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EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: 1-year Open-Label Extension to EPITOPE

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Disclosures

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- Member, Joint Task Force on Allergy Practice Parameters
- Member of Nutricia, DBV, Novartis, Sanofi, Aquestive, Prota, Allergy Therapeutics, GSK, ALK-Abello, AstraZeneca
- Consultant, Aquestive
- Received honorarium from ImSci, MedLearning Group, RMSI, multiple state and local allergy societies, and the CSACI
- Member of the Medical Advisory team for the Allergy and Asthma Foundation of America and the International Association for Food Protein Enterocolitis (nonfinancial)
- Has received support from K08-HS024599 (Agency for Healthcare Research and Quality)
- Member of AAAAI Practice/Diagnostics/Therapeutics, Anaphylaxis, Adverse Reaction to Food, Vaccine committees
- Co-chair, AAAAI Primary Prevention of Food Allergy Working Group; Co-chair, AAAAI Oral Immunotherapy Office-based Practice Working Group
- Member, NIAID Expert Panel on early introduction of peanut to prevent peanut allergy
- Senior Associate Editor, *Annals of Allergy, Asthma, and Immunology*
- International Advisory Board, Lancet Child and Adolescent Health
- Editorial board: *Medscape Pediatrics*; *Infectious Diseases in Children, Pediatric Allergy and Immunology*
- Member, Scientific Advisory Council, National Peanut Board
- Member, EAACI Task Forces on Nutrition and Immunomodulation; Outcomes of Food Allergy Therapies
- Member, Core Outcome Measures for Food Allergy (COMFA) consortium, COST Action
- Member, Brighton Criteria Collaboration Case Definition for Anaphylaxis working group 2.0

Background

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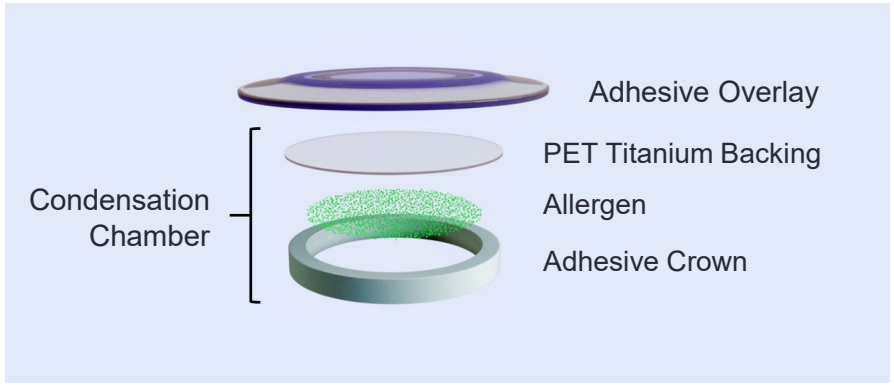
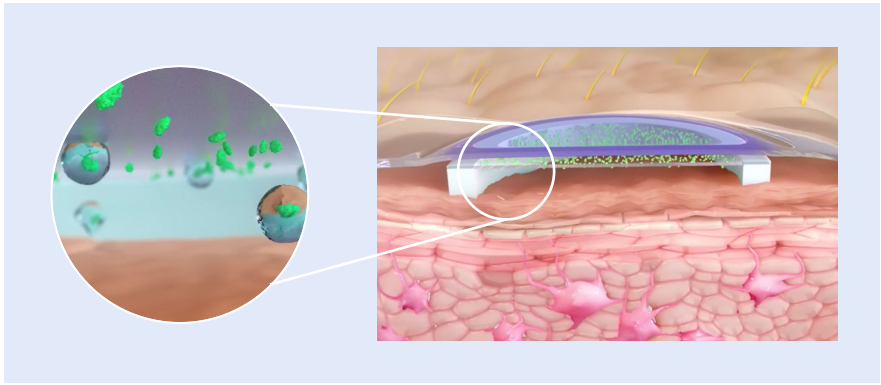
Epicutaneous immunotherapy (EPIT) with Viaskin Peanut 250 µg (VP250) for peanut allergy[1-3]

- EPIT with VP250 is a novel patch-based approach involving administration of microgram quantities of peanut allergen to intact skin to induce desensitization

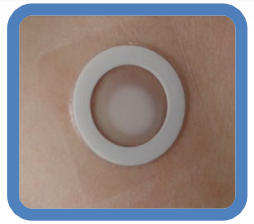


Condensation Chamber
Formed by adhesive crown, allergen and titanium backing, secured by adhesive overlay



Allergen Solubilization
Occurs within condensation chamber when natural epidermal water loss solubilizes dry antigen on titanium backing

- Each patch contains 250 µg peanut protein (~1/1000 of 1 peanut kernel); no up-dosing
- No restrictions or treatment disruptions based on daily activities or illness required in clinical trial protocols



Epicutaneous immunotherapy and Viaskin™ (VP250) are under clinical investigation and have not been approved for marketing by any health or regulatory authority.

1. Fleischer DM, et al. Allergy Asthma Proc. 2020;41:278-284. 2. Fleischer DM, et al. JAMA. 2019;32:946-955. 3. Hervé PL, et al. Front Allergy. 2023. doi:10.3389/falgy.2023.1290003.

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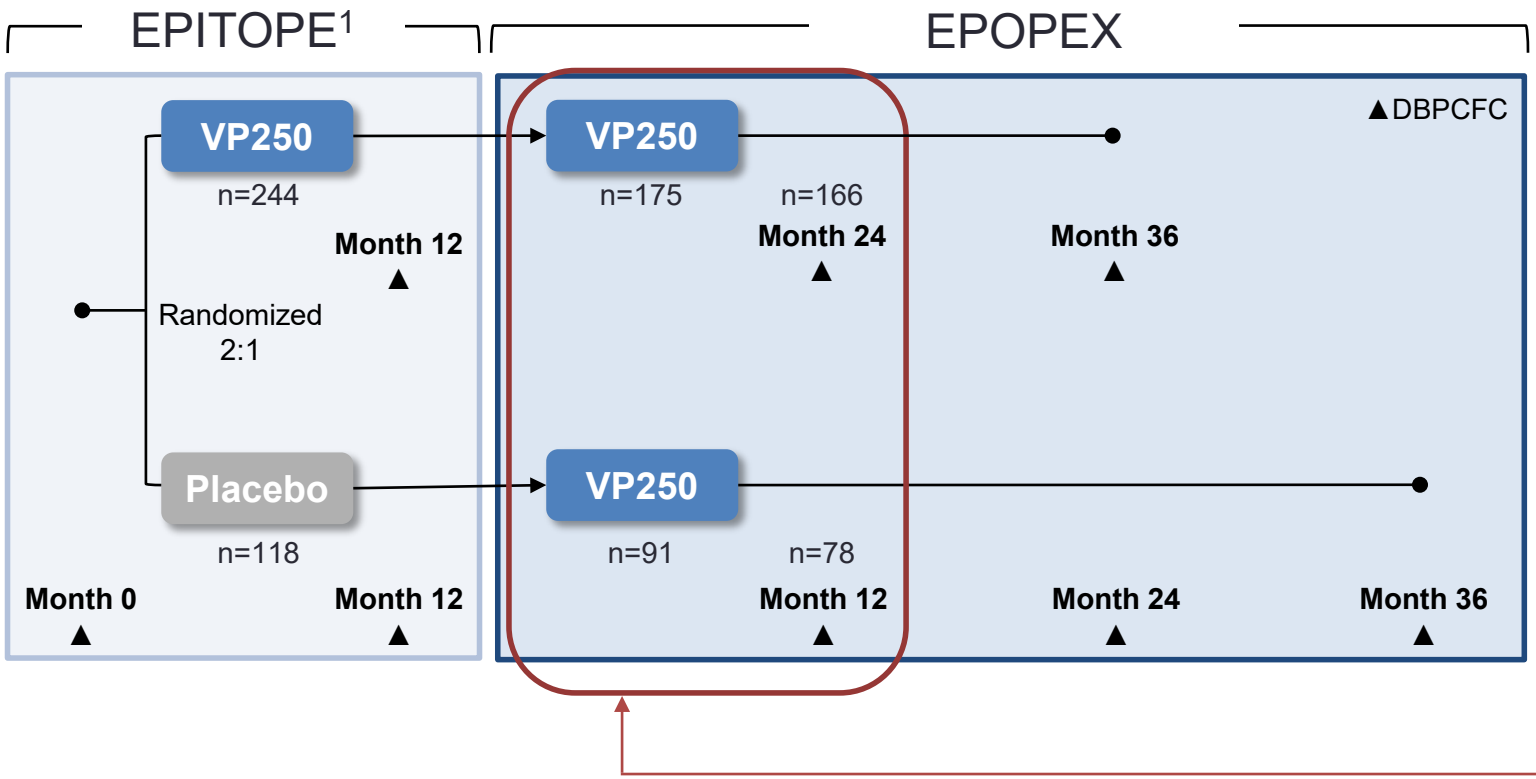
Study Design: Open-label, Long-term Extension to the EPITOPE Phase 3 Trial (EPOPEX)



Study Endpoints

- % reaching ED ≥1000 mg and ≥2000 mg
- % of treatment responders (as defined in EPITOPE*)
- % of participants not meeting stopping criteria at highest dose (2000 mg) during DBPCFC
- Safety as assessed by treatment-emergent adverse event rates, including anaphylaxis

Objective

- **To assess the efficacy and safety of EPIT with VP250 among peanut-allergic children from the first year of the open-label extension study to EPITOPE (EPOPEX)**

Epicutaneous immunotherapy and Viaskin™ (VP250) are under clinical investigation and have not been approved for marketing by any health or regulatory authority.
ED=eliciting dose; DBPCFC=double-blind, placebo-controlled food challenge.
*Treatment responder (assessed by DBPCFC) defined as: If ED ≤ 10 mg at baseline, responder if ED ≥ 300 mg at M12; If ED > 10 mg at baseline, responder if ED ≥ 1000 mg at M12.
1. Greenhawt M, et al. *N Engl J Med*. 2023;388:1755-1766.

Efficacy Results: Placebo+VP250 Group

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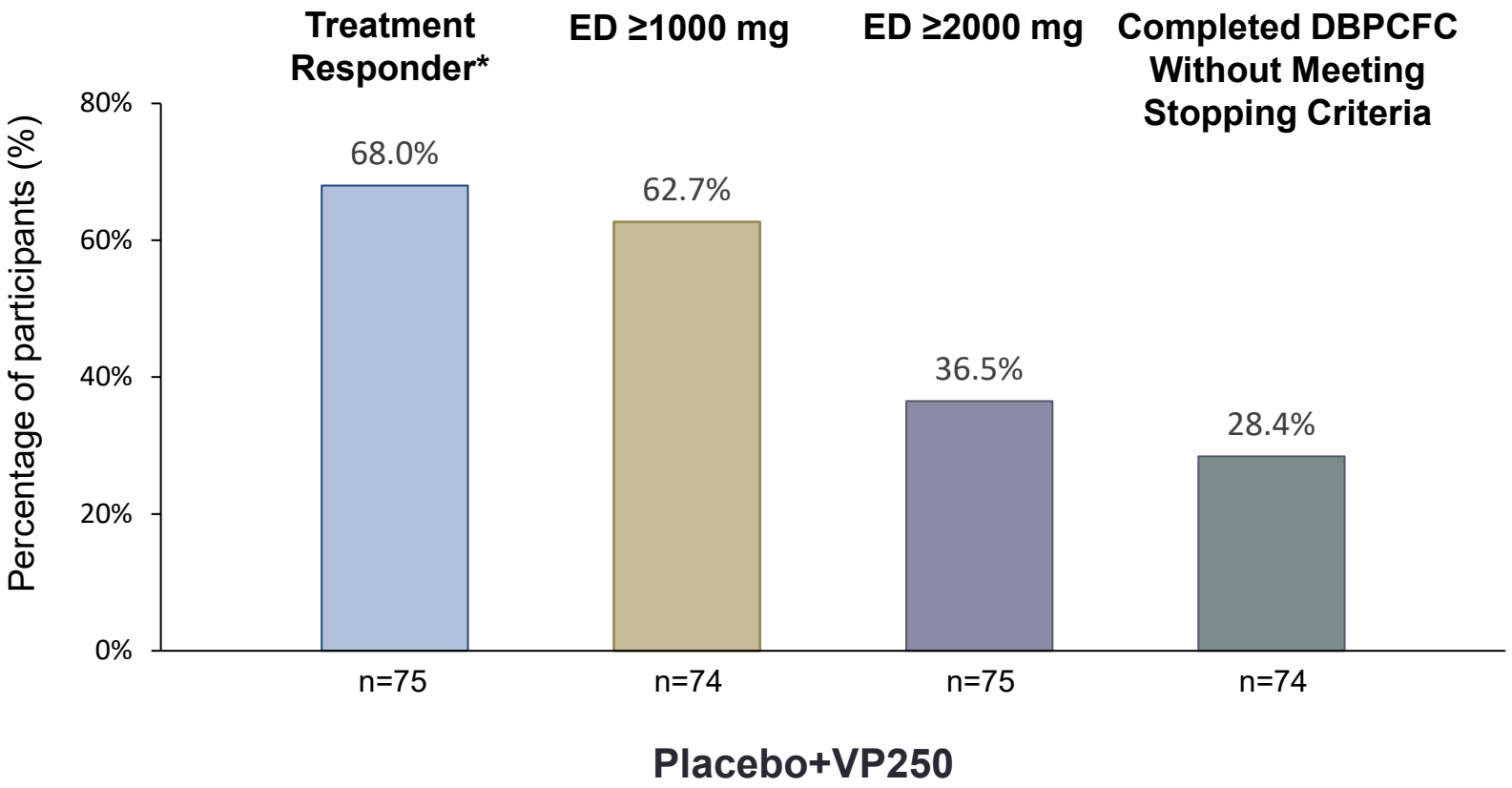
- In EPITOPE placebo participants receiving 12 months of VP250 in EPOPEX (Placebo+VP250 group), treatment outcomes were consistent with results seen after 12 months of VP250 in EPITOPE



	VP250 at M12 in EPITOPE (N=244)
Treatment Responder	67.0%
≥1000 mg	64.2%
≥2000 mg	37.0%
Completed DBPCFC Without Meeting Stopping Criteria	30.7%

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DBPCFC=double-blind, placebo-controlled food challenge; ED=eliciting dose.
*Treatment responder (assessed by DBPCFC) defined as: If ED ≤ 10 mg at baseline, responder if ED ≥ 300 mg at M12; If ED > 10 mg at baseline, responder if ED ≥ 1000 mg at M12.

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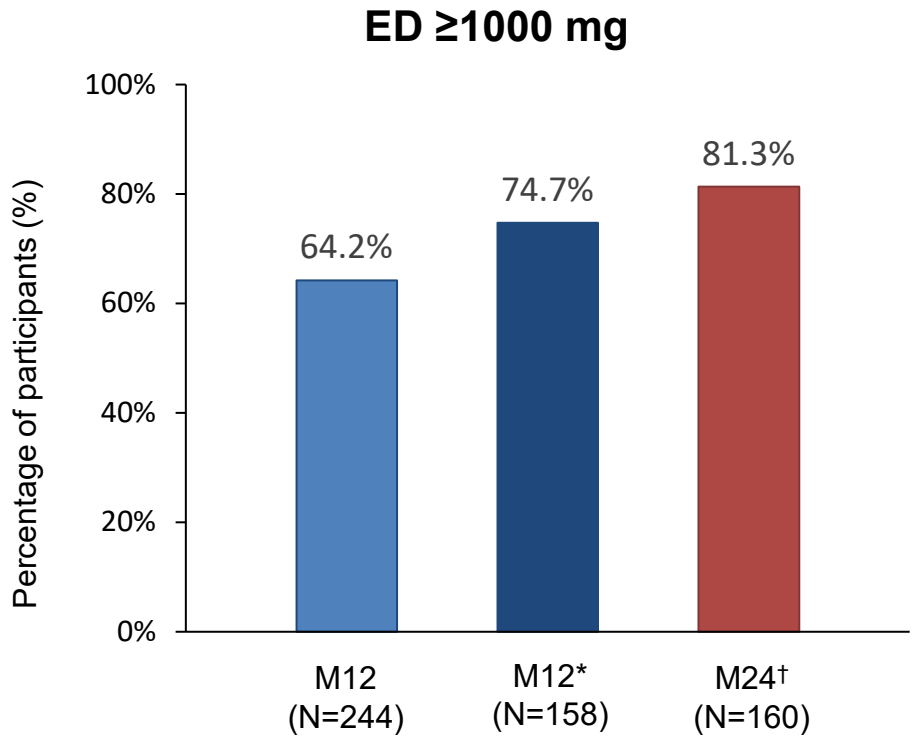
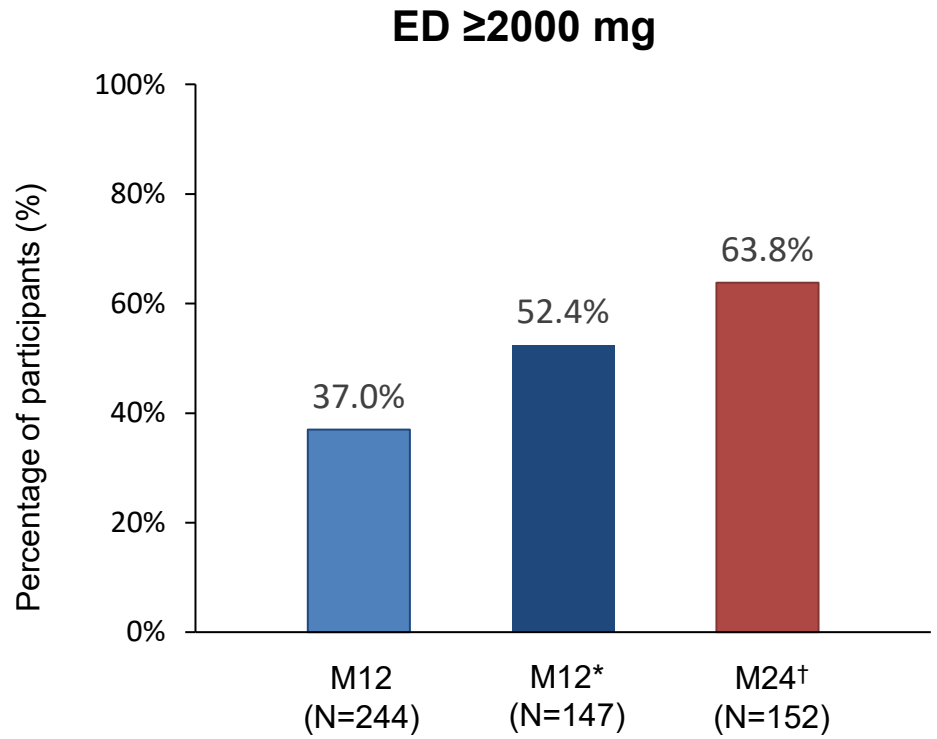
Efficacy Results: VP250+VP250 Group

- Increases in the percentage of participants achieving an ED of ≥1000 mg (3-4 peanuts) and ≥2000 mg (6-8 peanuts) were observed following an additional year of VP250 treatment





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ED=eliciting dose.
*Month 12 data among participants randomized to VP250 in EPITOPE who completed the EPOPEX Year 1 food challenge endpoint.
†Number of subjects with non-missing food challenge endpoint.

Efficacy Results: VP250+VP250 Group

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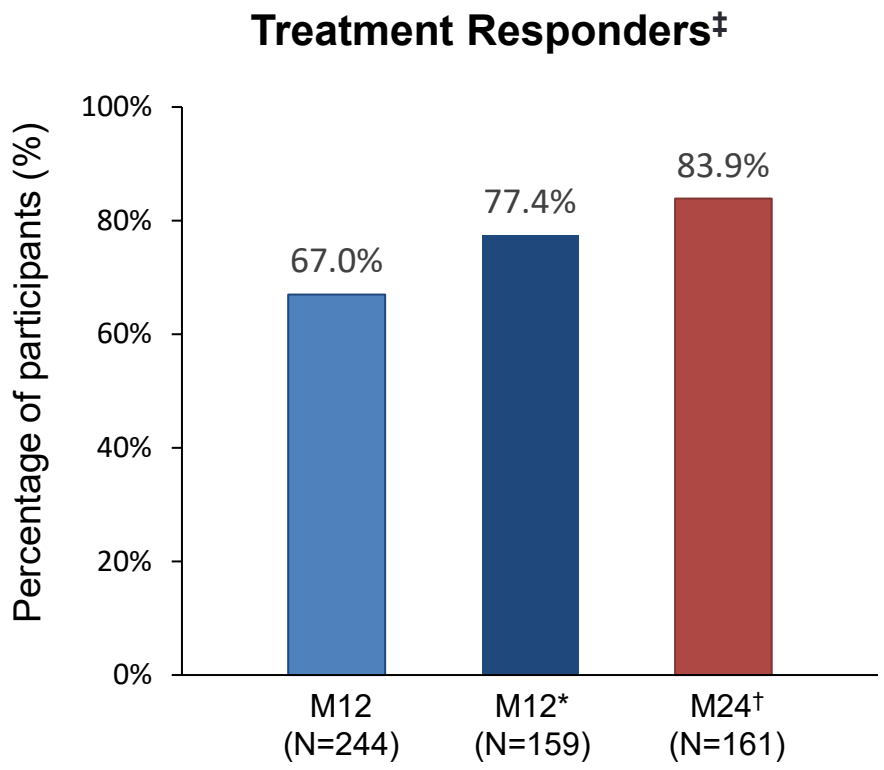
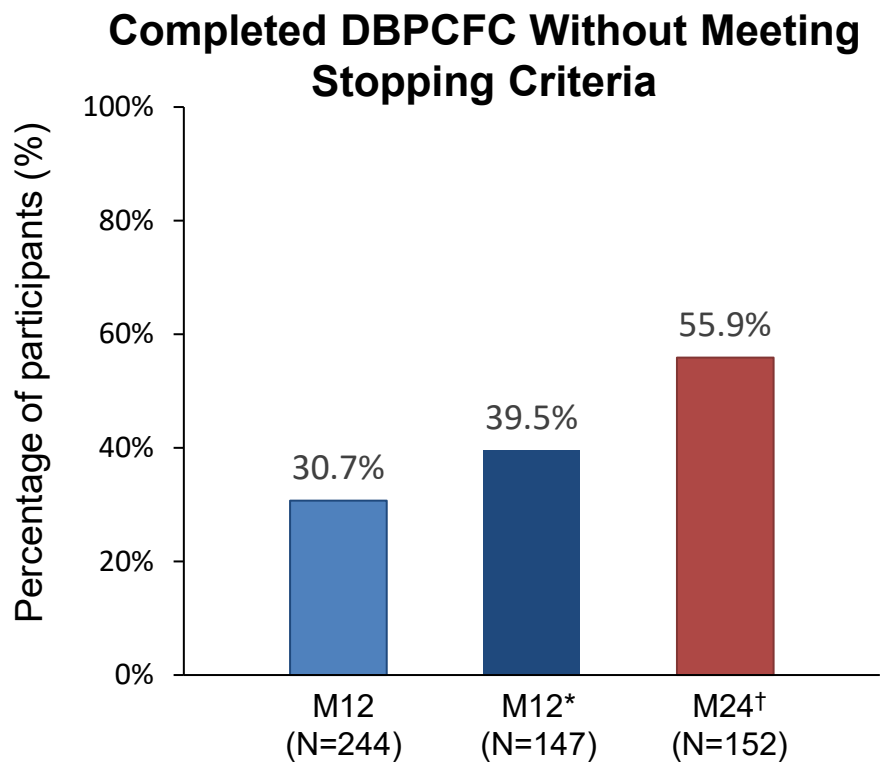
- A second year of treatment led to increases in both treatment responders and the proportion of participants able to complete the DBPCFC without meeting stopping criteria





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ED=eliciting dose; DBPCFC=double-blind, placebo-controlled food challenge; M=month.
*Month 12 data among participants randomized to VP250 in EPITOPE who completed the EPOPEX Year 1 food challenge endpoint.
†Number of subjects with non-missing food challenge endpoint.
‡In EPITOPE, a treatment responder (assessed by DBPCFC) was defined as: If ED ≤ 10 mg at baseline, responder if ED ≥ 300 mg at M12; If ED > 10 mg at baseline, responder if ED ≥ 1000 mg at M12.

Safety and Tolerability Results

- The frequency of treatment-related local TEAEs decreased in Year 2 compared to Year 1 of VP250 treatment
- During the first 12 months of the open-label extension:
  - One (1.1%) participant (Placebo+VP250 group) experienced 1 event of moderate treatment-related anaphylaxis, which was considered serious
  - There were no discontinuations due to a TEAE

Adverse Event Category [n (%)]	First Year of Active Treatment VP250 (N=175)	Second Year of Active Treatment VP250+VP250 (N=175)	First Year of Active Treatment PLB+VP250 (N=91)
TEAEs	175 (100%)	171 (97.7%)	90 (98.9%)
Treatment-related TEAEs	175 (100%)	160 (91.4%)	87 (95.6%)
Serious TEAEs	17 (9.7%)	7 (4.0%)	2 (2.2%)
Treatment-related serious TEAEs	1 (0.6%)	0	1 (1.1%)
TEAEs leading to permanent study treatment discontinuation	0	0	0
Treatment-related local TEAEs	175 (100%)	160 (91.4%)	85 (93.4%)
Treatment-emergent local AESI	40 (22.9%)	25 (14.3%)	2 (2.2%)
Anaphylactic reaction	11 (6.3%)	11 (6.3%)	6 (6.6%)
Treatment-related anaphylactic reaction	3 (1.7%)	0	1 (1.1%)

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AESI=adverse event of special interest; PLB=placebo; TEAE=treatment-emergent adverse event.

Summary

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A second year of EPIT with Viaskin Peanut 250 µg in peanut-allergic children aged 1 through 3 years resulted in continued increases in treatment effect, beyond those observed after one year in EPITOPE

The treatment effect after one year of Viaskin Peanut 250 µg was confirmed in participants receiving placebo in EPITOPE

Safety results were consistent with previous trials, with mainly local application site reactions which decreased over time, and low rates of treatment-related anaphylaxis

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TEAE=treatment-emergent adverse event.