VITESSE Phase 3 Study of Epicutaneous Immunotherapy for the Treatment of Peanut Allergy in Children

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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 epicutaneous immunotherapy (EPIT) involves the administration of a peanut patch containing 250 µg peanut protein (VP250) to intact skin to induce desensitization (**Figure 1**)[1-5]
- In the phase 3 PEPITES study (NCT02636699), daily use of VP250 demonstrated statistically significant desensitization in peanut-allergic children aged 4 through 11 years with responder rates of 35.3% for the VP250 group vs 13.6% for the placebo group (difference: 21.7%; 95% CI: 12.4, 29.8)[1]
  - A post hoc analysis in children aged 4 through 7 years showed an even greater treatment effect of VP250, with responder rates of 40.0% for the VP250 group vs 9.2% for the placebo group (difference: 30.8%; 95% CI: 18.3, 40.8)[6]
- The efficacy and safety of the VP250 patch is being investigated in children 4 through 7 years of age in the ongoing double-blind, placebo-controlled phase 3 VITESSE study (NCT05741476)

Figure 1. Patch for VITESSE

44 mm diameter

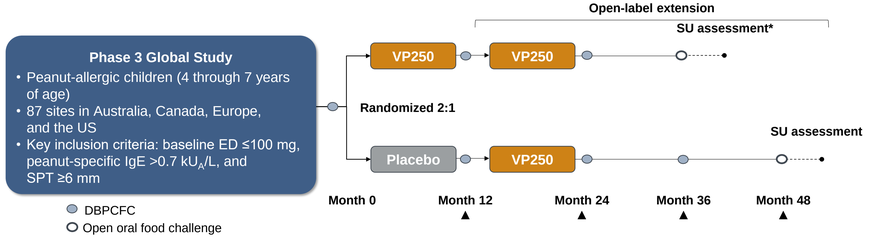
Objective

- To report baseline demographics and patient characteristics of peanut-allergic children 4 through 7 years of age from the ongoing VITESSE clinical trial

Methods

- Participants were randomized 2:1 to VP250 or placebo for 12 months, with the option of VP250 treatment for up to 36 months in an open-label extension (**Figure 2**)
- Eligibility criteria included peanut-specific immunoglobulin E (IgE) >0.7 kU_A/L, peanut skin prick test (SPT) ≥6 mm, and eliciting dose (ED) of ≤100 mg peanut protein on double-blind, placebo-controlled food challenge (DBPCFC)

Figure 2. Study Design



SU, sustained unresponsiveness.
*SU assessment involves an open, oral food challenge every 2 months for 6 months after stopping treatment in eligible participants.

- The primary endpoint is the difference in the proportion of responders between the VP250 and placebo groups at Month 12, defined as DBPCFC Month 12 ED ≥300 mg if baseline ED ≤30 mg or Month 12 ED ≥600 mg if baseline ED >30 mg
- Safety assessments include overall adverse events, local site reactions, and systemic allergic reactions

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. Fleischer DM et al. Efficacy of epicutaneous immunotherapy with Viaskin™ Peanut for 4 to 7-year-old peanut-allergic children in a phase 3 clinical trial (PEPITES). Presented at: Canadian Society of Allergy and Clinical Immunology (CSACI) 77th annual meeting; September 23-25, 2022; Quebec, Canada.

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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.

Key Points

- The VITESSE study cohort reflects the general population of peanut-allergic children 4 through 7 years of age, including a high frequency of allergic comorbidities
- The median age (12 months) at diagnosis and the skewing of the population toward 4- to 5-year-olds vs 6- to 7-year-olds indicates the need for potential treatments in young children
- ED ≤100 mg at entry and peanut-specific IgE values and SPT values support the hypothesis that the findings will establish the efficacy and safety of VIASKIN peanut patch in a highly sensitized population
- VITESSE, the largest food allergy immunotherapy trial to date, provides the opportunity to evaluate multi-year efficacy and safety of VIASKIN peanut patch, as well as sustained unresponsiveness up to 6 months
- Topline efficacy and safety results are anticipated in Q4 2025

Results

- 654 participants have been randomized in the VITESSE study (**Table 1**)

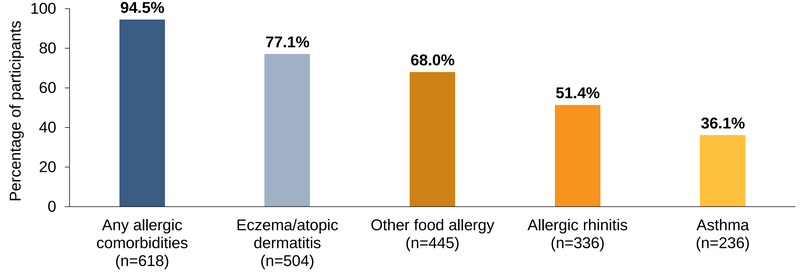
Table 1. Baseline Demographics*

	N=654
Age, n (%)	
4-5 years	370 (56.6)
6-7 years	284 (43.4)
Sex, n (%)	
Male	408 (62.4)
Female	245 (37.5)
Race, n (%)	
American Indian or Alaska Native	0
Asian	105 (16.1)
Black or African American	30 (4.6)
Native Hawaiian or Other Pacific Islander	2 (0.3)
White	416 (63.6)
Other	81 (12.4)
Not collected (not applicable, not reported, or missing)	20 (3.1)

*Data self-reported at the time of study enrollment.

- The median age at diagnosis of peanut allergy was 12 months
- Allergic comorbidities were common (94.5%) with eczema/atopic dermatitis being the most frequent (77.1%) (**Figure 3**)

Figure 3. Baseline Allergic Comorbidities



- At baseline, median peanut-specific IgE was 39.2 kU_A/L and median peanut SPT was 13.0 mm (**Table 2**)

Table 2. Baseline Biomarkers

	N=654
Peanut-specific IgE, kU_A/L	
n*	645
Median	39.2
Q1, Q3	11.0, 169.0
Min, max	0.6, 2276
SPT (longest wheal diameter), mm	
n*	649
Median	13.0
Q1, Q3	10.0, 17.0
Min, max	6.0, 45.0

max, maximum; min, minimum; Q1, quartile 1; Q3, quartile 3; SD, standard deviation.
*Participants with available data as of November 25, 2024.

- Most (86.5%) participants had a history of reactions to peanut consumption, and 22.3% (n=146) reported prior epinephrine use (**Figure 4**)

Figure 4. History of Reactions to Peanut Consumption and Prior Epinephrine Use