Immunologic Changes in VITESSE: A 12-Month Study of Epicutaneous Immunotherapy in Children With Peanut Allergy

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RATIONALE

- In addition to diagnosis, skin prick test (SPT) and serologic biomarkers are used in the monitoring and management of food allergy and can help to guide treatment decisions[1-4]
- Changes in biomarkers are consistently seen with allergen-specific immunotherapy, regardless of method of administration (eg, oral, subcutaneous, sublingual, or epicutaneous)[5]
  - Some of these changes in biomarker concentrations are the inverse to what is observed in the natural history of peanut allergy over time (eg, serum immunoglobulin E [IgE] concentrations tend to increase with patient age)[6]
- Epicutaneous immunotherapy (EPIT) is an innovative treatment approach for peanut allergy that uses the skin's immune properties to promote desensitization over time, while limiting systemic allergen exposure[7]
- The VIASKIN® Peanut Patch is a non-invasive and innovative 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 allergen desensitization[8-13]
- In the Phase 3 VITESSE trial, a significantly greater proportion of children with peanut allergy aged 4-7 years achieved desensitization at 12 months with EPIT via the VIASKIN® Peanut Patch vs placebo (46.6% vs 14.8%, respectively; p<0.0001)[14]
- In VITESSE, changes in immunologic biomarkers were assessed over time for children receiving the VIASKIN® Peanut Patch vs placebo

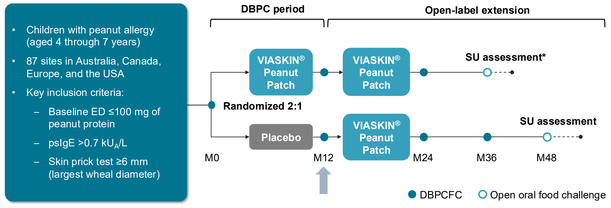
OBJECTIVES

- To assess changes in peanut-specific skin and serologic biomarkers from baseline to month 12 in VITESSE

METHODS

- The Phase 3 VITESSE trial was conducted to assess the efficacy and safety of EPIT with the VIASKIN® Peanut Patch vs placebo in children aged 4 to 7 years with peanut allergy (**Figure 1**)

Figure 1. VITESSE Study Design[15,16]



*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; pslg, peanut-specific immunoglobulin; SU, sustained unresponsiveness.

- Key inclusion criteria included children aged 4-7 years at screening with physician-diagnosed peanut allergy, a peanut-specific IgE level >0.7 kU_A/L, an SPT with the largest mean wheal diameter of ≥6 mm, and an eliciting dose (ED) of peanut protein of ≤100 mg, measured in a double-blind, placebo-controlled food challenge
- The primary endpoint was the proportion of treatment responders with the VIASKIN® Peanut Patch 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 of ≥600 mg of peanut protein at month 12
- Exploratory endpoints evaluated immunologic changes, as assessed by peanut-specific immunoglobulin G4 (IgG4) and IgE, and change in SPT* over the 12-month treatment period

*The SPT average wheal diameter was equal to the longest diameter in mm [D_1] + the size of the longest perpendicular diameter in D_1 in mm [d_2]/2.

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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

- In the VITESSE trial, VIASKIN® Peanut Patch treatment for 1 year resulted in statistically significantly greater responder rates vs placebo
- Immunologic changes observed with use of the VIASKIN® Peanut Patch were consistent with other forms of allergen immunotherapy:[5]
  - Statistically significant decreases in peanut-specific IgE, Ara h 2–specific IgE, and SPT wheal diameter
  - Statistically significant increases in peanut-specific IgG4 and Ara h 2–specific IgG4
- Changes in immunologic markers such as IgE, IgG4, and SPT wheal diameter provide evidence of immune modulation as a result of treatment with the VIASKIN® Peanut Patch, and may play a potential future role in monitoring patients treated with VIASKIN® Peanut Patch, if approved

RESULTS

Participants

- In the Phase 3 VITESSE trial, 654 eligible participants were randomized 2:1 to 12 months of treatment with the VIASKIN® Peanut Patch or placebo
- Participant demographics and baseline characteristics are outlined in **Table 1**
  - Baseline characteristics, including the concentrations of serum immunologic markers, were similar between treatment groups

Table 1. Participant Demographics and Baseline Characteristics

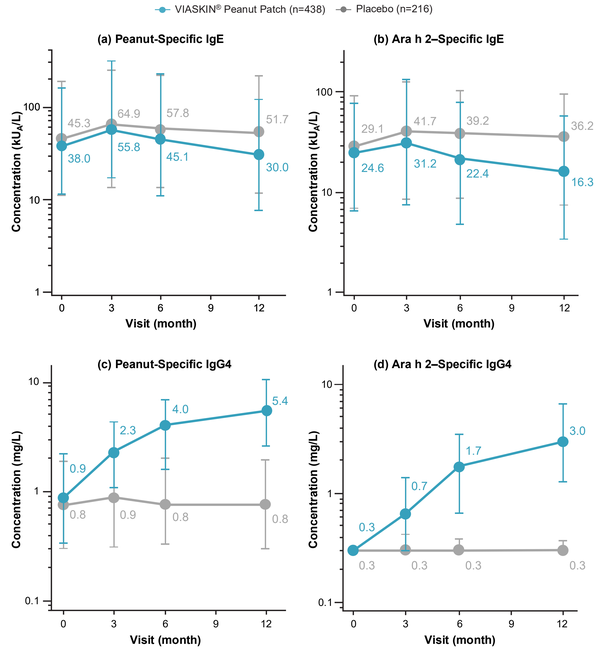
	VIASKIN® Peanut Patch (n=438)	Placebo (n=216)
Age, years, median (Q1, Q3)	5.7 (4.8, 6.9)	5.7 (4.8, 6.7)
Sex, n (%)		
Male	265 (60.5)	142 (65.7)
Peanut-specific IgE, kU_A/L		
n	438	214
Mean (SD)	130.7 (219.7)	153.4 (293.9)
Median (Q1, Q3)	38.0 (11.1, 161.0)	45.3 (10.9, 185.0)
Peanut-specific IgE Ara h 2, kU_A/L		
n	436	214
Mean (SD)	67.4 (106.7)	79.1 (138.9)
Median (Q1, Q3)	24.6 (6.6, 76.5)	29.1 (7.2, 92.6)
Peanut-specific IgG4, mg/L		
n	437	214
Mean (SD)	1.8 (2.4)	2.0 (3.0)
Median (Q1, Q3)	0.9 (0.3, 2.2)	0.8 (0.3, 1.9)
Peanut-specific IgG4 Ara h 2, mg/L		
n	437	214
Mean (SD)	0.4 (0.4)	0.4 (0.2)
Median (Q1, Q3)	0.3 (0.3, 0.3)	0.3 (0.3, 0.3)
Skin prick test, mm		
n	438	216
Mean (SD)	11.4 (4.1)	11.5 (3.9)
Median wheal diameter (Q1, Q3)	11.0 (9.0, 13.0)	10.8 (9.0, 13.0)

Ara h, *Arachis hypogaea*; Ig, immunoglobulin; Q, quartile; SD, standard deviation.

Immunologic Changes Over Time

- At month 12, median peanut-specific IgE and *Arachis hypogaea* (Ara h) 2–specific IgE levels were significantly lower with the VIASKIN® Peanut Patch vs placebo (both p=0.001) (**Figure 2a and 2b**)
- Median peanut-specific IgG4 and Ara h 2–specific IgG4 significantly increased following treatment with the VIASKIN® Peanut Patch vs placebo by month 3, and remained elevated through month 12 (both p<0.001) (**Figure 2c and 2d**)

Figure 2. Change in Median a) Peanut-Specific IgE, b) Ara h 2–Specific IgE, c) Peanut-Specific IgG4, d) Ara h 2–Specific IgG4

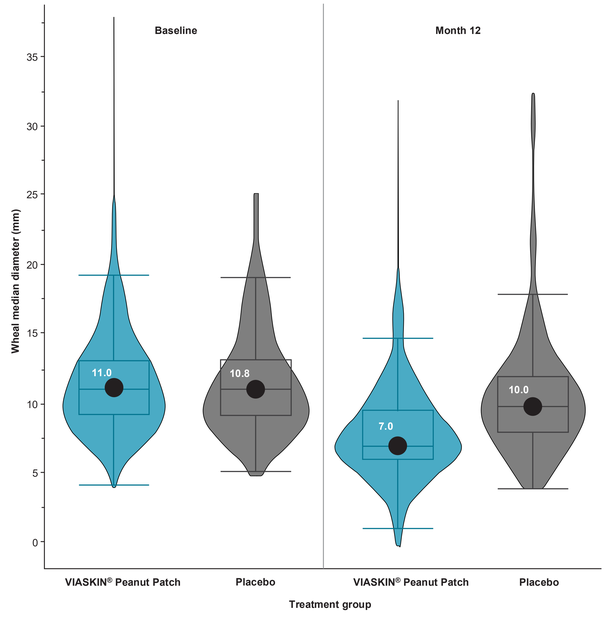


Error bars represent interquartile ranges, Q1 and Q3.
Ara h, *Arachis hypogaea*; Ig, immunoglobulin; Q, quartile.

Change in Peanut Skin Prick Test Over Time

- Median SPT wheal diameter decreased significantly in the VIASKIN® Peanut Patch group vs placebo group at month 12 (p<0.001) (**Figure 3**)
  - The geometric least-squares means ratio (VIASKIN® Peanut Patch/placebo) favored the VIASKIN® Peanut Patch group: 0.7 (95% confidence interval: 0.69, 0.79; p<0.001)

Figure 3. Change in Median SPT Wheal Diameter Over Time in the VIASKIN® Peanut Patch and the Placebo Groups at Baseline and Month 12



The shape of the "violin" illustrates the distribution of the data; width indicates data density, with wider sections representing more data points at those values, whereas narrow sections represent fewer data points.
Dot = median; box = Q1, Q3; upper bar = non-outlier maximum; lower bar = non-outlier minimum.
Q, quartile; SPT, skin prick test.