# Long-Term Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Toddlers: EPITOPE Open-Label Extension (EPOPEX) End-of-Study Results

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# Disclosures


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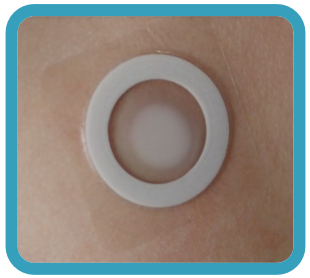
Disclosures: Dr Greenhawt is an employee of the Asthma and Allergy Foundation of America; is a consultant for Aquestive; is a member of physician/medical advisory boards for DBV Technologies, Takeda, Novartis, Aquestive, ALK-Abelló, Bryn Pharma, Genentech, and Prota Therapeutics; is a speaker for Genentech and ARS Pharma; is an unpaid member of the scientific advisory council for the National Peanut Board and medical advisory board of the International Food Protein-Induced Enterocolitis Syndrome Association; is a member of the Brighton Collaboration Criteria Vaccine Anaphylaxis 2.0 working group; is the senior associate editor for the *Annals of Allergy, Asthma, and Immunology*, and is member of the Allergy Immunology Joint Taskforce on Practice Parameters.

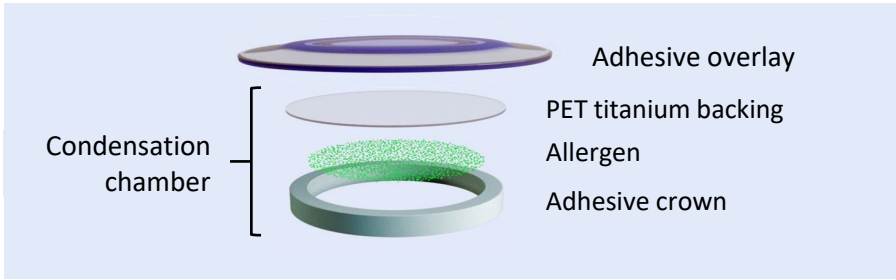
# Background: Epicutaneous Immunotherapy (EPIT) With the VIASKIN® Peanut Patch (VP250)

- With limited treatment options for peanut allergy,[1,2] there is a strong unmet need for additional approaches, particularly those with the potential for disease modification early in life
- EPIT with VP250 involves the administration of a patch containing 250 µg peanut protein (~1/1000 of 1 peanut kernel) to intact skin to induce desensitization[3-7]

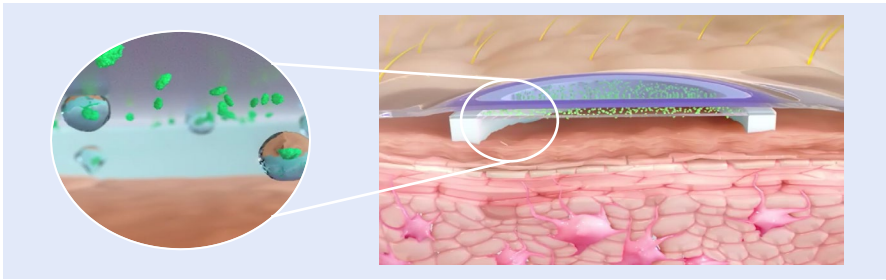
Designed to be a single fixed dose, without dose-related restrictions or treatment disruptions based on daily activities, illness, or other factors required, as noted across multiple clinical trials



**VIASKIN Peanut Patch (VP250)**




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



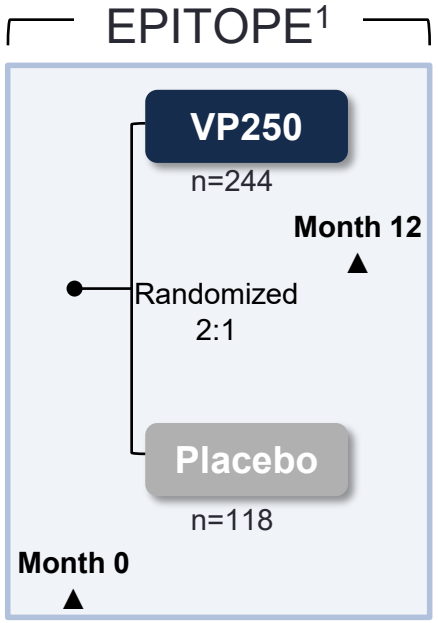
**Allergen Solubilization**
Occurs within condensation chamber when natural epidermal water loss solubilizes dry antigen on titanium backing

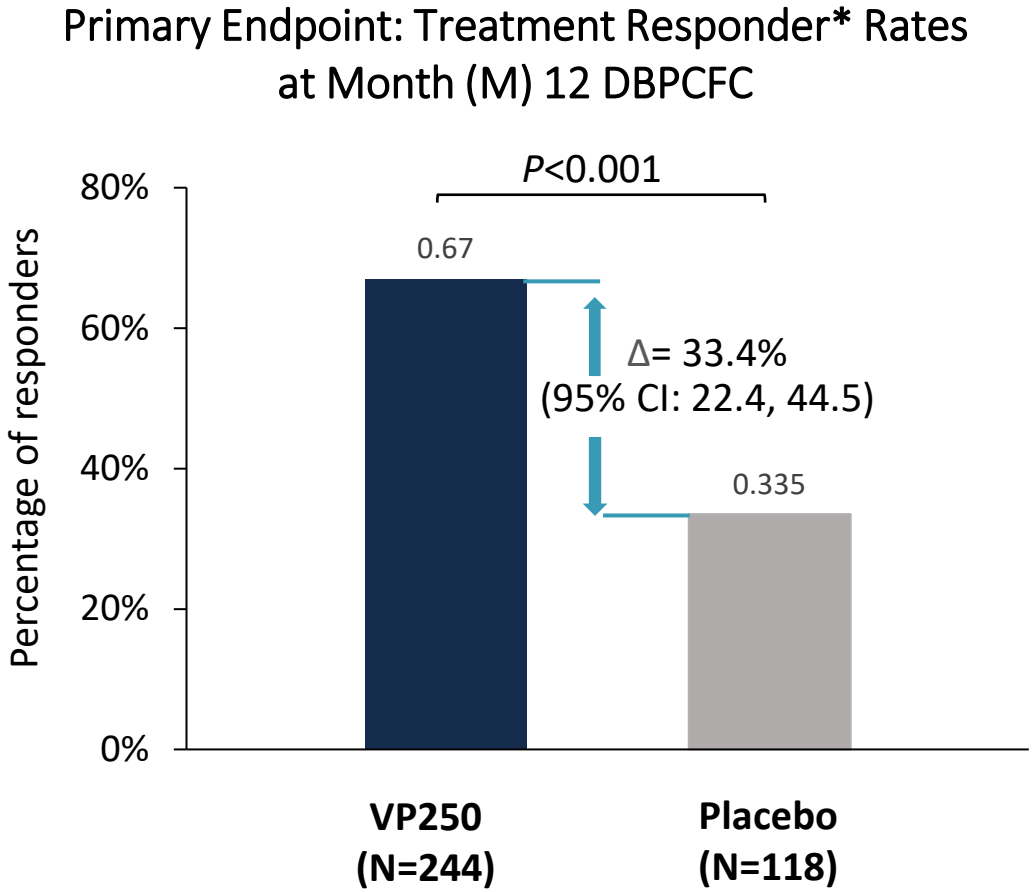
PET, positron emission tomography.

1. Dantzer JA, Kim EH. *J Allergy Clin Immunol Pract*. 2024;12(3):546-552. 2. Capucilli P et al. *Ann Allergy Asthma Immunol*. 2020;124(5):459-465. 3. Fleischer DM et al. *JAMA*. 2019;321(10):946-955. 4. Fleischer DM et al. *J Allergy Clin Immunol*. 2020;146(4):863-874. 5. Pongracic JA et al. *J Allergy Clin Immunol Pract*. 2022;10(7):1864-1873.e10. 6. Wang J, Sampson HA. *Pediatr Allergy Immunol*. 2018;29(4):341-349. 7. Greenhawt M et al. *N Engl J Med*. 2023;388(19):1755-1766.

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

# Background: Efficacy and Safety of 12 Months of VP250 in Toddlers Aged 1 Though 3 Years (EPITOPE)




A significantly larger percentage of participants achieved the **primary endpoint** in the **VIASKIN peanut patch group vs placebo**

Key inclusion criteria for EPITOPE included baseline ED ≤300 mg, psIgE >0.7 $kU_A/L$, and skin prick test ≥6 mm.
DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; psIgE, peanut-specific immunoglobulin E.
*Treatment responders were defined as having a post-treatment ED ≥300 mg (if baseline ED ≤10 mg) or ED ≥1000 mg (if baseline ED >10 to ≤300 mg).[1]

1. Greenhawt M et al. *N Engl J Med*. 2023;388(19):1755-1766.

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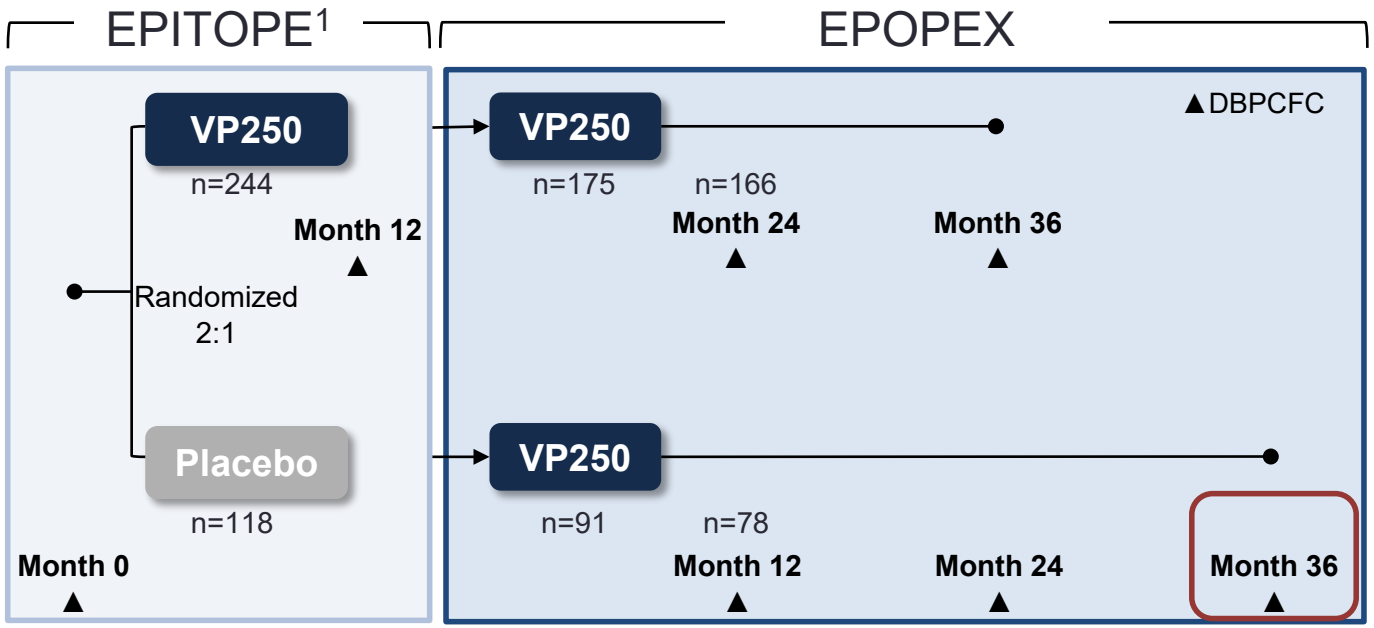
# Study Design: EPITOPE Open-Label Extension (EPOPEX) to Assess Long-Term Use of VP250




## Efficacy and Safety Endpoints

- % of treatment responders* (as defined in EPITOPE[1])
- % reaching ED[†] ≥1000 mg and ≥2000 mg
- % of participants completing the DBPCFC without meeting stopping criteria[‡]
- Maximum severity of objective symptoms during DBPCFC
- Safety as assessed by treatment-emergent adverse event rates, including anaphylaxis

## Objective

- To assess the efficacy and safety of up to 36 months of treatment with VP250 among peanut-allergic children who received placebo for 12 months in EPITOPE and crossed over to active treatment in the OLE

Key inclusion criteria for EPITOPE included baseline ED ≤300 mg, psIgE >0.7 $kU_A/L$, and skin prick test ≥6 mm.
DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; OLE, open-label extension; psIgE, peanut-specific immunoglobulin E.
*Treatment responders were defined as having a post-treatment ED ≥300 mg (if baseline ED ≤10 mg) or ED ≥1000 mg (if baseline ED >10 to ≤300 mg).[1] [†]ED defined as the dose at which allergic reaction signs or symptoms met the prespecified stopping criteria and ended the DBPCFC. [‡]DBPCFC conducted per PRACTALL guidelines using a standardized, blinded food matrix and were ended when signs or symptoms sufficiently met prespecified stopping criteria.
1. Greenhawt M et al. *N Engl J Med*. 2023;388(19):1755-1766.
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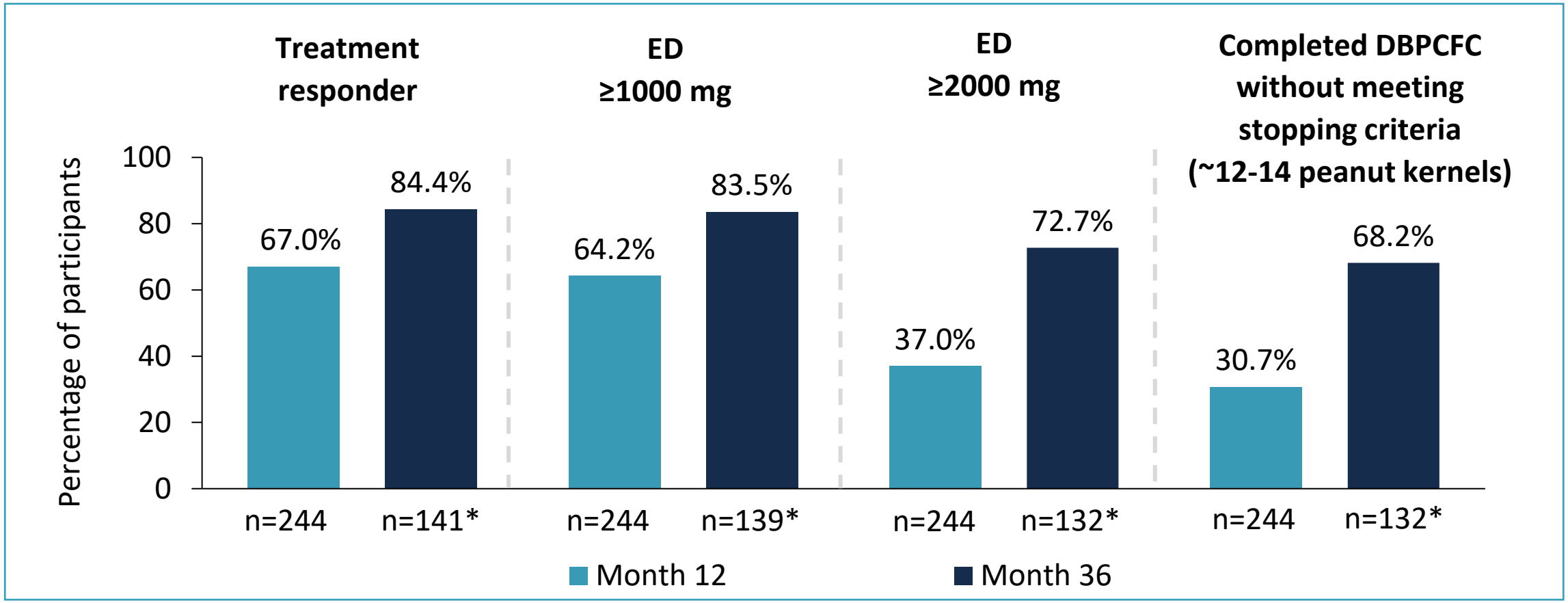
# Three-Year Efficacy Results: VP250+VP250 Group

Increases across all efficacy endpoints were observed in the VP250+VP250 group at M36 vs M12 of treatment




DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; M, month.
*Number of participants with non-missing endpoint.
Greenhawt M et al. Presented at: Eastern Food Allergy and Comorbidity Conference; January 9-12, 2025; Palm Beach, FL.
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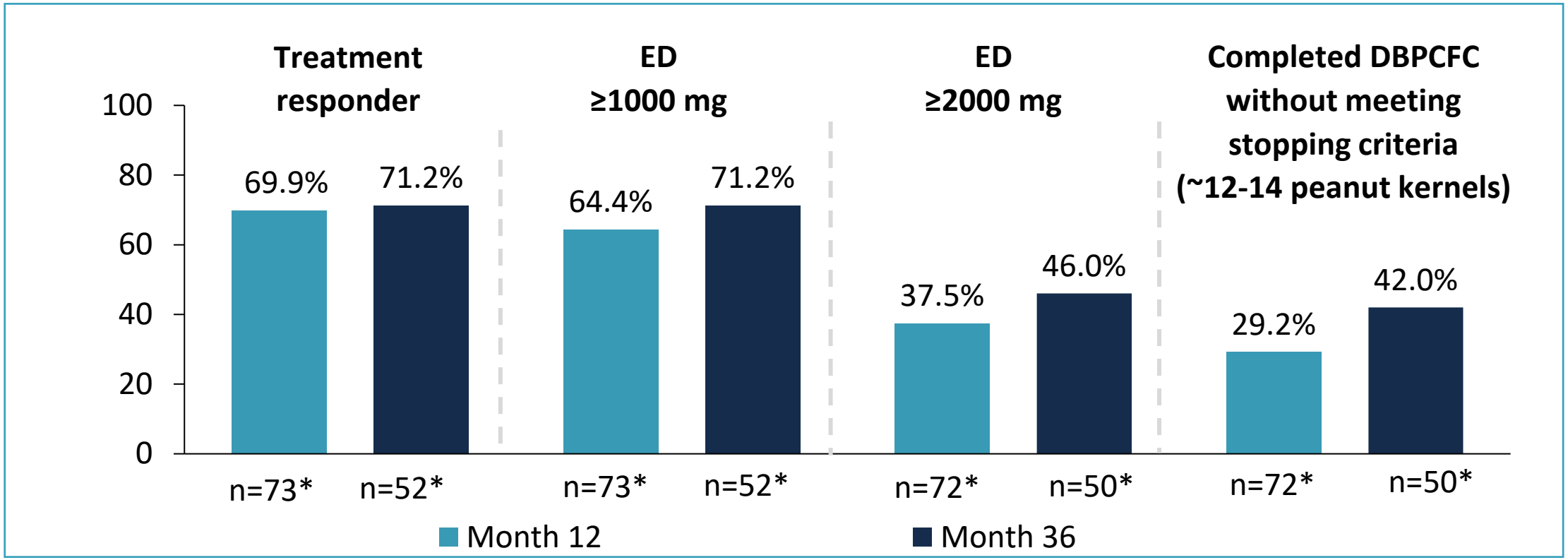
# Three-Year Efficacy Results: Placebo+VP250 Group

Results were consistent with the VP250+VP250 group, though lower in magnitude, possibly due to initiating treatment 1 year later and smaller n numbers




- The percentage of participants with severe reactions during the DBPCFC was nearly half at M36 vs M12 (10.0% vs 19.4%) and similar to that in the VP250+VP250 group at M36 (9.8%)

DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; M, month.
*Number of participants with non-missing endpoint.
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# Safety Results: Placebo+VP250 Group

- Consistent with safety results in the VP250+VP250 group,[1] there were no treatment-related anaphylactic reactions or treatment-related serious TEAEs beyond the first year of active treatment
- The frequency and severity of treatment-related local TEAEs decreased over the course of VP250 treatment

| Adverse event category, n (%) | Year 1 of active treatment PBO+VP250 (N=91) | Year 3 of active treatment PBO+VP250 (N=65) |
|---|---|---|
| **TEAEs** | 90 (98.9) | 59 (90.8) |
| **Treatment-related TEAEs** | 88 (96.7) | 40 (61.5) |
| **Serious TEAEs** | 2 (2.2) | 4 (6.2) |
| **Treatment-related serious TEAEs** | 1 (1.1) | 0 |
| **TEAEs leading to permanent study treatment discontinuation** | 1 (1.1) | 0 |
| **Treatment-related local TEAEs** | 86 (94.5) | 40 (61.5) |
| **Severe treatment-related local TEAEs** | 15 (16.5) | 1 (1.5) |
| **Anaphylactic reaction** | 6 (6.6) | 1 (1.5) |
| **Treatment-related anaphylactic reaction** | 1 (1.1) | 0 |

PBO, placebo; TEAE, treatment-emergent adverse event.

1. Greenhawt M et al. Presented at: Eastern Food Allergy and Comorbidity Conference; January 9-12, 2025; Palm Beach, FL.

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# Key Points

36 months of VP250 in young children showed continued increases in treatment effect, consistent with the VP250+VP250 group

Safety results were consistent with previous VP250 trials,[1-4] demonstrating a favorable safety profile with mainly local application-site reactions, which decreased over time, and low rates of treatment-related anaphylaxis

These data support the potential of VP250 as a long-term treatment option for peanut-allergic children, if approved

1. Greenhawt M et al. *N Engl J Med*. 2023;388(19):1755-1766. 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.
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