Changes in Reaction Severity Following Epicutaneous Immunotherapy in Children With Peanut Allergy in the Phase 3 VITESSE Trial

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RATIONALE

- Peanut allergy is often challenging to manage due to the risk of unpredictable reactions to accidental exposure[1,2]
  - Children with peanut allergy and caregivers experience anxiety due to vigilance for unintended exposures[3,4]
- The VIASKIN® Peanut Patch is a non-invasive and innovative form of epicutaneous immunotherapy (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[5-9]
- In the Phase 3 VITESSE trial, a significantly greater proportion of children with peanut allergy aged 4 through 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)[10]
- In addition to desensitization, an important goal of peanut allergen immunotherapy is a reduction in the severity of allergic reactions[11]
  - Evaluating the maximum severity of reactions during baseline and month 12 double-blind, placebo-controlled food challenges (DBPCFCs) may provide insight into the clinical meaningfulness of peanut allergen immunotherapy
  - Comparing the baseline eliciting dose reaction severity with the month 12 reaction severity at that same dose could further contextualize these outcomes for children with peanut allergy, their caregivers, and clinicians[12]

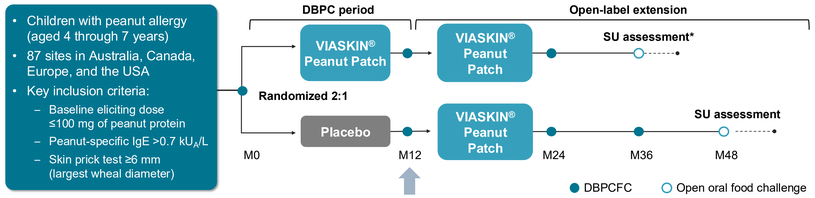
OBJECTIVES

- To characterize changes in reaction severity during DBPCFCs at baseline and month 12 in VITESSE

METHODS

- The Phase 3 VITESSE trial (NCT05741476) assessed the efficacy and safety of EPIT with the VIASKIN® Peanut Patch in children with peanut allergy aged 4 through 7 years (**Figure 1**)
- Participants were randomized 2:1 to receive the VIASKIN® Peanut Patch or placebo for 12 months
  - Eligible participants enrolled in an open-label extension to receive active treatment for up to 36 months
- The primary endpoint was the proportion of treatment responders with the VIASKIN® Peanut Patch vs placebo
  - Responders were defined as participants with a baseline eliciting dose ≤30 mg of peanut protein who achieved an eliciting dose ≥300 mg at month 12, or participants with a baseline eliciting dose of 100 mg who achieved an eliciting dose ≥600 mg at month 12
- Secondary endpoints included the eliciting dose of peanut protein after 12 months of treatment and maximum severity of allergic reaction at the baseline and month 12 DBPCFCs
- In addition, a post-hoc analysis evaluated reaction severity when participants were given their baseline eliciting dose during the month 12 DBPCFC

Figure 1. VITESSE Study Design[13,14]



*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; IgE, immunoglobulin E; M, month; SU, sustained unresponsiveness.

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KEY POINTS

- After 12 months of VIASKIN® Peanut Patch treatment, more than half (52.7%) of participants had no reaction at their baseline eliciting dose, compared with 19.2% on placebo†
- This suggests that EPIT with the VIASKIN® Peanut Patch may provide clinically meaningful outcomes by reducing the severity of allergic reactions in children with peanut allergy

RESULTS

- A total of 654 participants were randomized to treatment with the VIASKIN® Peanut Patch (n=438) or placebo (n=216)
- VITESSE enrolled a highly sensitized population of children with peanut allergy (**Table 1**)

Table 1. Baseline Demographics and Clinical Characteristics

	VIASKIN® Peanut Patch (n=438)	Placebo (n=216)
Age, median (Q1, Q3), years	5.7 (4.8, 6.9)	5.7 (4.8, 6.7)
Male, n (%)	265 (60.5)	142 (65.7)
Eliciting dose, median (Q1, Q3), mg	30.0 (10.0, 100.0)	30.0 (10.0, 100.0)
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 mean wheal diameter, median (Q1, Q3), mm	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)
Concomitant food allergy	247 (56.4)	123 (56.9)

IgE, immunoglobulin E; Q, quartile; SD, standard deviation.

- Participants treated with the VIASKIN® Peanut Patch experienced a significant increase in their eliciting dose at month 12 compared with placebo (median: 300 mg vs 100 mg, respectively; geometric least-squares mean ratio of 3.0 [95% confidence interval: 2.4, 3.8]; p<0.0001)
- In the prespecified analysis, maximum reaction severity was similar between both treatment groups at the baseline DBPCFC and was significantly lower with the VIASKIN® Peanut Patch vs placebo at the month 12 DBPCFC
  - Baseline: no reactions: 0% vs 0%; mild: 0% vs 0%; moderate: 85.9% vs 85.9%; severe: 14.1% vs 14.1%
  - Month 12: no reactions: 5.7% vs 1.0%; mild: 6.8% vs 0.5%; moderate: 79.1% vs 85.9%; severe: 8.4% vs 12.5%; p=0.004

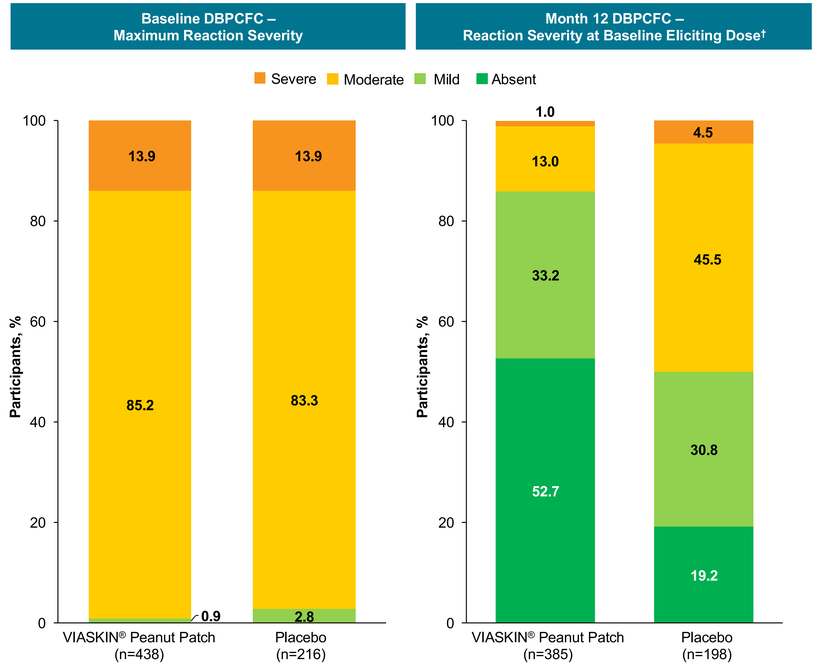
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VIASKIN® Peanut Patch is an investigational agent and has not yet been approved by the US Food and Drug Administration or any other regulatory authority.

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- The post-hoc analysis of month 12 reaction severity to baseline eliciting dose included all participants who initiated the DBPCFC at the specified timepoint
- After 12 months of VIASKIN® Peanut Patch treatment, 85.9% of participants had no or mild reactions at their baseline eliciting dose compared with 50.0% of participants in the placebo group (**Figure 2**)†

Figure 2. Reaction Severity to Baseline Eliciting Dose at Baseline and Month 12 (Post-Hoc Analysis)



†For participants with a month 12 eliciting dose below their baseline eliciting dose (VIASKIN® Peanut Patch: n=23 [6.0%]; placebo: n=46 [23.2%]), reaction severity at the month 12 eliciting dose was used.
DBPCFC, double-blind, placebo-controlled food challenge.