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VITESSE Phase 3 Study: Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Children 4 Through 7 Years of Age

David M. Fleischer, Douglas P. Mack, Julie Wang, Jeffrey Leflein, Michael O'Sullivan, Anne-Sophie Chhim, Katharine J. Bee, Hugh A. Sampson

David M. Fleischer, MD

Professor of Pediatrics
Section Head, Allergy and Immunology
Director, Allergy and Immunology Center
University of Colorado School of Medicine
Aurora, CO, USA

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Introduction: Epicutaneous Immunotherapy for Peanut Allergy

VIASKIN® peanut patch, a novel approach to epicutaneous immunotherapy (EPIT) for peanut allergy in children, involves the administration of a patch (VP250) to intact skin to induce desensitization[1-5]

VP250 contains 250 µg of peanut protein (1/1000th of 1 peanut kernel) and there is no dose escalation

- Exposure amount over 3 years of treatment equates to ~1 peanut kernel

VP250 is designed to be a noninvasive approach, applied once a day at home, with no restrictions related to exercise, illness, or NSAID use

VIASKIN® peanut patch

Figure from DBV Technologies.

Objective: Assess the efficacy and safety of VP250 in peanut-allergic children aged 4 through 7 years in the phase 3 VITESSE trial[6]

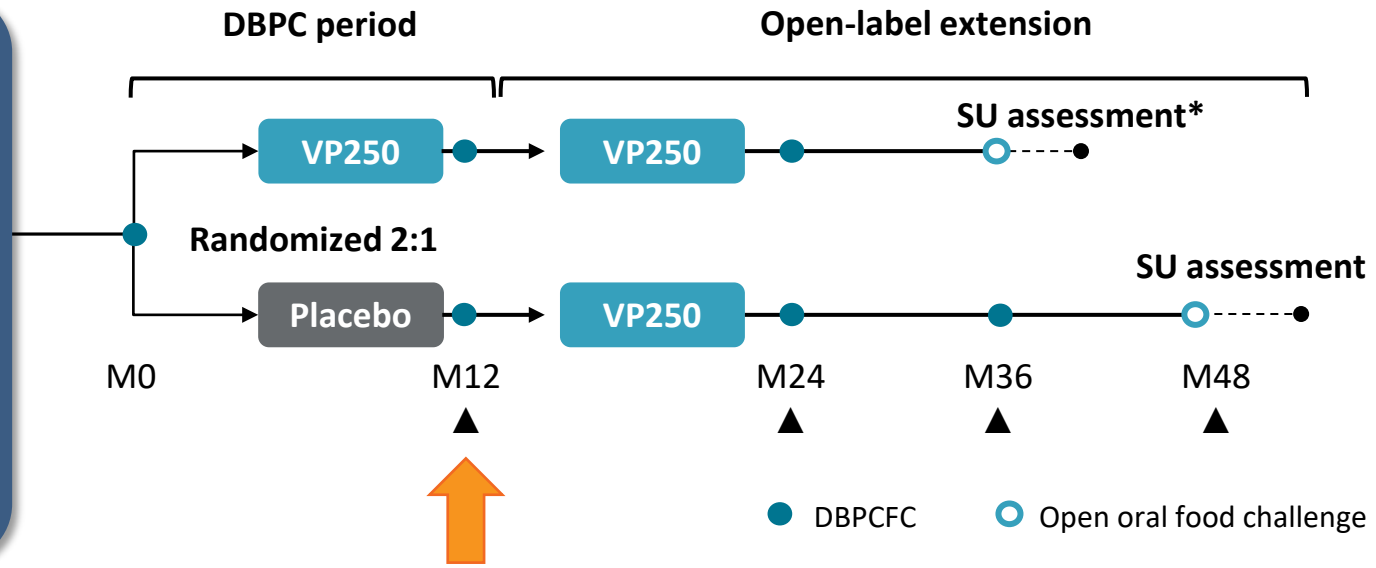
EPIT, epicutaneous immunotherapy; NSAID, nonsteroidal anti-inflammatory drug; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.

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. ClinicalTrials.gov. Updated January 22, 2026. Accessed February 25, 2026. https://clinicaltrials.gov/study/NCT05741476.

VITESSE Study Design: 12-Month Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial[1]

Phase 3 global trial (NCT05741476)

- Peanut-allergic children (aged 4 through 7 years)
- 87 sites in Australia, Canada, Europe, and the USA
- Key inclusion criteria:
  - Baseline ED ≤100 mg
  - psIgE >0.7 kU_A/L
  - Skin prick test ≥6 mm



Key efficacy outcomes[1,2]

- **Primary outcome:** % of treatment responders, defined as:
  - For baseline ED ≤30 mg, responder if M12 ED ≥300 mg
  - For baseline ED =100 mg, responder if M12 ED ≥600 mg
  - Changes in ED at M12, including any change and proportion reaching ED ≥600 mg

Safety outcomes[1]

- Frequency, severity, and treatment relatedness of TEAEs, serious TEAEs, AESIs, and systemic allergic reactions
- Discontinuations due to TEAEs

*SU assessment involves an open oral food challenge every 2 months for 6 months after stopping treatment in eligible participants.[1]

AESI, adverse event of special interest; DBPC, double-blind, placebo-controlled; DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; M, month; psIg, peanut-specific immunoglobulin; SU, sustained unresponsiveness; TEAE, treatment-emergent adverse event; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.

1. ClinicalTrials.gov. Updated January 22, 2026. Accessed February 25, 2026. https://clinicaltrials.gov/study/NCT05741476; 2. DBV Technologies. Data on file, 2026.

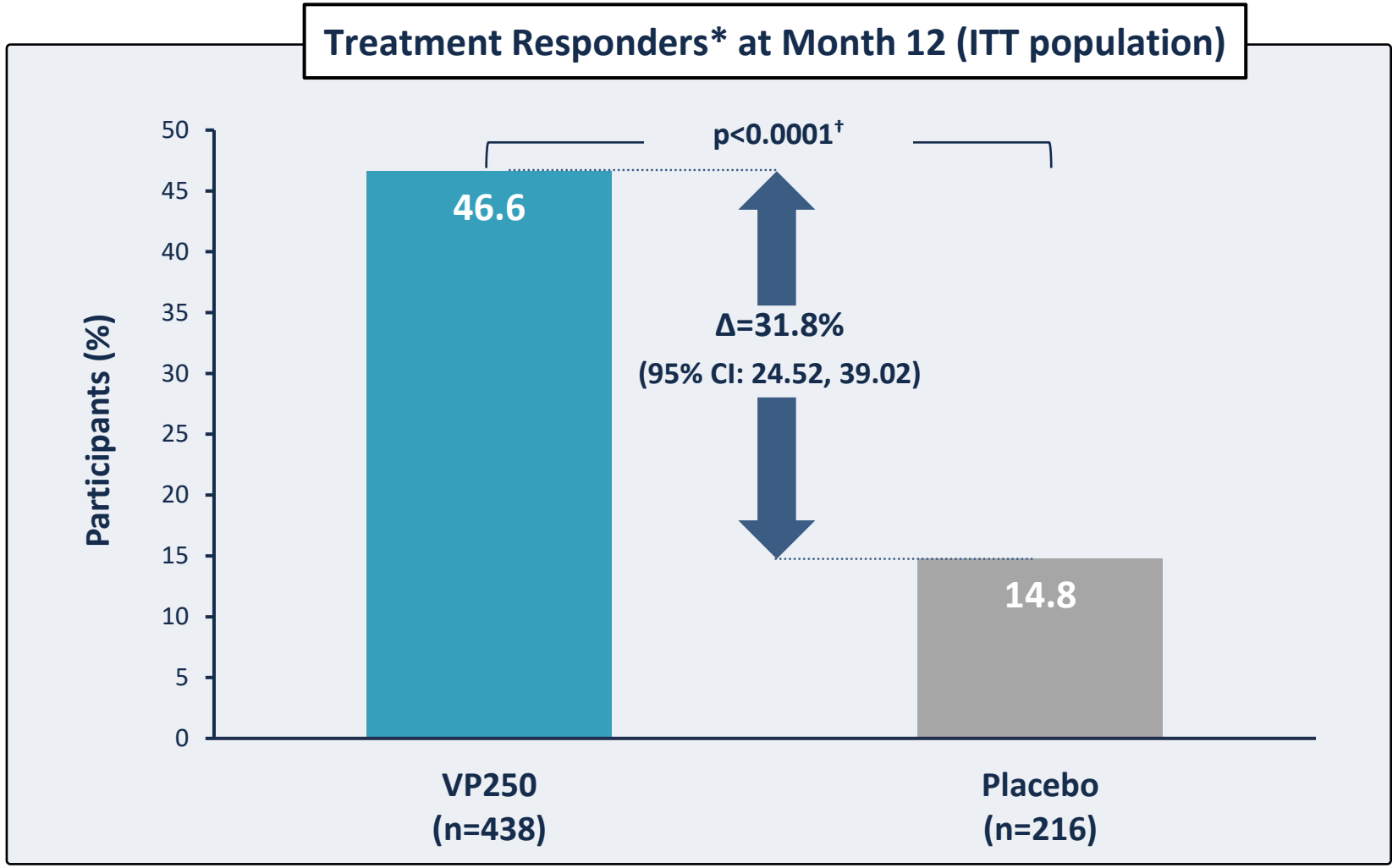
Participant Demographics and Baseline Characteristics Were Well Balanced Between Study Groups

	VP250 (n=438)	Placebo (n=216)
Age, years, median (Q1, Q3)	5.7 (4.78, 6.88)	5.7 (4.84, 6.68)
Gender, n (%)		
Male	265 (60.5)	142 (65.7)
Female	172 (39.3)	74 (34.3)
Undifferentiated	1 (0.2)	0 (0.0)
Peanut-specific IgE, kU_A/L		
Mean (SD)	130.7 (219.73)	153.4 (293.94)
Median (Q1, Q3)	38.0 (11.1, 161.0)	45.3 (10.9, 185.0)
Skin prick test, median wheal diameter (mm)	11.0	10.8
Medical history (ongoing at baseline), n (%)		
Atopic dermatitis / eczema	269 (61.4)	135 (62.5)
Asthma	155 (35.4)	79 (36.6)
Other food allergy	247 (56.4)	123 (56.9)

Ig, immunoglobulin; Q, quartile; SD, standard deviation; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.

DBV Technologies. Data on file, 2026.

VP250 Met the Primary Endpoint and Demonstrated Significantly Greater Responder Rates vs Placebo

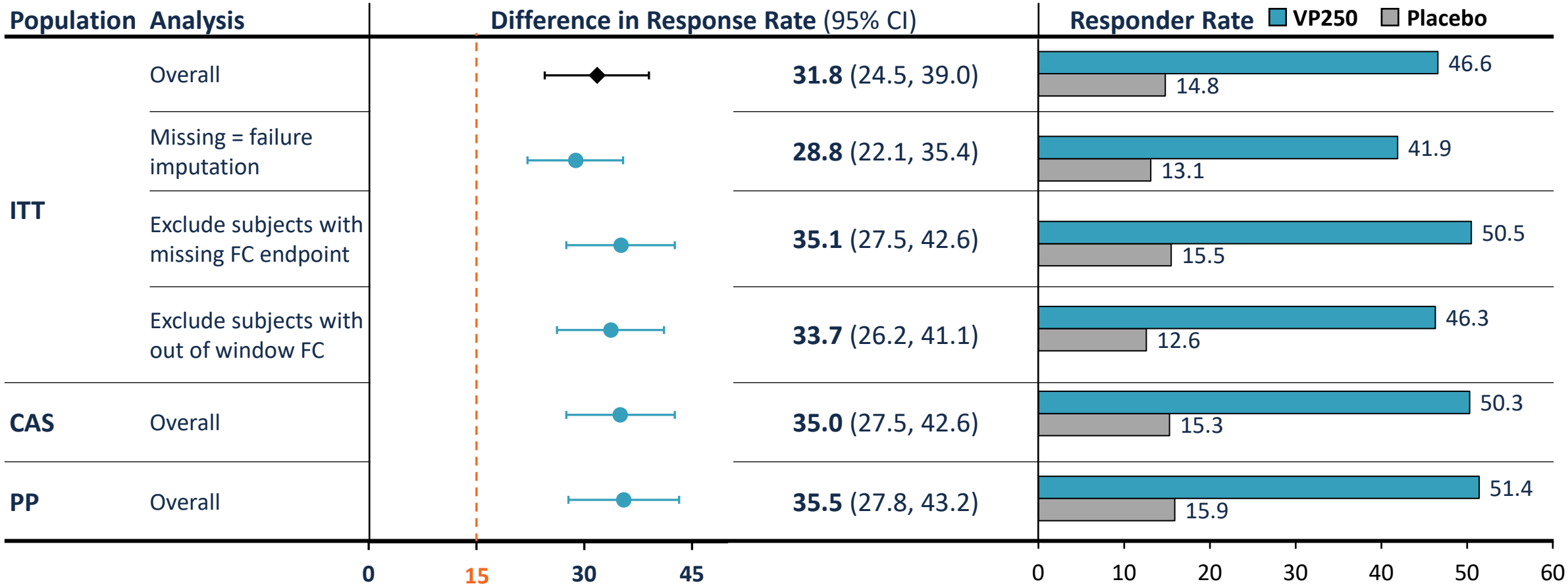


*Responders were defined as children with a baseline ED ≤30 mg who achieved an ED ≥300 mg of peanut protein at month 12, or children with a baseline ED of 100 mg who achieved an ED ≥600 mg of peanut protein at month 12. †P=10^{-17}.

CI, confidence interval; ED, eliciting dose; ITT, intent-to-treat; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.

DBV Technologies. Data on file, 2026.

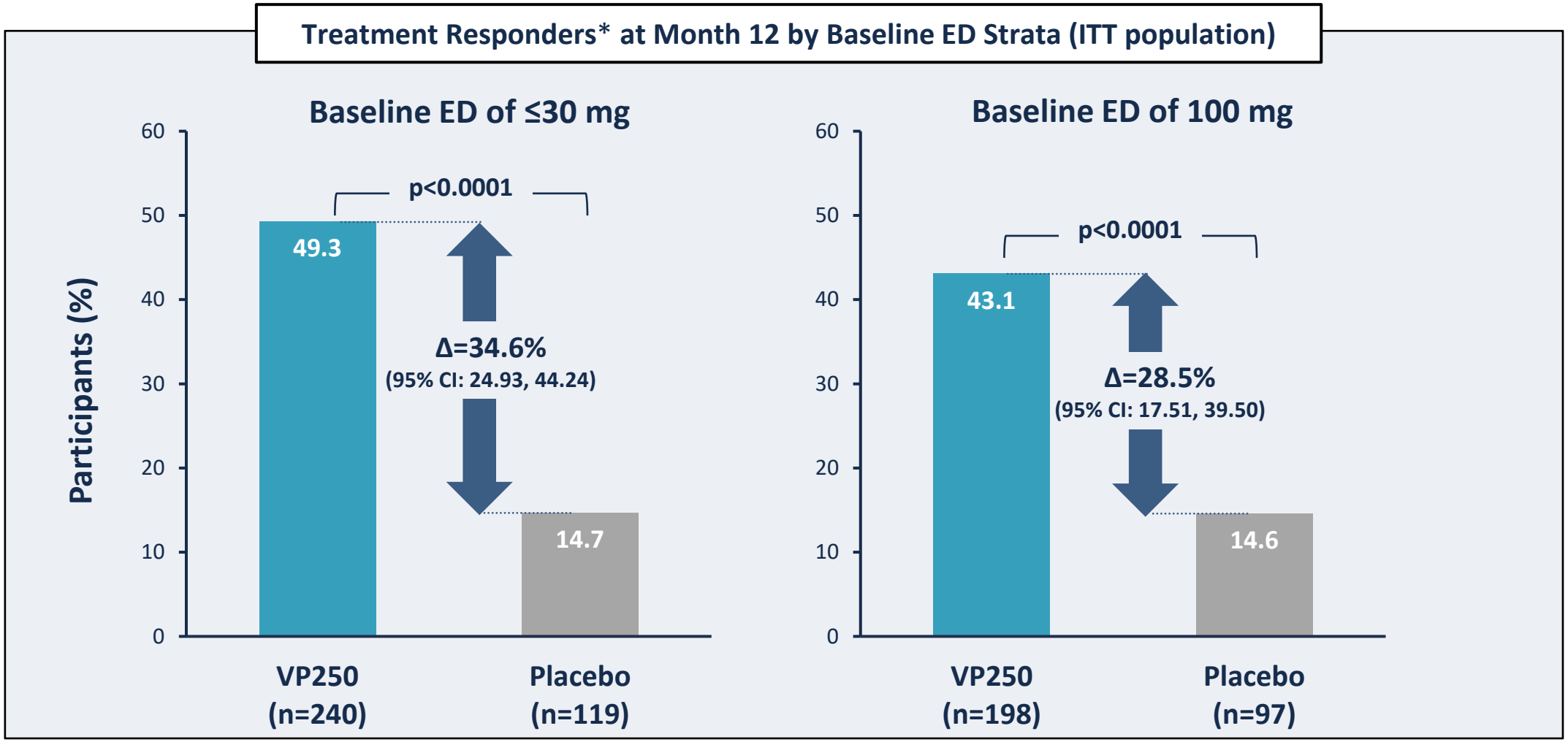
Sensitivity Analyses of the Primary Endpoint Demonstrate Consistency of Treatment Effect



Similar treatment effects were observed across multiple sensitivity analyses, all of which met the primary endpoint

CAS, completer analysis set; CI, confidence interval; FC, food challenge; ITT, intent-to-treat; PP, per protocol; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.

Significantly Greater Proportion of Treatment Responders Observed With VP250, Regardless of Baseline ED Strata



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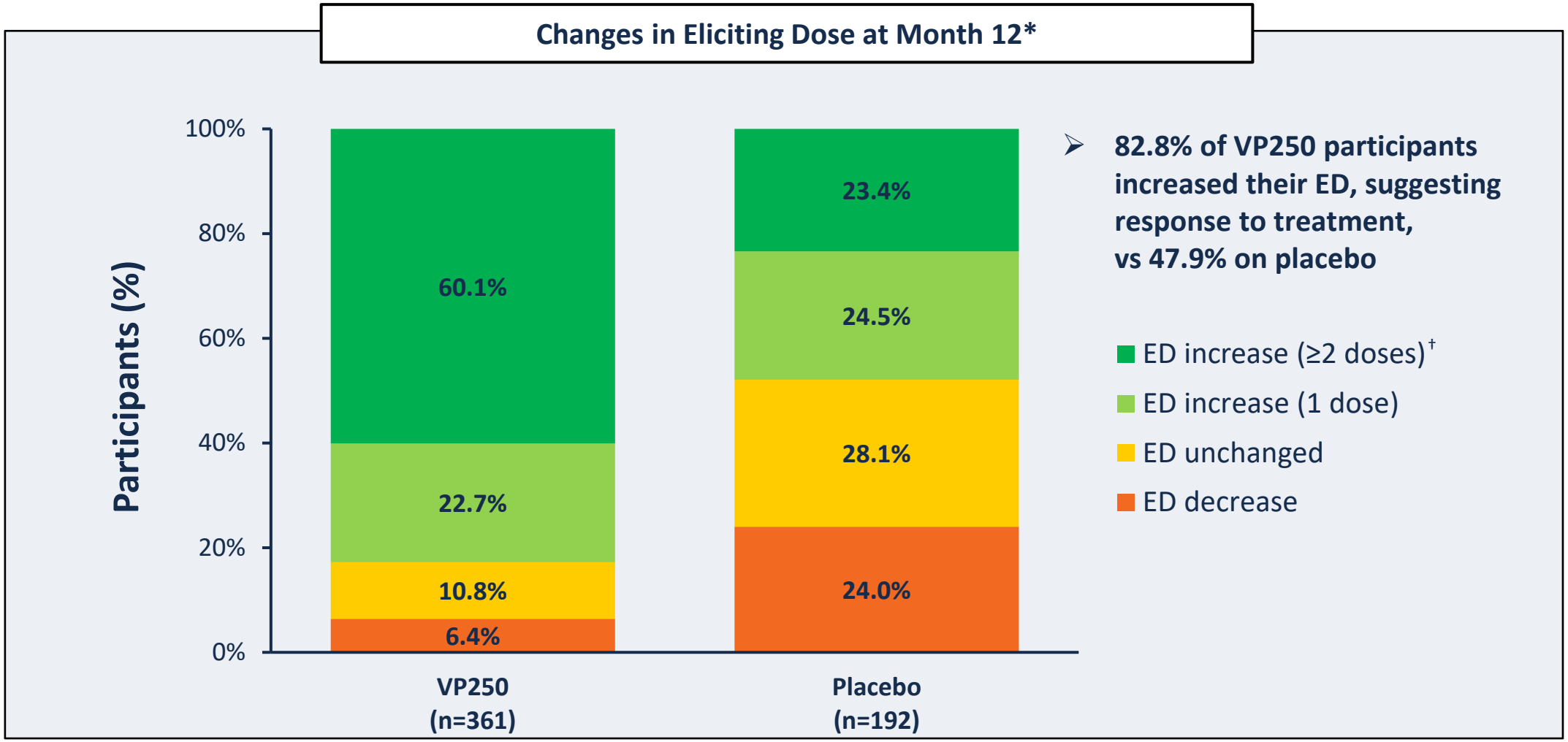
CI, confidence interval; ED, eliciting dose; ITT, intent-to-treat; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.

DBV Technologies. Data on file, 2026.

The Majority of VP250 Participants Increased Their Eliciting Dose by at Least Two Doses



*Among participants who completed the month 12 DBPCFC. †Doses given during the DBPCFC: 1 mg, 3 mg, 10 mg, 30 mg, 100 mg, 300 mg, 600 mg, 1000 mg.

DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.

DBV Technologies. Data on file, 2026.

Low Rates of Participants With Severe Treatment-Related Adverse Events

	VP250 (n=438)	Placebo (n=216)
TEAEs, number of participants (%)		
Overall	432 (98.6)	207 (95.8)
Mild	421 (96.1)	198 (91.7)
Moderate	231 (52.7)	83 (38.4)
Severe	5 (1.1)	6 (2.8)
Serious	6 (1.4)	5 (2.3)
Treatment-related TEAEs, number of participants (%)		
Overall	405 (92.5)	139 (64.4)
Local	399 (91.1)	135 (62.5)
Severe	2 (0.5)	0 (0)
Serious	0 (0)	0 (0)
Treatment-related anaphylactic reaction	2 (0.5)	0 (0)
Treatment-related TEAEs leading to epinephrine use	3 (0.7)	1 (0.5)

The majority of TEAEs were mild local application-site reactions, consistent with previous VP250 studies

TEAE, treatment-emergent adverse event; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.

DBV Technologies. Data on file, 2026.

Treatment With VP250 Was Well Tolerated

	VP250 (n=438)	Placebo (n=216)	Overall (n=654)
TEAEs leading to permanent study discontinuation, n (%)	14 (3.2)	1 (0.5)	15 (2.3)
Mean compliance* (%)	96.1	96.5	96.2

The low rates of discontinuations due to TEAEs and high compliance suggest that VP250 was well tolerated in the VITESSE trial

*Overall compliance (%) over the study period is defined as the number of systems dispensed minus the number of systems returned divided by overall exposure duration (days) × 100.

TEAE, treatment-emergent adverse event; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.

DBV Technologies. Data on file, 2026.

Summary

Efficacy results from VITESSE, the largest food allergy immunotherapy trial to date, demonstrated that EPIT with VP250 resulted in significantly greater responder rates vs placebo (46.6% vs 14.8%; $p<0.0001$) in a highly sensitized population of peanut-allergic children aged 4-7 years

The safety profile of VP250 was favorable:

- Most TEAEs were mild local skin reactions
- Low rates of treatment-related anaphylaxis (0.5%; n=2) were recorded
- These results were consistent with previous VP250 trials within pediatric populations

VP250 was well tolerated with a high adherence rate (96.1%; n=421) over the 12-month period, suggesting treatment was practical and allowed for continuation of usual daily activities

EPIT, epicutaneous immunotherapy; TEAE, treatment-emergent adverse event; VP250, VIASKIN® peanut patch containing 250 µg of peanut protein.