Efficacy and safety of epicutaneous immunotherapy in clinical studies of children with peanut allergy

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RATIONALE

- Peanut allergy affects 1-4% of children in the USA, Canada, and Europe;[1,2] and is typically a lifelong condition[3]
- Strict avoidance is the cornerstone of management for peanut allergy, which can be challenging as peanut is a common food ingredient, and treatment options are limited[4,5]
- Epicutaneous immunotherapy (EPIT) is an innovative treatment approach for peanut allergy that uses the immune properties of the skin to promote tolerance over time, while limiting systemic allergen exposure[6]
- The VIASKIN® Peanut Patch is a noninvasive form of EPIT in development that involves applying a patch containing 250 µg of peanut protein (1/1000th of 1 peanut kernel) to intact skin to induce desensitization[5-11]

OBJECTIVE

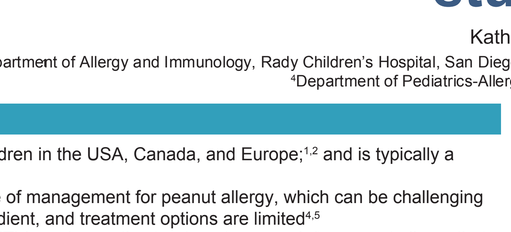
- To report the efficacy and safety of EPIT via the VIASKIN® Peanut Patch in children with peanut allergy in the Phase 3 EPITOPE and VITESSE trials

METHODS

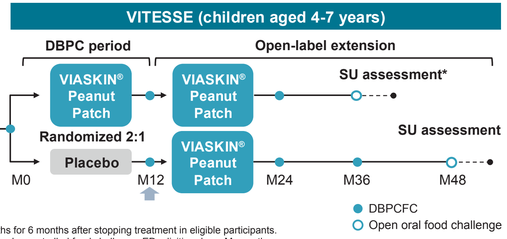
- EPITOPE (NCT03211247) and VITESSE (NCT05741476) were Phase 3, randomized, double-blind, placebo-controlled trials in children with peanut allergy aged 1-3 years and 4-7 years, respectively (**Figure 1**)
- Key eligibility criteria for both studies included peanut-specific immunoglobulin E >0.7 kU_A/L and a peanut skin prick test wheal diameter ≥6 mm; baseline eliciting dose requirements on entry double-blind placebo-controlled food challenge were ≤300 mg and ≤100 mg of peanut protein for EPITOPE and VITESSE, respectively
- Participants were randomized 2:1 to receive the VIASKIN® Peanut Patch or placebo for 12 months in both studies
  - Eligible participants enrolled in optional open-label extensions to receive active treatment for up to 36 months
- The primary endpoint for both studies was the proportion of treatment responders with the VIASKIN® Peanut Patch vs placebo
- Safety assessments evaluated treatment-emergent adverse events (TEAEs), including systemic allergic reactions

Figure 1. EPITOPE and VITESSE Study Designs[10-14]

- Children with peanut allergy (aged 1 through 3 years)
- 51 sites in Australia, Canada, Europe, and the USA
- Key inclusion criteria:
  - Baseline ED ≤300 mg of peanut protein
  - psIgE >0.7 kU_A/L
  - Skin prick test ≥6 mm (largest wheal diameter)



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



*SU assessment involves an open oral food challenge every 2 months for 6 months after stopping treatment in eligible participants.
DBPC, double-blind, placebo-controlled; DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; M, month; psIgE, peanut-specific immunoglobulin E; SU, sustained unresponsiveness.

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VIASKIN® Peanut Patch is an investigational agent and has not yet been approved by the US Food and Drug Administration or any other regulatory authority.

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KEY POINTS

- Data from EPITOPE and VITESSE contribute to a robust wider clinical development program that has evaluated the VIASKIN® Peanut Patch in >1600 children with peanut allergy aged 1-7 years, with >1.1 million patches administered[4,12]
- Efficacy results from both studies demonstrated that 12 months of EPIT with the VIASKIN® Peanut Patch resulted in a consistent treatment effect with significantly greater responder rates vs placebo (treatment difference in EPITOPE: 33.4%; VITESSE: 31.8%)
- The VIASKIN® Peanut Patch had a favorable safety profile; most TEAEs were mild-to-moderate local skin reactions and rates of treatment-related anaphylaxis and epinephrine use were low
  - Safety results were consistent with the previous VIASKIN® Peanut Patch clinical studies[6-8]
- The VIASKIN® Peanut Patch was well tolerated by participants, with high rates of treatment compliance and low rates of discontinuations due to TEAEs

RESULTS

Participants

- In EPITOPE, 362 participants were randomized to treatment with the VIASKIN® Peanut Patch (n=244) or placebo (n=118)
- In VITESSE, 654 participants were randomized to receive the VIASKIN® Peanut Patch (n=438) or placebo (n=216)
- In both studies, baseline demographics and clinical characteristics were balanced between both groups (**Table 1**)
- In both studies, mean (standard deviation) values for treatment compliance were high in both study groups (EPITOPE: 97.0% [6.9%]; VITESSE: 96.2% [6.7%])

Table 1. Baseline Demographics and Clinical Characteristics in EPITOPE and VITESSE

	EPITOPE (aged 1-3 years)		VITESSE (aged 4-7 years)	
	VIASKIN® Peanut Patch (n=244)	Placebo (n=118)	VIASKIN® Peanut Patch (n=438)	Placebo (n=216)
Age, years, median (Q1, Q3)	2.5 (1.8, 3.2)	2.4 (1.7, 3.1)	5.7 (4.8, 6.9)	5.7 (4.8, 6.7)
Sex, n (%)*				
Male	165 (67.6)	84 (71.2)	265 (60.5)	142 (65.7)
Female	79 (32.4)	34 (28.8)	172 (39.3)	74 (34.3)
Peanut-specific IgE, kU_A/L, median (Q1, Q3)	13.4 (4.0, 65.9)	14.8 (4.9, 52.1)	38.0 (11.1, 161.0)	45.3 (10.9, 185.0)
Peanut-specific IgG4, mg/L, median (Q1, Q3)	0.4 (0.1, 1.3)	0.4 (0.1, 1.0)	0.9 (0.3, 2.2)	0.8 (0.3, 1.9)
Atopic comorbidities (ongoing at baseline), n (%)				
Asthma	39 (16.0)	27 (22.9)	155 (35.4)	79 (36.6)
Atopic dermatitis/eczema	194 (79.5)	96 (81.4)	269 (61.4)	135 (62.5)
Other food allergy	161 (66.0)	81 (68.6)	247 (56.4)	123 (56.9)
Allergic rhinitis	49 (20.1)	23 (19.5)	218 (49.8)	105 (48.6)

*In VITESSE, one participant (0.2%) in the VIASKIN® Peanut Patch group identified as 'Undifferentiated'.
Ig, immunoglobulin; Q, quartile.

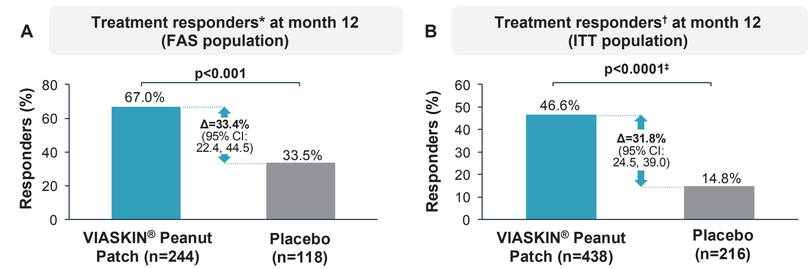
Efficacy

- Treatment with VIASKIN® Peanut Patch resulted in significantly greater responder rates vs placebo at month 12 in both studies (**Figure 2**)
  - EPITOPE: 67.0% vs 33.5%; difference: 33.4% [95% confidence interval [CI]: 22.4, 44.5]; p<0.001
  - VITESSE: 46.6% vs 14.8%; difference: 31.8% [95% CI: 24.5, 39.0]; p<0.0001
- In EPITOPE, treatment benefit with the VIASKIN® Peanut Patch increased over time through month 36; treatment responder rates increased from 67.0% at month 12 to 84.4% at month 36
- A number of participants in the placebo group met the responder endpoint in EPITOPE and VITESSE; this observation may reflect the population of children who were at an age where natural resolution of peanut allergy typically occurs

Safety

- In EPITOPE and VITESSE, the most common TEAEs experienced by participants in both study groups were mild to moderate in severity, and rates of discontinuations due to TEAEs were low in both treatment groups (**Table 2**)
- In both studies, rates of treatment-related anaphylaxis and epinephrine use were low across both treatment groups (**Table 2**)

Figure 2. Treatment Responder Rates in EPITOPE (A) and VITESSE (B)



*Responders were defined as children with a baseline ED ≤10 mg who achieved an ED ≥300 mg of peanut protein at month 12, or children with a baseline ED >10 mg who achieved an ED ≥1000 mg of peanut protein at month 12. †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; FAS, full analysis set; ITT, intention-to-treat.

Table 2. Safety Outcomes in EPITOPE and VITESSE

	EPITOPE (aged 1-3 years) (safety set)*,†		VITESSE (aged 4-7 years) (safety set)*,‡	
	VIASKIN® Peanut Patch (n=244)	Placebo (n=118)	VIASKIN® Peanut Patch (n=438)	Placebo (n=216)
TEAEs, number of participants (%)				
Overall	244 (100)	117 (99.2)	431 (98.4)	206 (95.4)
Mild	242 (99.2)	117 (99.2)	420 (95.9)	197 (91.2)
Moderate	225 (92.2)	91 (77.1)	231 (52.7)	82 (38.0)
Severe	63 (25.8)	12 (10.2)	5 (1.1)	6 (2.8)
Serious	21 (8.6)	3 (2.5)	6 (1.4)	5 (2.3)
TEAEs leading to permanent study discontinuation	8 (3.3)	0 (0.0)	14 (3.2)	0 (0.0)
Treatment-related TEAEs, number of participants (%)				
Overall	244 (100)	112 (94.9)	404 (92.2)	132 (61.1)
Mild	238 (97.5)	110 (93.2)	273 (62.3)	117 (54.2)
Moderate	208 (85.2)	59 (50.0)	129 (29.5)	15 (6.9)
Severe	57 (23.4)	11 (9.3)	2 (0.5)	0 (0.0)
Serious	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Local	243 (99.6)	111 (94.1)	398 (90.9)	127 (58.8)
Treatment-related anaphylactic reaction	4 (1.6)	0 (0.0)	2 (0.5)	0 (0.0)
Treatment-related TEAEs leading to epinephrine use	3 (1.2)	0 (0.0)	3 (0.7)	1 (0.5)

*Safety set included all participants who were randomized and had received ≥1 dose of VIASKIN® Peanut Patch or placebo. †AEs were graded as mild, moderate, severe, or serious according to the CTCAE, version 4.03, and classified using the MedDRA, version 20.1. ‡AEs were coded using the MedDRA, version 28.0.
AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.