Practicality of Daily Epicutaneous Immunotherapy in Young Children With Peanut Allergy

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RATIONALE

- Although peanut allergy is a prevalent and generally lifelong condition, there are few approved therapies that enable desensitization.[1,2] Moreover, currently available therapies may require frequent injections, complex dosing schedules (including modifications related to allergic cofactors), and/or daily lifestyle and social restrictions, limiting accessibility[2-4]
- Epicutaneous immunotherapy (EPIT) is a novel treatment approach for peanut allergy that takes advantage of the immune properties of the skin to increase tolerance over time, while limiting systemic allergen exposure and related allergic reactions[5]
- The VIASKIN® Peanut Patch is a non-invasive and innovative form of EPIT in development that involves the daily application of a patch containing 250 µg of peanut protein (1/1000th of 1 peanut kernel) to intact skin to induce allergen desensitization[5-10]
- In the Phase 3 VITESSE trial, significantly more 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)[11]
- Secondary and safety endpoints from VITESSE assess the potential practicality of the VIASKIN® Peanut Patch to treat children with peanut allergy

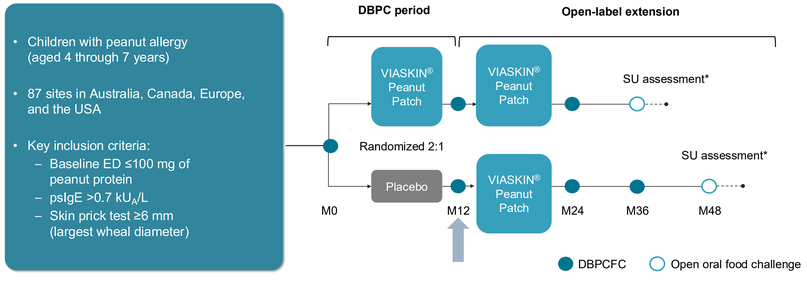
OBJECTIVES

- To characterize the potential practicality of EPIT with the VIASKIN® Peanut Patch as a treatment for young, active children with peanut allergy from the VITESSE trial

METHODS

- In the Phase 3 VITESSE trial, eligible participants were randomized 2:1 to 12-month treatment with the VIASKIN® Peanut Patch or placebo (**Figure 1**)
  - The primary endpoint was the proportion of treatment responders with VIASKIN® Peanut Patch vs placebo 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
  - Participants completing the study could continue in an open-label extension where they received active treatment for up to 36 months
- A patch was applied to the back once-daily by the parent or caregiver, at a time convenient for them
- Compliance, wear time, pain and ease of patch removal, and daily activities were assessed
- Participants were allowed to perform all regular exercise and activities without restriction throughout the trial
- There were no dosing modifications, and no restrictions related to activity, illness, use of nonsteroidal anti-inflammatory drugs, or atopic comorbidities
- Practicality assessments were captured via electronic diaries during the first 3 months as well as months 4 and 10 of the DBPC period. Analyses were conducted using eDiary data at the patch level, providing information on:
  - Participants' daily activities
  - Ease and pain of patch removal

Figure 1. VITESSE Study Design



Arrow indicates month 12 primary endpoint assessment (proportion of treatment responders with VIASKIN® Peanut Patch vs placebo). A participant is defined as a treatment responder if: the initial ED was ≤30 mg and the ED was ≥300 mg of peanut protein at the post-treatment month 12 DBPCFC; **OR** the initial ED was equal to 100 mg of peanut protein and the ED was ≥600 mg of peanut protein at the post-treatment month 12 DBPCFC.
*SU assessment involves an open oral food challenge every 2 months for 6 months after stopping treatment in eligible participants.[1]
DBPC, double-blind, placebo-controlled; DBPCFC, double-blind, placebo-controlled food challenge; ED, eliciting dose; M, month; pslg, peanut-specific immunoglobulin; 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. © 2026, DBV Technologies. All rights reserved.

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KEY POINTS

- The VITESSE trial is the largest food allergy immunotherapy study to date, with a population consisting of highly sensitized children, including those with common allergic comorbidities such as atopic dermatitis, asthma, and concomitant food allergies
- The practicality of using daily EPIT with the VIASKIN® Peanut Patch to desensitize children to peanut is supported by results from the VITESSE trial: treatment compliance was high with a high average daily wear time; most of the patches were easy to remove and without pain; there were no restrictions on daily living, including activity or exercise

RESULTS

Participants

- Participant demographics and baseline characteristics are outlined in **Table 1**
  - 654 participants were enrolled in the trial
  - The trial included a highly sensitized population, with well-balanced baseline characteristics between treatment groups
  - Ongoing atopic comorbidities were prevalent in both 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)
Male sex, n (%)	265 (60.5)	142 (65.7)
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)

*n=214 for placebo
Ig, immunoglobulin; Q, quartile; SD, standard deviation.

Treatment Exposure, Compliance, and Wear Time

- Treatment exposure and compliance were high and comparable across treatment groups (**Table 2**)
  - Both groups demonstrated >95% treatment compliance

Table 2. Treatment Exposure and Compliance

	VIASKIN® Peanut Patch (n=438)	Placebo (n=216)
Treatment exposure duration, days*		
Mean (SD)	353.9 (81.0)	362.2 (64.9)
Mean treatment compliance,† %	96.1	96.5

*Treatment exposure was calculated as: Date of last patch application in DBPC Period - Date of first patch application DBPC Period + 1.
†Overall compliance (%) over the study period was defined as: (number of patches dispensed − number of patches returned) ÷ DBPC exposure duration (days) × 100. The calculation considered treatment dispensed and returned up to visit 11. If a patient did not bring back unused patches, the number of patches that have been applied could not be accurately assessed. During the data review meeting, before database lock, each patient having unreturned kits was evaluated, and a decision was taken whether the patient compliance should be considered as missing. Compliance exceeding 100% was set to 100%.
DBPC, double-blind, placebo-controlled; Q, quartile; SD, standard deviation.

- The median average daily wear time of the VIASKIN® Peanut Patch was 24 hours, similar to placebo (**Table 3**)

Table 3. Median Average Daily Wear Time

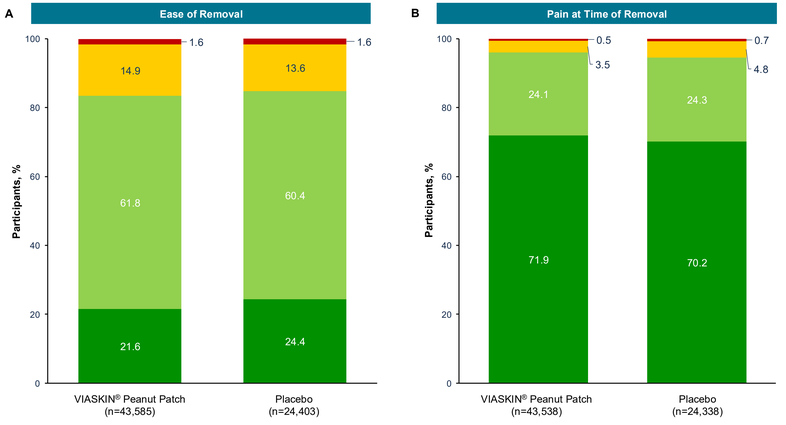
	Global diary (daily) safety set†	
	VIASKIN® Peanut Patch (n=431)	Placebo (n=214)
ADWT* hours, median	24.0	24.8

*ADWT is based on the number of participants, not VIASKIN® Peanut Patches. †The daily reporting allowed for a 4-hour reporting window that resulted in >24 hours for some mean values. The daily recording of system applications and removals, over the entire DBPC period, is referred to as the 'Global diary'.
ADWT, average daily wear time; DBPC, double-blind, placebo-controlled.

Practicality Assessments

- The majority of patches were reported as "very easy" or "easy" to remove (VIASKIN® Peanut Patch: 83.5%; placebo: 84.8%; **Figure 2A**) and "not painful" to remove (VIASKIN® Peanut Patch: 71.9%; placebo: 70.2%; **Figure 2B**)

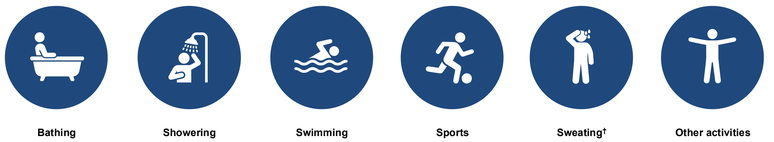
Figure 2. Ease and Pain of Patch Removal



Percentages provided are based on the patches with an assessment of ease of removal and pain at time of removal reported, and do not include those patches considered not applicable. Ease and pain of patch removal were assessed throughout the first 3 months of the DBPC treatment period, and during the two 28-day adhesion assessment periods (recorded in the Adhesion Diary). If a patch detached before completion of the removal form, the ease and pain assessments could not be performed. In cases where the patch had already fallen off at the time of removal form completion, caregivers were instructed to select "not applicable."

- Participants across both groups engaged in various physical and water-related activities, categorized into bathing, showering, swimming, sports, sweating, and other activities, as reported by caregivers in the daily eDiary (**Figure 3**)

Figure 3. Participant Daily Activities*



*The participants' activities of daily living were reported throughout the first 3 months of the DBPC treatment period, and during the two 28-day adhesion assessment periods. †Occurring during any activity and reported as a discrete factor.
DBPC, double-blind, placebo-controlled.