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VITESSE Phase 3 Study: Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Children Aged 4-7 Years With Atopic Comorbidities

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- **KBe**, **A-SC**, and **EJ** are employees of DBV Technologies
- **DF** is a consultant for DBV Technologies

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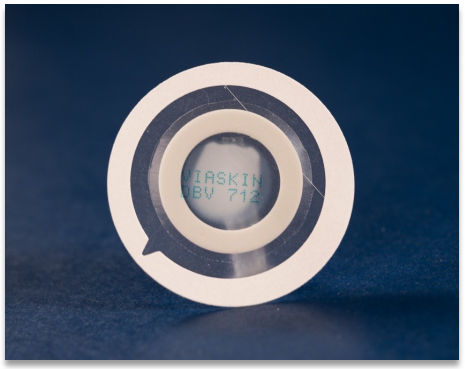
Epicutaneous Immunotherapy for Peanut Allergy

In the Phase 3 VITESSE trial, a greater proportion of children with peanut allergy aged 4 through 7 years achieved desensitization at 12 months with epicutaneous immunotherapy via the VIASKIN® Peanut Patch (250 µg of peanut protein) vs placebo ($p<0.0001$)[1]

Asthma, atopic dermatitis, and concomitant food allergy are common comorbidities among children with peanut allergy, and present important considerations for immunotherapy[2]

VIASKIN® Peanut Patch



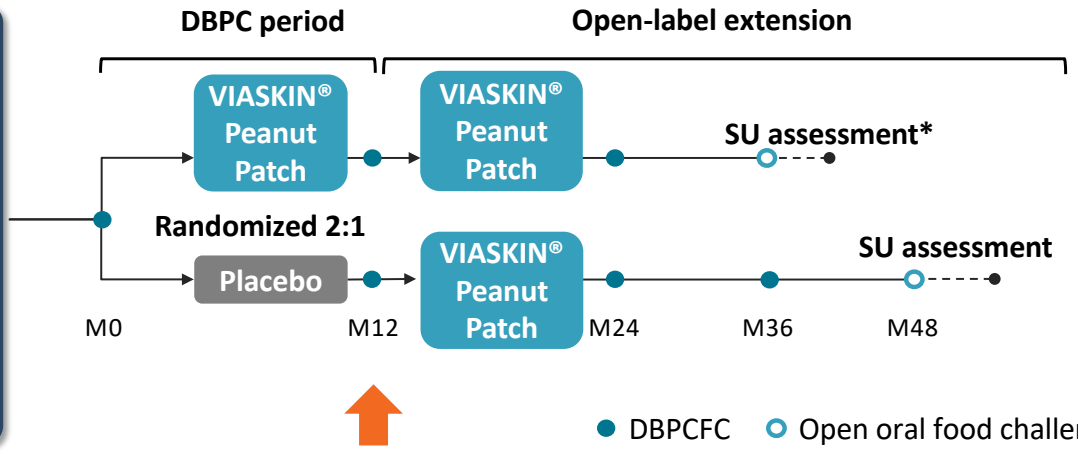
The VIASKIN® Peanut Patch is 44 mm in diameter.
Figure from DBV Technologies.

Objective: To assess the efficacy and safety of the VIASKIN® Peanut Patch in VITESSE participants with and without ongoing atopic comorbidities[3]

1. Fleischer DM, et al. Presented at: American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting; February 27 to March 2, 2026; Philadelphia, PA, USA; **2.** Mahr TA, et al. *J Allergy Clin Immunol Pract*. 2021;9(4):1683-1694.e5;
3. DBV Technologies. Data on file, 2026.

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

- Children with peanut allergy (aged 4 through 7 years)[1]
- 87 sites in Australia, Canada, Europe, and the USA[1]
- Key inclusion criteria:[1]
  - Baseline ED ≤100 mg of peanut protein
  - psIgE >0.7 kU_A/L
  - Skin prick test ≥6 mm (largest wheal diameter)



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 of 100 mg, responder if M12 ED ≥600 mg

Safety outcomes[1,2]

- 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.

1. ClinicalTrials.gov. NCT05741476. Updated January 22, 2026. Accessed June 10, 2026. https://clinicaltrials.gov/study/NCT05741476; **2.** DBV Technologies. Data on file, 2026.

Participant Demographics and Baseline Characteristics Were Well Balanced Between Study Groups

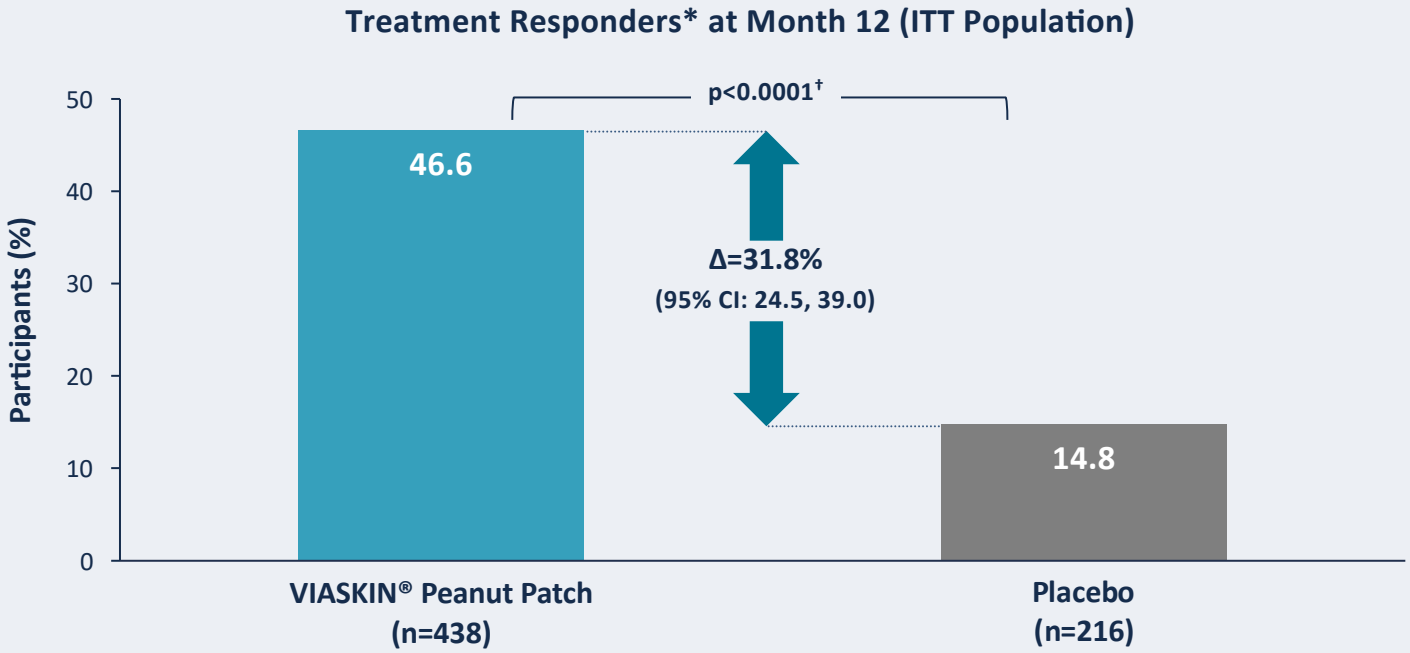
ITT population	VIASKIN® Peanut Patch (n=438)	Placebo (n=216)
Age, years, median (Q1, Q3)	5.7 (4.8, 6.9)	5.7 (4.8, 6.7)
Sex, n (%)		
Male	265 (60.5)	142 (65.7)
Female	172 (39.3)	74 (34.3)
Undifferentiated	1 (0.2)	0 (0.0)
Peanut-specific IgE, kU_A/L		
Mean (SD)	130.7 (219.7)	153.4 (293.9)
Median (Q1, Q3)	38.0 (11.1, 161.0)	45.3 (10.9, 185.0)
Skin prick test, median wheal diameter, mm (Q1, Q3)	11.0 (9.0, 13.0)	10.8 (9.0, 13.0)
Atopic comorbidities (ongoing at baseline), n (%)		
Asthma	155 (35.4)	79 (36.6)
Atopic dermatitis/eczema	269 (61.4)	135 (62.5)
Other food allergy	247 (56.4)	123 (56.9)

Atopic comorbidities were highly prevalent

Ig, immunoglobulin; ITT, intention-to-treat; Q, quartile; SD, standard deviation.

DBV Technologies. Data on file, 2026.

VIASKIN® Peanut Patch Met the Primary Endpoint and Demonstrated Significantly Greater Responder Rates vs Placebo

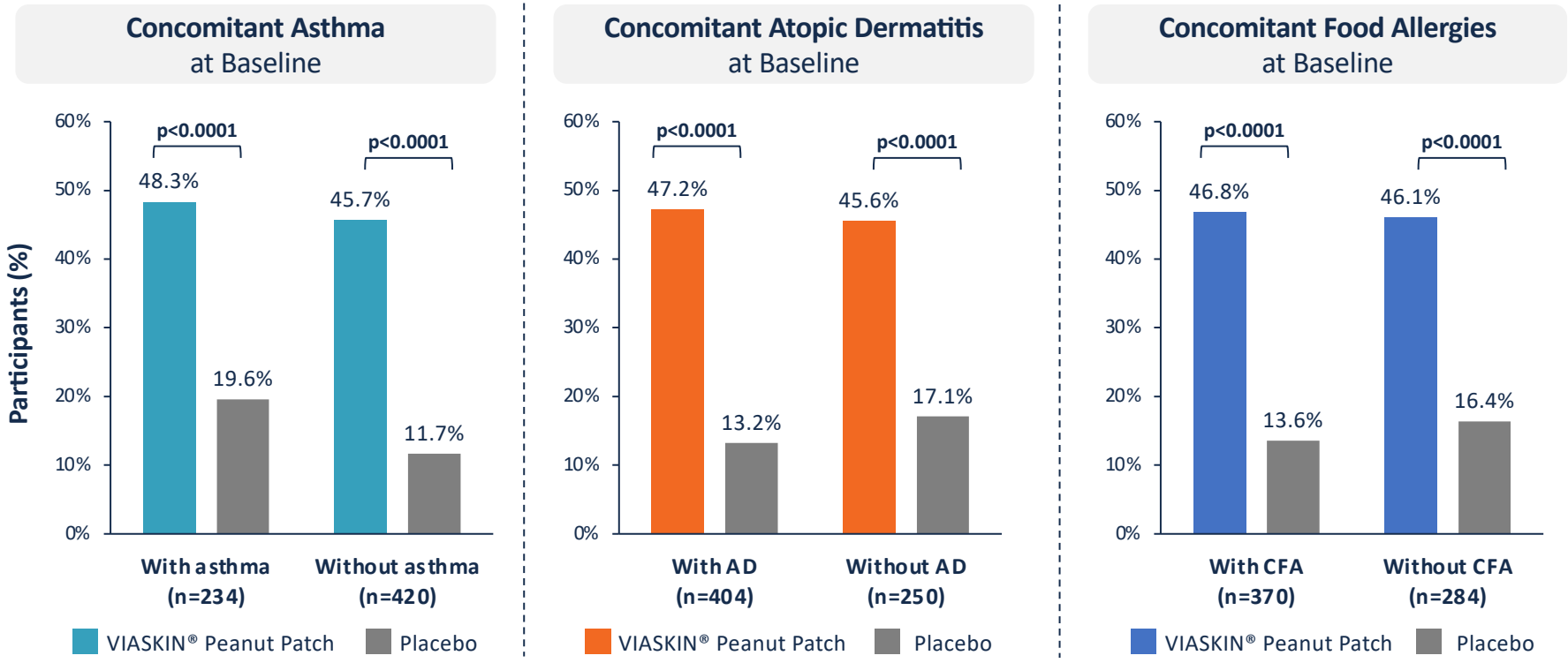


*Responders were defined as children with a baseline ED ≤30 mg who achieved an ED ≥300 mg of peanut protein at month 12, or children with a baseline ED of 100 mg who achieved an ED ≥600 mg of peanut protein at month 12. †$p=10^{-17}$.

CI, confidence interval; ED, eliciting dose; ITT, intention-to-treat.

DBV Technologies. Data on file, 2026.

Treatment Responder Rates Were Significantly Greater With VIASKIN® Peanut Patch vs Placebo Regardless of Comorbidity Status



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.

AD, atopic dermatitis; CFA, concomitant food allergy; ED, eliciting dose. DBV Technologies. Data on file, 2026.

Overview of TEAEs for Participants With and Without Comorbidities at Baseline

	With asthma		Without asthma		With AD		Without AD		With CFA		Without CFA	
	VIASKIN® Peanut Patch (n=155)	Placebo (n=79)	VIASKIN® Peanut Patch (n=283)	Placebo (n=137)	VIASKIN® Peanut Patch (n=269)	Placebo (n=135)	VIASKIN® Peanut Patch (n=169)	Placebo (n=81)	VIASKIN® Peanut Patch (n=247)	Placebo (n=123)	VIASKIN® Peanut Patch (n=191)	Placebo (n=93)
TEAEs*, %												
Overall	98.1	93.7	98.6	96.4	98.5	94.1	98.2	97.5	98.0	95.9	99.0	94.6
Mild	96.8	89.9	95.4	92.0	95.9	89.6	95.9	93.8	94.7	91.9	97.4	90.3
Moderate	56.1	39.2	50.9	37.2	52.8	37.8	52.7	38.3	55.1	39.0	49.7	36.6
Severe	1.3	2.5	1.1	2.9	0.7	3.7	1.8	1.2	1.6	4.1	0.5	1.1
Serious	1.3	3.8	1.4	1.5	0	3.0	3.6	1.2	1.6	2.4	1.0	2.2
Leading to permanent discontinuation	4.5	0	2.5	0	4.1	0	1.8	0	3.2	0	3.1	0

*TEAE rates were calculated as the percentage of participants with ≥1 TEAE in each category.

AD, atopic dermatitis; CFA, concomitant food allergy; TEAE, treatment-emergent adverse event. DBV Technologies. Data on file, 2026.

Overview of Treatment-Related TEAEs for Participants With and Without Comorbidities at Baseline

	With asthma		Without asthma		With AD		Without AD		With CFA		Without CFA	
	VIASKIN® Peanut Patch (n=155)	Placebo (n=79)	VIASKIN® Peanut Patch **(n=283)**	Placebo (n=137)	VIASKIN® Peanut Patch (n=269)	Placebo (n=135)	VIASKIN® Peanut Patch (n=169)	Placebo (n=81)	VIASKIN® Peanut Patch (n=247)	Placebo (n=123)	VIASKIN® Peanut Patch (n=191)	Placebo (n=93)
Treatment-related TEAEs*, %												
Overall	92.9	53.2	91.9	65.7	92.9	57.0	91.1	67.9	92.7	60.2	91.6	62.4
Local	91.6	50.6	90.5	63.5	91.1	55.6	90.5	64.2	91.1	58.5	90.6	59.1
Severe	0.6	0	0.4	0	0.7	0	0	0	0.8	0	0	0
Serious	0	0	0	0	0	0	0	0	0	0	0	0
Treatment-related anaphylactic reaction	0	0	0.7	0	0.4	0	0.6	0	0.8	0	0	0

*TEAE rates were calculated as the percentage of participants with ≥1 TEAE in each category.

AD, atopic dermatitis; CFA, concomitant food allergy; TEAE, treatment-emergent adverse event.

DBV Technologies. Data on file, 2026.

Summary

EPIT via the VIASKIN® Peanut Patch (250 µg) resulted in statistically significant efficacy vs placebo ($p<0.0001$) in children with peanut allergy with ongoing asthma, atopic dermatitis, or concomitant food allergy

- These results were consistent with those observed in the primary population

Safety outcomes in the VIASKIN® Peanut Patch and placebo groups were similar across all comorbidity subgroups

VIASKIN® Peanut Patch

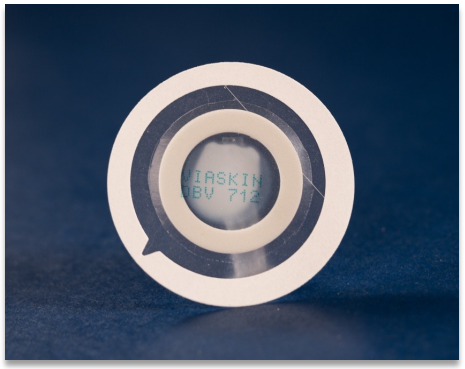


Figure from DBV Technologies.

Results suggest that the presence of atopic comorbidities commonly seen in children with peanut allergy does not impact the efficacy or safety profile of the VIASKIN® Peanut Patch (250 µg)

EPIT, epicutaneous immunotherapy.

DBV Technologies. Data on file, 2026.

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Thank you

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