treatment group and over 2 years of treatment
  - Data include participants receiving both VP100 and VP250
- Continuous data were summarized, and annual event rates were determined
- For participant-level analyses, the most recent APC was analyzed if multiple events occurred

References: 1. Capucilli P et al. *Ann Allergy Asthma Immunol*. 2020;124(5):459-465. 2. Fleischer DM et al. *JAMA*. 2019;321(10):946-955. 3. Fleischer DM et al. *J Allergy Clin Immunol*. 2020;146(4):863-874. 4. Pongracic JA et al. *J Allergy Clin Immunol Pract*. 2022;10(7):1864-1873.e10. 5. Wang J, Sampson HA. *Pediatr Allergy Immunol*. 2018;29(4):341-349. 6. Greenhawt M et al. *N Engl J Med*. 2023;388(19):1755-1766. 7. Arends N et al. Presented at: European Academy of Allergy and Clinical Immunology Congress; May 31-June 3, 2024; Valencia, Spain.

FUNDING SOURCE/ACKNOWLEDGMENTS: The EPITOPE study and its open-label extension were sponsored by DBV Technologies. Editorial support for the preparation of this poster was provided by Red Nucleus, funded by DBV Technologies.

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

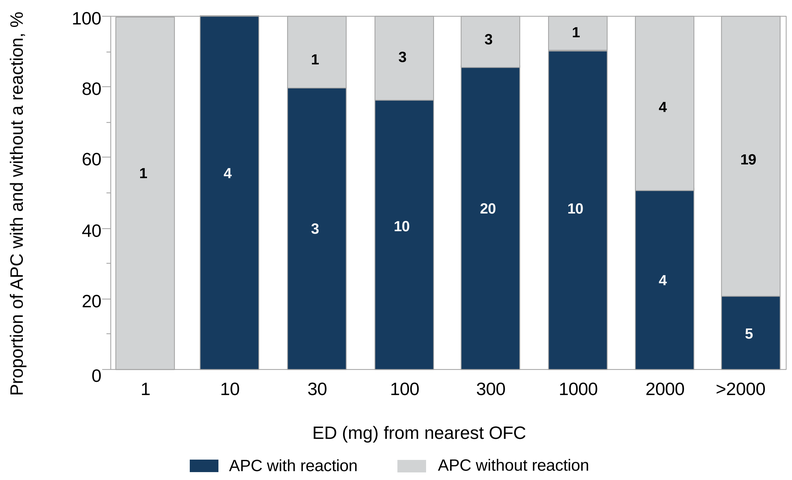
Key Points

- EPIT with VIASKIN peanut patch demonstrated reduced rates of reactions related to accidental peanut consumption in young children compared to those treated with placebo in the EPITOPE clinical trial
  - Further reductions are observed with increased time on treatment and increased eliciting dose in the open-label extension study
- These results suggest the potential of the VIASKIN peanut patch, if approved, to provide real-world effectiveness, including mitigating accidental peanut consumption reactions

Results

- Beyond Month 12, further increases in eliciting dose (ED) were observed following long-term active treatment in the OLE
  - In VP participants, the proportion with an ED ≥1000 mg was 84.6% after 3 years of active treatment; in placebo-crossover participants, the proportion with an ED ≥1000 mg after 2 years of active treatment was 67.7%
- Over 3 years of treatment, there were 88 APCs reported in 75 participants; 13 participants had 2 APCs (**Figure 3**)

Figure 3. Number of Reactions to APC by ED at Nearest Oral Food Challenge



OFC, oral food challenge.
Values within bars indicate number of APC.

- Participants who reached a higher ED were less likely to experience a reaction following APC (**Table 1**)
  - 23/40 (58%) participants with ED ≥1000 mg did not experience a reaction following APC vs 8/35 (23%) with ED <1000 mg
  - Most participants (22/30) with an ED ≥2000 mg did not experience an adverse reaction to APC
- Of the reactions that occurred, the majority (77%) were mild in nature and none were severe

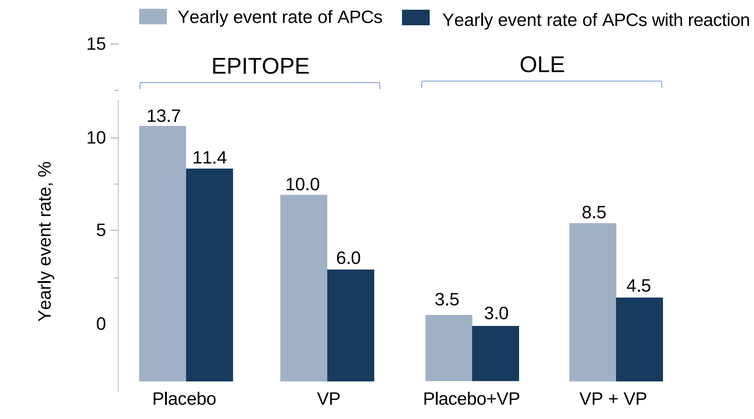
Table 1: ED Association With APC Reaction Severity by Participant*

	Absent (N=31) n (%)	Mild/moderate (N=44) n (%)	Total (N=75) n (%)
ED, mg			
1	1 (3.2)	0	1 (1.3)
10	0	2 (4.5)	2 (2.7)
30	1 (3.2)	2 (4.5)	3 (4.0)
100	3 (9.7)	8 (18.2)	11 (14.7)
300	3 (9.7)	15 (34.1)	18 (24.0)
1000	1 (3.2)	9 (20.5)	10 (13.3)
2000	4 (12.9)	3 (6.8)	7 (9.3)
>2000	18 (58.1)	5 (11.4)	23 (30.7)

*Participants were categorized based on the highest severity of reaction upon APC.

- Yearly event rates of APC, with or without reaction, declined over time (**Figure 4**)
  - The yearly event rate of APC-related reactions decreased by 3.8-fold (from 11.4 to 3.0) and 1.3-fold (from 6.0 to 4.5) for placebo-crossover and VP participants, respectively, between EPITOPE and the OLE Year 2

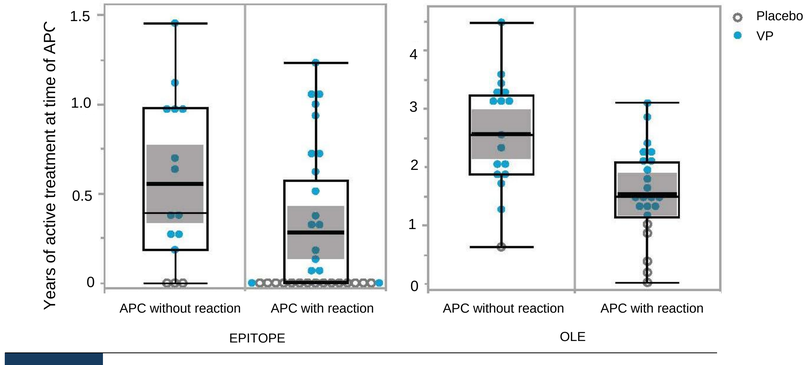
Figure 4: Yearly Event Rates of APC by Treatment Group



	Placebo	VP	Placebo+VP	VP + VP
Total participants	128	285	99	205
Total APCs	18	30	6	34
Total APCs with reaction, n (%)	15 (83.3)	18 (60.0)	5 (83.3)	18 (52.9)

- Participants without an APC-related reaction tended to have longer time on active treatment than those with a reaction (**Figure 5**)

Figure 5. Timing of APCs With and Without Reaction in EPITOPE and OLE



N	15	33	17	23
Standard deviation	0.5	0.4	1	0.8
Mean	0.6	0.3	2.6	1.5

Boxplot shows distribution of time on active treatment in APCs with and without reactions, in EPITOPE and OLE. The solid black line with grey shading indicates the mean and standard deviation, which are also annotated in the table along the x-axis. Each point represents an APC and is colored by the participant's randomization in EPITOPE.