Impact of Duration of Wear on Efficacy of Epicutaneous Immunotherapy With Viaskin Peanut in Toddlers Aged 1 Through 3 Years During the Phase 3 EPITOPE Study

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RATIONALE
- There is currently no approved treatment for peanut allergy in children younger than 4 years, demonstrating a strong unmet need for an available treatment.
- 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 daily administration of a patch, VP250, containing 250 μg of peanut allergen (~1/1000 of 1 peanut) to intact skin in order to induce desensitization.
- In the EPITOPE phase 3 study, the primary measure of treatment effect was the percent difference in responders between VP250 and placebo, defined as an eliciting dose (ED) of ≥300 mg at Month 12 double-blind, placebo-controlled food challenge (DBPCFC) if baseline ED ≤10 mg or a Month 12 ED of ≥1000 mg if baseline ED > 10 mg to ≤300 mg.
- Daily VP250 treatment resulted in statistically superior desensitization vs placebo (responder rate: 67.0% vs 33.5%) after 12 months in peanut-allergic toddlers aged 1 through 3 years (Figure 1).

OBJECTIVE
- To characterize average daily wear time and treatment response of EPIT with VP250 among children aged 1 through 3 years with peanut allergy.

METHODS
- EPITOPE was a phase 3, multicenter, double-blind, placebo-controlled, randomized study with a protocol-specified daily wear time for VP250 of 24±4 hours (Figure 2).
- The primary responder outcome (using missing-failure imputation) was assessed by deciles of average daily duration of wear (Figure 3), and (for participants with non-missing outcome data) according to mean daily wear time, categorized by integer hours (Figure 4).

RESULTS
- The median average daily wear times in the EPITOPE study were 22.2 hours (VP250) and 23.7 hours (placebo).
- The results of the study showed a strong association between duration of wear and efficacy (Figures 3 and 4).

CONCLUSIONS
- A small group of participants (~10%) had low (≤13.1 hours) mean daily wear times; these participants could be identified within the first 3 months with approximately 96% sensitivity and 89% specificity by using a median wear time in the first 90 days of 12 hours.
- Figure 5 shows individual participants’ median duration of patch wear times with duration increasing from left to right (in blue); larger red bars denote a higher within-subject variability, which was associated with lower wear times in the active arm.
- The higher variability in wear time in VP250 participants (relative to placebo) suggests that participant-specific immunological factors interacting with patch antigen contribute to the lower wear times.

Figure 1: Treatment Responder Rates at Month 12 DBPCFC

Figure 2: Study Design Diagram

Figure 3: Responder Rate by Average Daily Duration of Wear Decile

Figure 4: Responder Rate by Average Daily Duration of Wear

Figure 5: Median and Absolute Deviation in Duration of Patch Application by Participant