COMFORT Toddlers: Phase 3 Supplemental Safety Study of Epicutaneous Immunotherapy in 1- Through 3-Year-Old Peanut-Allergic Toddlers

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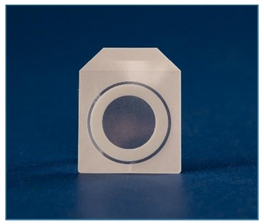
Rationale

- Evidence is accumulating to suggest that allergic responses to foods may be more modifiable in younger children than in older children. As such, prioritizing treatments that target younger age groups is of importance[1]
- VIASKIN®, a patch-based technology platform, is currently being investigated for the treatment of peanut allergy. This novel approach to epicutaneous immunotherapy involves the administration of a peanut patch containing 250 µg peanut protein (VP250) to intact skin to induce desensitization[1-6] (**Figure 1**)
  - VP250 has previously demonstrated statistically significant desensitization in several phase 3 studies in children aged 1 through 11 years over multiple years of treatment[1-3,6]
  - VP250 has demonstrated a favorable long-term safety profile in clinical studies, with the most common treatment-related adverse events being local skin reactions, which decreased in frequency and severity over time[3,4,6]
  - Compliance rates of >93% over 5 years of treatment,[7] and the lack of updosing and lifestyle restrictions suggest the practicality of the treatment[8]

Figure 1. VP250 Patch



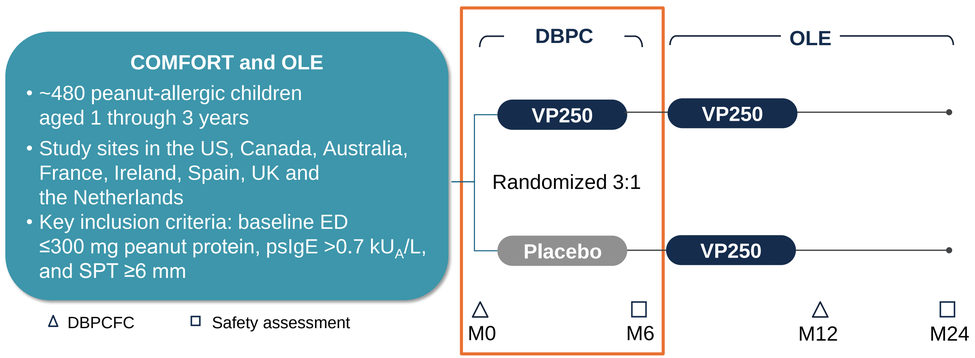
Objective

- To describe a new 6-month study aimed at gathering additional data to support the current safety profile of VP250 among peanut-allergic toddlers who initiate treatment at 1 through 3 years of age

Methods

- COMFORT Toddlers is a phase 3, randomized, double-blind, placebo-controlled (DBPC) supplemental safety study of VP250 in peanut-allergic toddlers aged 1 through 3 years (**Figure 2**)

Figure 2. Study Design Diagram



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

- Eligible participants will be randomized 3:1 to receive 6 months of a daily patch, VP250 or placebo, followed by an optional OLE study where all participants will receive VP250 for a total of 18 months
- Key eligibility criteria include physician-diagnosed peanut allergy, peanut-specific immunoglobulin E (IgE) >0.7 kU_A/L, positive peanut skin prick test (SPT) with largest wheal diameter ≥6 mm, an eliciting dose ≤300 mg peanut protein at screening DBPC food challenge
- Participants with uncontrolled asthma or a history of severe anaphylaxis will be excluded

References: 1. Greenhawt M et al. *J Allergy Clin Immunol Pract*. 2025;13(5):1176-1187.e7. 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*. 2025;13(5):1190-1200.e3. 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. Fleischer DM et al. Presented at: American Academy of Allergy, Asthma, and Immunology and World Allergy Organization Joint Congress; February 28-March 3, 2025; San Diego, CA. 8. Ravindran M et al. *Allergy*. 2025;80(1):63-76.

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Key Points

- Previous VP250 phase 3 clinical trials have demonstrated statistically significant desensitization and a favorable safety profile in children aged 1 through 11 years over multiple years of treatment[1-4,6]
- The COMFORT Toddlers study aims to contribute to a robust safety dataset to support VP250 as a potential treatment option in young toddlers with peanut allergy
- Participant screening is anticipated to begin in Q2 2025
- For more information, please visit: https://clinicaltrials.gov

Results

- Safety will be assessed on an ongoing basis and at each study visit by site investigators
- Results will include safety assessments, adverse events of special interest (AESI), and exploratory assessments (**Table 1**)

Table 1. Safety Endpoints

Safety assessments		
AEs and TEAEs by SOC and PT	TEAEs by severity, duration, and relatedness to treatment	TEAEs leading to discontinuation
Severity of local application-site reactions	Serious AEs	Systemic allergic reactions
AEs leading to topical corticosteroid use	SCORAD	Physical examinations
Exploratory assessments		
Change from baseline in peanut-specific IgE and IgG4	Change from baseline in peanut-component–specific IgE and IgG4	Change from baseline in peanut SPT mean wheal diameters

AE, adverse event; IgG4, immunoglobulin G4; PT, preferred term; SCORAD, SCORing Atopic Dermatitis; SOC, system organ class; TEAE, treatment-emergent AE.