VP250 Average Daily Wear Time: Impact on Efficacy and Safety in the Phase 3 EPITOPE Study

Edwin H. Kim, MD,[1] David M. Fleischer, MD,[2] Stephanie Leonard, MD,[3] J. Andrew Bird, MD,[4] Rachel G. Robison, MD,[5,6] Henry T. Bahnson, MPH,[7] Katharine J. Bee, PhD,[7] Todd D. Green, MD,[7,8] A. Wesley Burks, MD[1]

[1]Division of Pediatric Allergy and Immunology, Department of Pediatrics, University of North Carolina School of Medicine, Chapel Hill, NC, USA; [2]Children's Hospital Colorado, University of Colorado, Aurora, CO, USA; [3]Department of Pediatrics, University of California San Diego; San Diego, CA, USA; [4]University of Texas Southwestern Medical Center, Department of Pediatrics, Division of Allergy and Immunology, Dallas, TX, USA; [5]Department of Pediatrics, Division of Allergy Immunology and Pulmonology, Vanderbilt University Medical Center, Nashville, TN, USA; [6]Ann and Robert H. Lurie Children's Hospital of Chicago, Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [7]DBV Technologies SA, Chatillon, France; [8]UPMC Children's Hospital of Pittsburgh and University of Pittsburgh School of Medicine, Pittsburgh, PA, USA

Rationale

- There are limited treatments for peanut allergy[1,2] and patients, caregivers, and physicians have expressed a need for a safe and practical option[3]
- VIASKIN®, a patch-based technology platform, is currently being investigated for the treatment of peanut allergy. This novel approach to epicutaneous immunotherapy (EPIT) involves the administration of a peanut patch (VP250) containing 250 µg peanut protein to intact skin to induce desensitization[4-8] (**Figure 1**)

Figure 1.The VIASKIN® Patch

- In the previously reported phase 3 EPITOPE study (NCT03211247), 12 months of daily EPIT with VP250 was statistically superior to placebo in desensitizing peanut-allergic toddlers aged 1 through 3 years, with treatment responder rates of 67% in the VP250 group vs 33.5% in the placebo group (difference: 33.4%; 95% CI: 22.4, 44.5 [*P*<0.001])[8]

Objective

- To characterize the patch wear-time experience with VP250, including association with efficacy and safety in EPITOPE participants

Methods

- EPITOPE was a phase 3, randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of VP250 in peanut-allergic toddlers aged 1 through 3 years (N=362)[8]
- During the first 4 weeks of treatment (Days 1-28), the duration of VP250 daily wear time was gradually increased each week (ie, 2, 4, 8, 12 hours per day) to reach a protocol-specified targeted daily wear time of 24±4 hours beginning on Day 29
- Patch wear time (assessed daily by caregivers) was averaged over the 12-month study and over the first 90 days of treatment (excluding treatment initiation Days 1-28) for each participant
- Among VP250 participants, a logistic regression model was used to predict the primary responder endpoint based upon each participant's average daily wear time (ADWT) during the first 90 days
  - A treatment responder was defined as achieving an eliciting dose (ED) ≥300 mg at Month 12 if the baseline ED was ≤10 mg, or a Month 12 ED ≥1000 mg if the baseline ED was >10 to ≤300 mg
  - A cutoff point of 20 hours was determined by regression to optimize the sensitivity and specificity of the primary endpoint
- Efficacy and safety were compared for VP250 participants according to the ADWT cutoff ≥20 hours during the first 90 days

References: 1. Xolair (omalizumab). Package insert. Genentech Inc; 2024. Accessed January 6, 2025. https://www.gene.com/download/pdf/xolair_prescribing.pdf 2. Palfozia [Peanut (Arachis hypogaea) Allergen Powder-dnfp]. Package insert. Aimmune Therapeutics, Inc; 2024. Accessed January 6, 2025. https://www.palforzia.com/palforzia-pi.pdf 3. Herbert L, et al. *Curr Treat Options Allergy*. 2021;8(1):9-20. 4. Fleischer DM, et al. *JAMA*. 2019;321(10):946-955. 5. Fleischer DM, et al. *J Allergy Clin Immunol*. 2020;146(4):863-874.6. Pongracic JA, et al. *J Allergy Clin Immunol Pract*. 2022;10(7):1864-1873.e10. 7. Wang J, Sampson HA. *Pediatr Allergy Immunol*. 2018;29(4):341-349. 8. Greenhawt M, et al. *N Engl J Med*. 2023;388(19):1755-1766.

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VIASKIN® peanut patch is an investigational agent, and it has not yet been approved by the US FDA or any other regulatory authority.

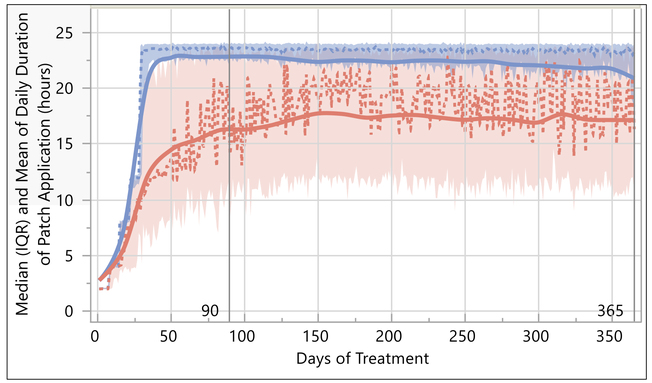
Key Points

- In EPITOPE, the majority of VP250 participants had low day-to-day wear time variability and achieved an ADWT ≥20 hours
- Participants with ADWT ≥20 hours demonstrated greater efficacy versus those with <20 hours
- ADWT during the first 90 days on treatment is highly predictive of ADWT over the course of 1 year
- Participants with ADWT <20 hours reported more scratching as a reason for patch detachment compared to the ADWT ≥20 hours participants, despite similar baseline characteristics. This strongly suggests that these participants experienced lower tolerability to peanut-induced local skin immune response
- If approved, average daily wear time within the first 90 days of VP250 treatment could be an effective marker of future clinical response

Results

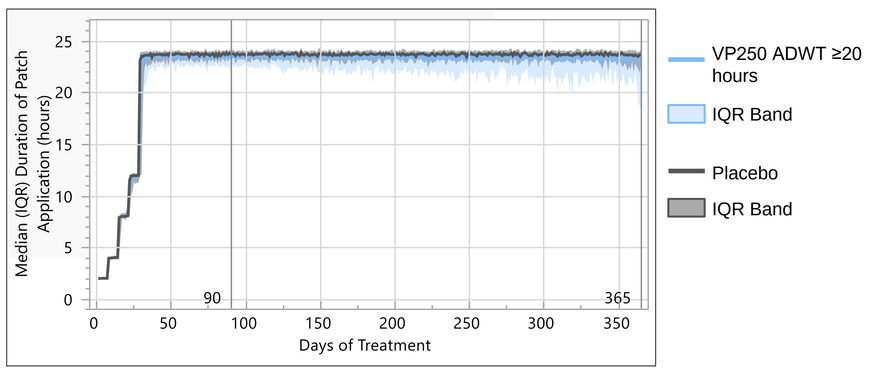
- 167/244 (68.4%) VP250 participants had low day-to-day wear time variability (blue) and an ADWT ≥20 hours, with median ADWT (22.9 hours); 77/244 (31.6%) participants had high day-to-day wear time variability (red) and an ADWT <20 hours (median: 16.7 hours) (**Figure 2**)

Figure 2. Median, Mean, and Variability in Daily Duration of VP250 Wear Time



- The ADWT ≥20 hours group had similar median ADWT relative to placebo (23.7 hours) (**Figure 3**)

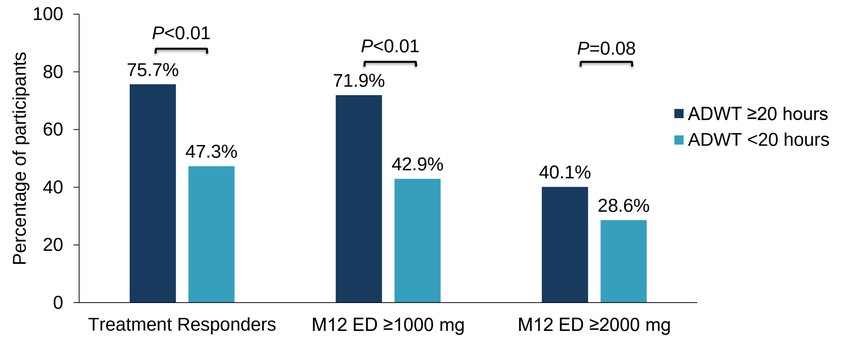
Figure 3. Median Daily Wear Time in VP250 Participants with ADWT ≥20 Hours and Placebo Participants



- ADWT during the first 90 days on treatment was highly predictive of ADWT over the 12-month treatment period (r=0.81)
- Participants with ADWT ≥20 vs <20 hours during the first 90 days had similar baseline characteristics, including median ED (100 mg), peanut-specific sIgE, skin prick test, SCORing Atopic Dermatitis scores, and history of atopic dermatitis and asthma

- At Month 12, participants with ADWT ≥20 hours vs <20 hours had greater efficacy, according to responder rates (75.7% vs 47.3%), ED ≥1000 mg (71.9% vs 42.9%), and ED ≥2000 mg (40.1% vs 28.6%) (**Figure 4**)

Figure 4. Month 12 Efficacy Measures in VP250 Participants According to ADWT During the First 90 Days



- No imbalances were reported in total number of treatment-emergent adverse events (TEAEs), severe treatment-related TEAEs, or systemic adverse events of special interest (AESIs) (**Table 1**)
  - Rates of key safety outcomes of interest were lower in participants with ADWT ≥20 vs <20 hours, based on treatment-related: epinephrine use (0.6% vs 2.6%), anaphylaxis (0.6% vs 3.9%), and permanent treatment discontinuations (0.6% vs 7.8%) (**Table 1**)
- While incidence rates (% days with local skin reaction) and management (TEAEs leading to topical corticosteroid use) of local skin reactions were similar between groups, higher rates of scratching as a reason for patch detachment were observed in participants with ADWT <20 vs ≥20 hours (63.6% vs 26.9%, respectively), suggesting lower treatment tolerability in this group (**Table 1**)

Table 1. 12-month Safety Outcomes in VP250 Participants According to ADWT During the First 90 Days

Adverse event category	ADWT ≥20 hours (n=167)	ADWT <20 hours (n=77)
TEAEs (mean)	45.0	44.7
Treatment-related TEAEs leading to temporary discontinuation, n (%)	16 (9.6%)	15 (19.5%)
Treatment-related TEAEs leading to permanent discontinuation, n (%)	1 (0.6%)	6 (7.8%)
Treatment-related TEAEs leading to epinephrine use, n (%)	1 (0.6%)	2 (2.6%)
Treatment-related anaphylaxis events, n (%)	1 (0.6%)	3 (3.9%)
Severe treatment-related TEAE (mean)	1.3	0.9
Systemic AESI, n (%)	17 (10.2%)	8 (10.4%)
Serious systemic AESI, n (%)	3 (1.8%)	2 (2.6%)
Days with local skin reaction (mean %)	83.7%	81.4%
Treatment-related TEAEs leading to topical corticosteroid use (mean per participant)	13.6	13.9
Number of patch detachments with scratching listed as reason, median	26.9	63.6

AESI, adverse event of special interest; ADWT, average daily wear time; TEAE, treatment-emergent adverse event.