Long-Term Efficacy Results of Epicutaneous Immunotherapy With VIASKIN® Peanut Patch in Peanut-Allergic Children Aged 4-11 Years in the Phase 3 PEOPLE Study

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Introduction

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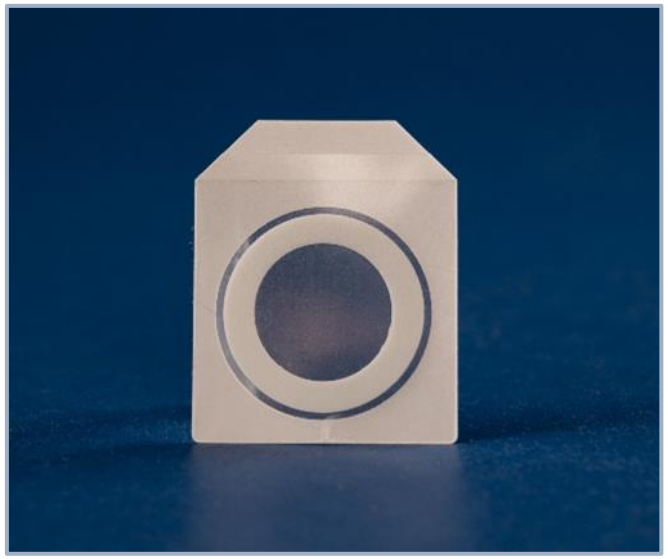
Background

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[1-5]

Maintenance treatment for allergen-specific immunotherapy has historically ranged from 3 to 5 years[6]; thus, it is important to characterize the long-term efficacy of VP250

The efficacy and safety of VP250 up to 5 years in peanut-allergic children was studied in the phase 3 PEPITES[1] trial and in the open-label extension, PEOPLE[2]



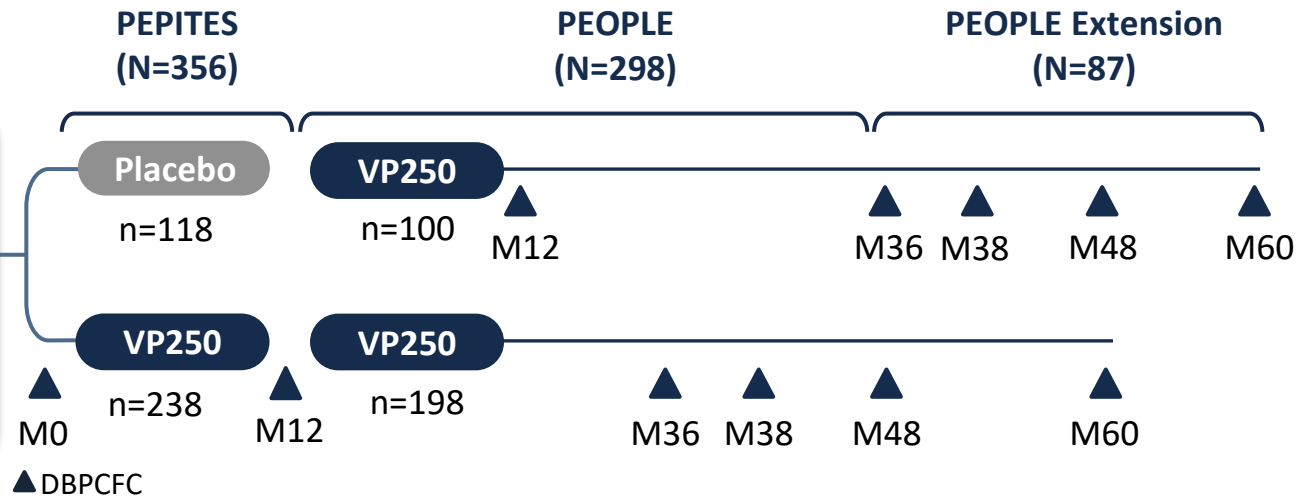
1. Fleischer DM et al. *JAMA*. 2019;321(10):946-955. 2. Fleischer DM et al. *J Allergy Clin Immunol*. 2020;146(4):863-874. 3. Pongracic JA et al. *J Allergy Clin Immunol Pract*. 2022;10(7):1864-1873.e10. 4. Wang J, Sampson HA. *Pediatr Allergy Immunol*. 2018;29(4):341-349. 5. Greenhawt M et al. *N Engl J Med*. 2023;388(19):1755-1766. 6. Moote W et al. *Allergy Asthma Clin Immunol*. 2018;14(suppl 2):53.

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

Study Design

PEPITES[1] and PEOPLE[2]

- **PEPITES**: 356 peanut-allergic children (aged 4 through 11 years)
- **PEOPLE:** 298 children continued in PEOPLE
- 31 sites in Australia, Canada, Europe, and the US
- Key inclusion criteria: baseline ED ≤300 mg, psIgE >0.7 kU_A/L, and skin prick test ≥6 mm (4- to 5-year-olds) or ≥8 mm (6- to 11-year-olds)



Safety Outcomes

- Safety outcomes included duration and severity of treatment-emergent adverse events (TEAEs) and serious TEAEs

Efficacy Outcomes

- Percentage of treatment responders (as defined in PEPITES*)
- Percentage reaching ED ≥1000 mg
- Percentage who tolerated the 2000 mg dose without symptoms meeting the stopping criteria
- Maximum severity of objective symptoms during DBPCFC
- psIgE and psIgG4

DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; EPIT, epicutaneous immunotherapy; M, month; psIgE, peanut-specific immunoglobulin E; psIgG4, peanut-specific immunoglobulin G4.
*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]

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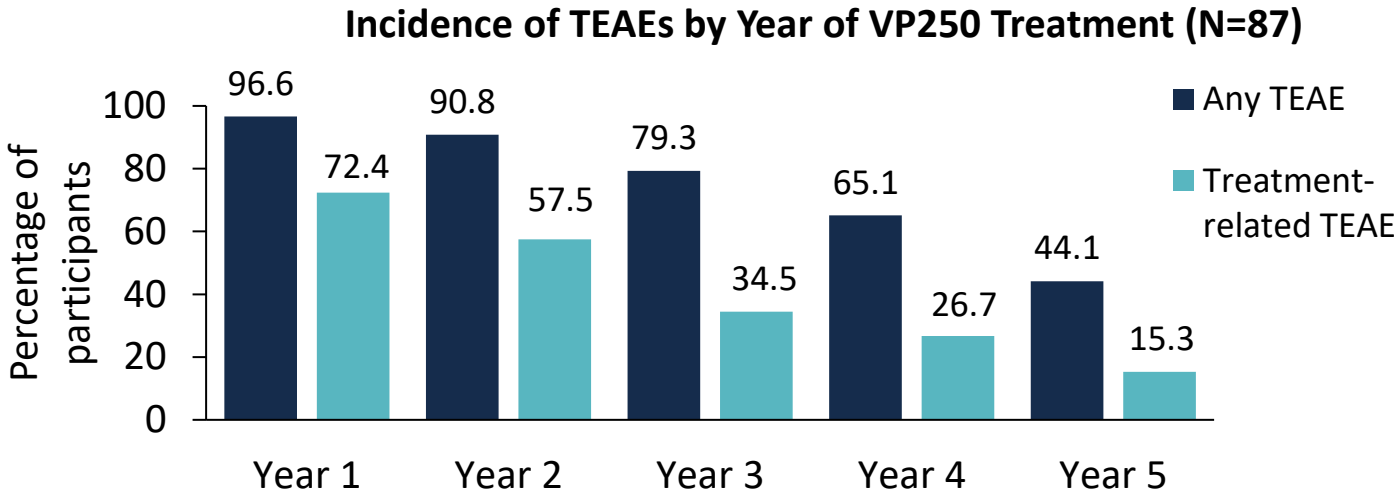
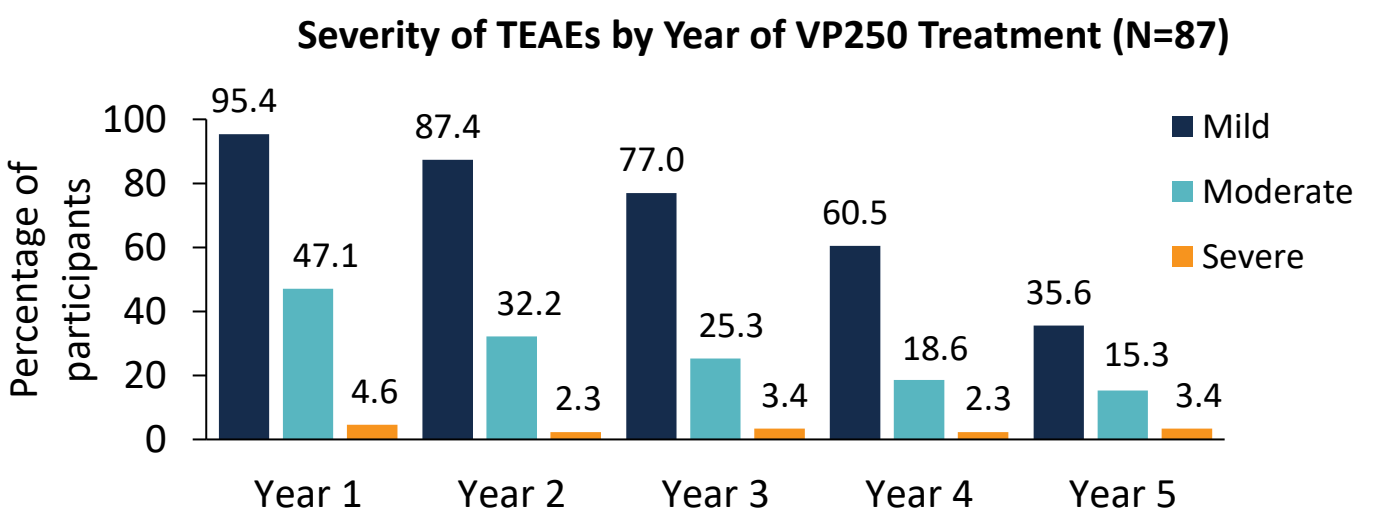
Safety Results From PEOPLE Extension

- Over 5 years, all participants experienced a TEAE; majority were mild or moderate
- Approximately 93% experienced a treatment-related TEAE
- Severity of TEAEs was mild to moderate and decreased in frequency and severity over time
- Most TEAEs were application-site reactions





Fleischer DM et al. Presented at: American Academy of Allergy, Asthma, and Immunology 2024; February 23-26, 2024; Washington, DC.

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Safety Results From PEOPLE Extension (*cont*)

- Treatment-related local application-site reactions decreased in frequency and severity over time
- Treatment-related TEAEs leading to epinephrine use occurred in 1/87 (1.1%) participants (Year 1 only)
- One serious treatment-related TEAE in Year 1 (active treatment)
- Treatment-related anaphylactic reactions occurred in 2/87 (2.3%) participants (Years 1 and 2 only)

Category, n (%)	Year 1* (n=87)	Year 2* (n=87)	Year 3* (n=87)	Year 4* (n=86)	Year 5* (n=59)
VP250-induced local TEAEs	63 (72.4)	44 (50.6)	30 (34.5)	22 (25.6)	9 (15.3)
Severe VP250-induced local TEAEs	3 (3.4)	2 (2.3)	1 (1.1)	1 (1.2)	0
TEAEs leading to epinephrine intake	4 (4.6)	4 (4.6)	6 (6.9)	2 (2.3)	1 (1.7)
Considered related to VP250	1 (1.1)	0	0	0	0
TEAE leading to topical corticosteroid	47 (54.0)	34 (39.1)	17 (19.5)	16 (18.6)	4 (6.8)

*At each year, percentages are based on the number of participants in the extension safety population who applied at least 1 patch during this year.

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Results[1,2]

Of the 217 participants who completed PEOPLE Year 3, 87 (40%) participants continued treatment in the PEOPLE extension period; 130 participants either elected not to continue or were ineligible

Mean (range) age at extension entry was 11.1 (8-16) years

No permanent study discontinuations occurred due to TEAEs

Overall mean treatment compliance remained high at 5 years at 93.1%

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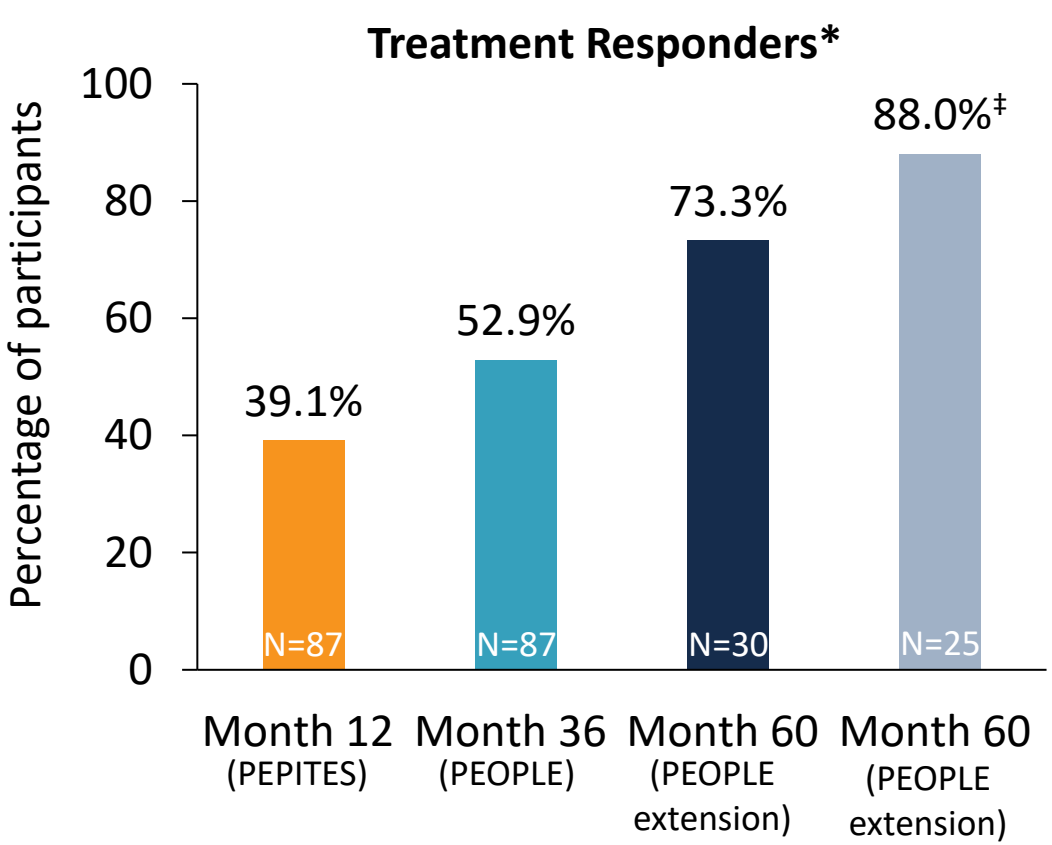
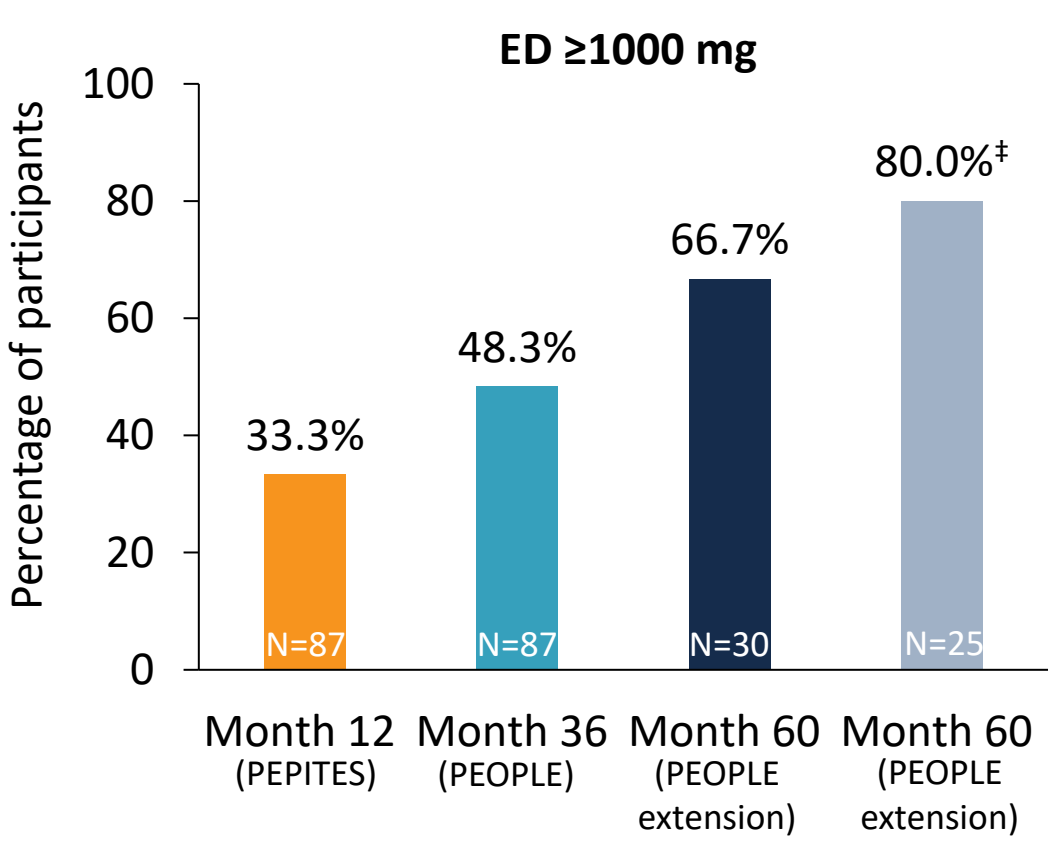
Treatment Responders and ED ≥1000 mg

- Increases in treatment responders* and ED ≥1000 mg were seen after 60 months of VP250 in the safety population (N=30)†





DBPCFC, double blind, placebo-controlled food challenge; ED, eliciting dose. N, number of participants who performed the DBPCFC at the timepoint.
*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]
†The safety population included all participants enrolled in the extension who received at least one dose of study treatment in the extension period.
‡At Month 60, 25 participants completed the DBPCFC; 5 did not complete and were considered nonresponders (N=30).

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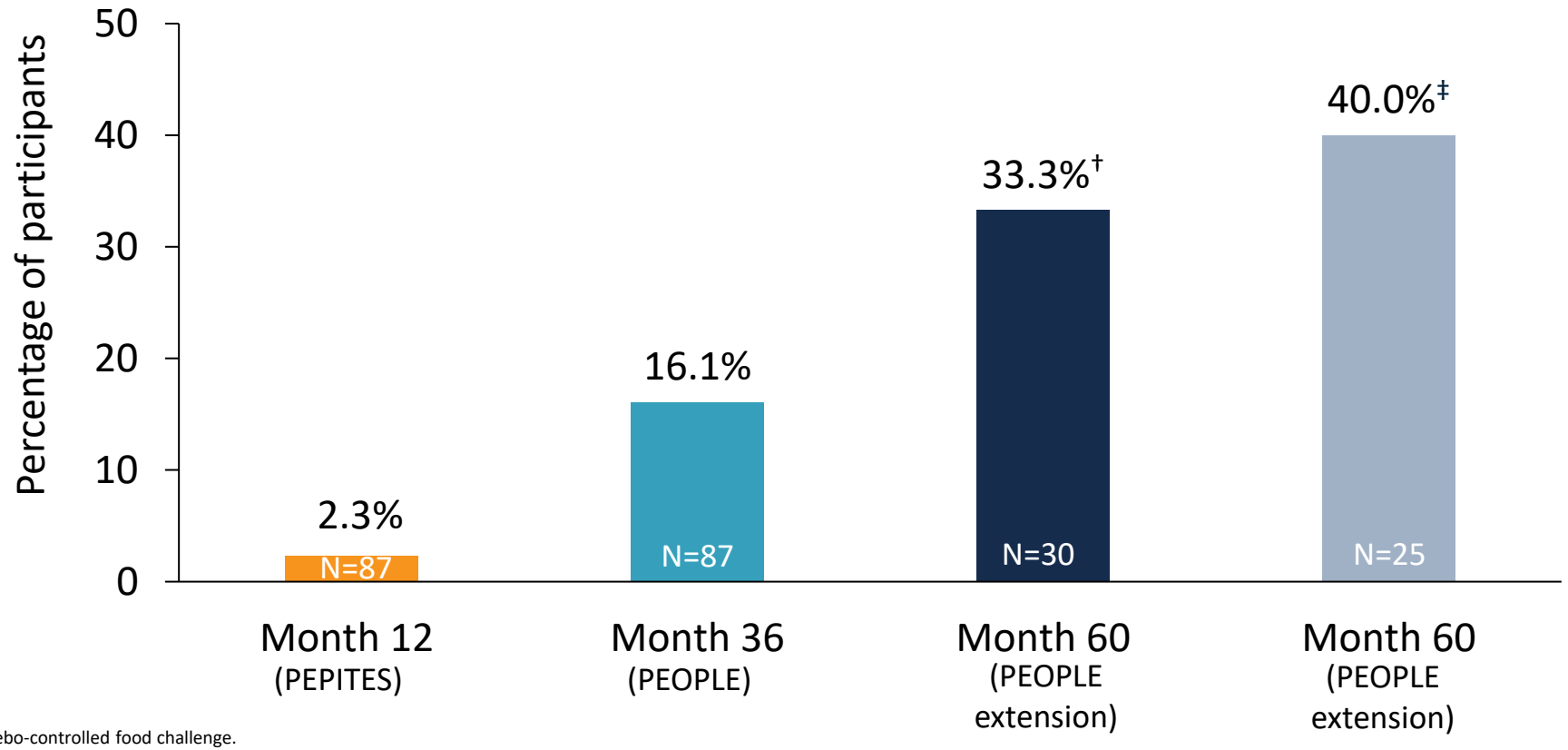
Tolerated 2000 mg Dose*

- Increases in participants who tolerated the 2000 mg dose without meeting the stopping criteria were seen after 60 months of VP250



DBPCFC, double-blind, placebo-controlled food challenge.
*Tolerated the 2000 mg dose without symptoms meeting the stopping criteria.
†The safety population included all participants enrolled in the extension who received at least one dose of study treatment in the extension period.
‡At Month 60, 25 participants completed the DBPCFC; 5 did not complete and were considered nonresponders (N=30).

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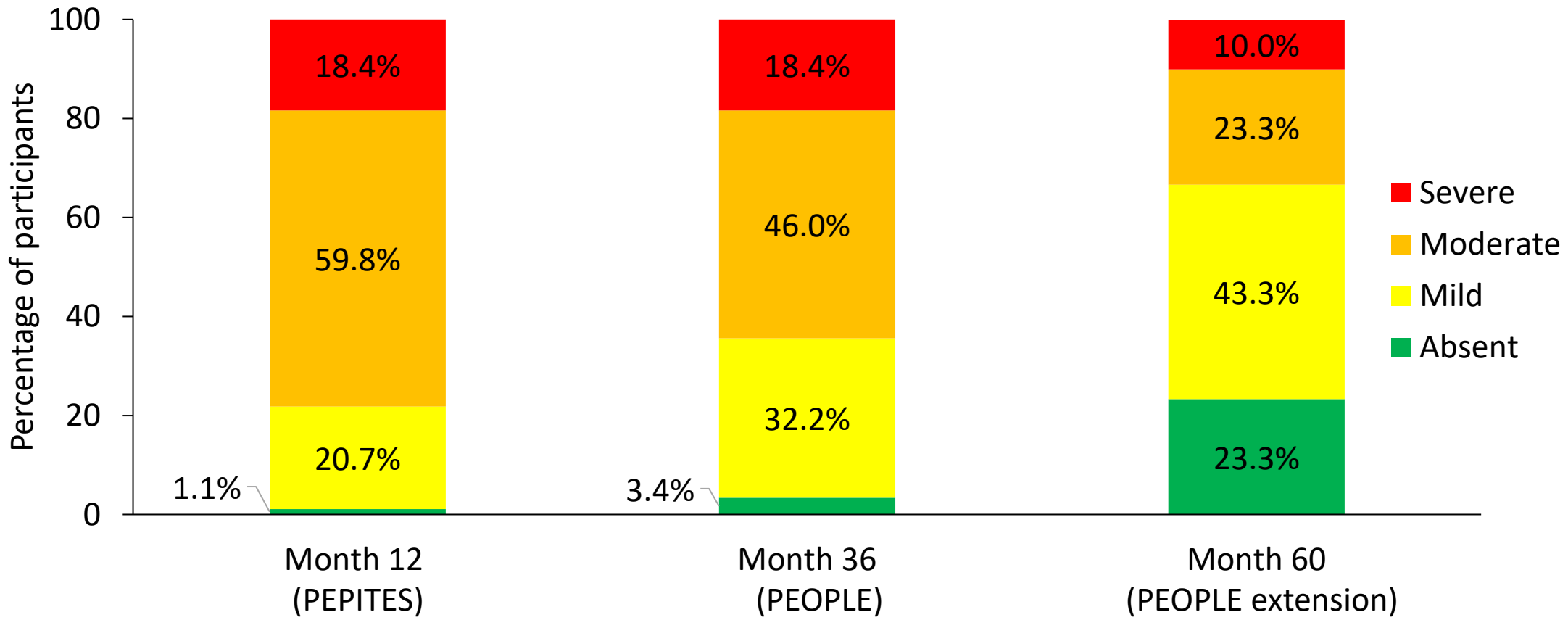
Maximum Severity of Symptoms During DBPCFC

- DBPCFC symptom severity decreased from Month 12 (PEPITES) to Month 60 (PEOPLE extension), with 66.6% of participants having no or mild symptoms



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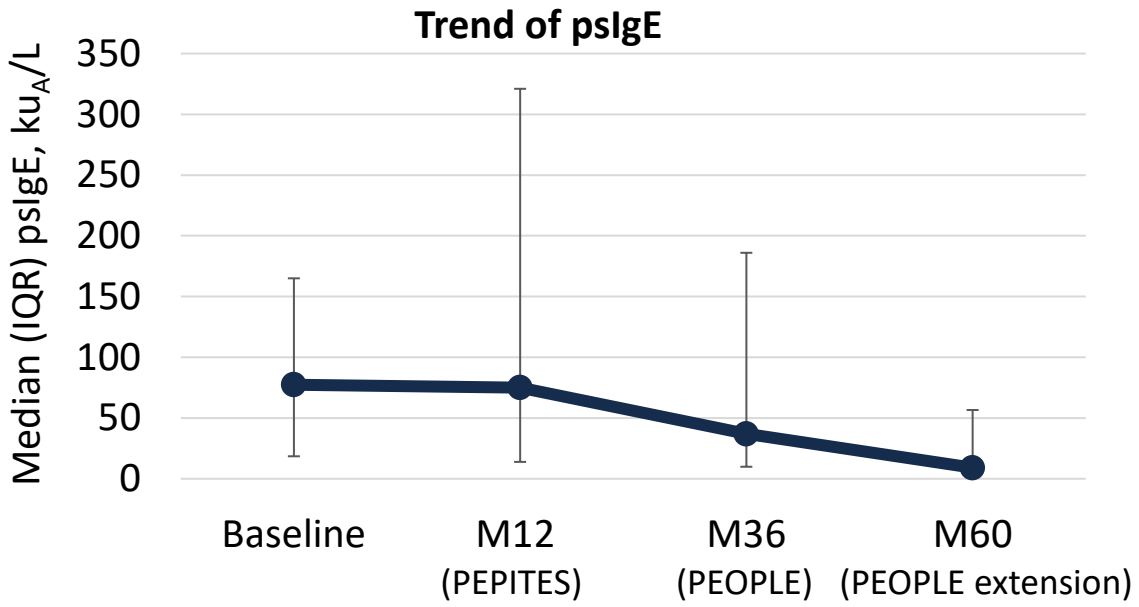
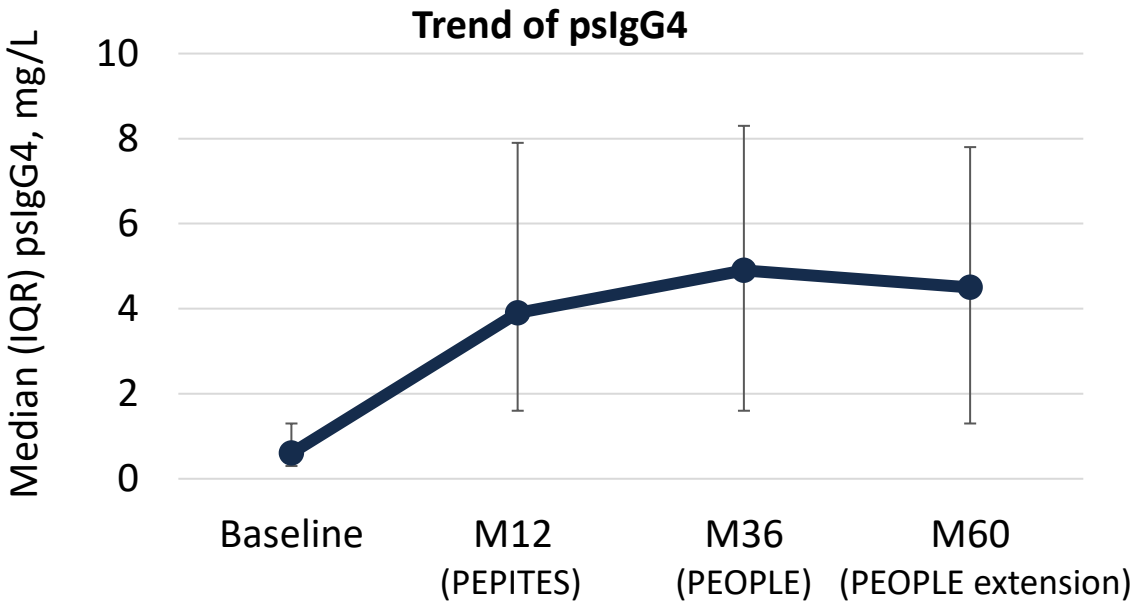
Immunological Markers

- Median peanut-specific IgE and IgG4 levels decreased and increased, respectively, from baseline, consistent with other VP250 studies[1,2] and allergen immunotherapy studies[3]



	Baseline	M12 (PEPITES)	M36 (PEOPLE)	M60 (PEOPLE extension)
Median	77.4	75.0	37.0	9.1
Min	0.8	0.1	0.2	0.1
Max	1208.0	1773.0	1644.0	668.0



	Baseline	M12 (PEPITES)	M36 (PEOPLE)	M60 (PEOPLE extension)
Median	0.6	3.9	4.9	4.5
Min	0.1	0.1	0.1	0.2
Max	11.8	44.3	24.7	20.4

M, month; min, minimum; max, maximum; psIgE, peanut-specific immunoglobulin E; psIgG4, peanut-specific immunoglobulin G4.

1. Fleischer DM et al. *JAMA*. 2019;321(suppl 3):1-16. 2. Greenhawt M et al. *N Engl J Med*. 2023;388(19):1755-1766. 3. Vickery BP et al. *J Allergy Clin Immunol*. 2013;131(1):128-134.e3.

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Key Points

Data suggest long-term VP250 treatment in peanut-allergic children who initiate treatment during ages 4 through 11 years may lead to:

- Continued accumulation of treatment benefit over 5 years
- A tolerable safety profile, as evidenced by high treatment compliance (93%) over 5 years

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Question and Answer Session

Thank you!

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