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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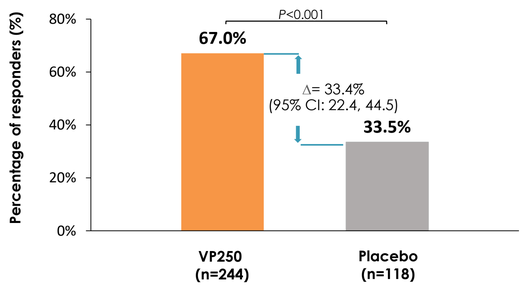
RATIONALE

- There is currently no approved treatment for peanut allergy in children younger than 4 years, demonstrating a strong unmet need for an available treatment[1]
- 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[2-5]
- 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 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**)[6]

Figure 1: Treatment Responder Rates at Month 12 DBPCFC



- As treatment involves daily patch placement/removal in an atopic population, VP250 is designed to balance sufficient patch adhesion while minimizing removal pain/irritation

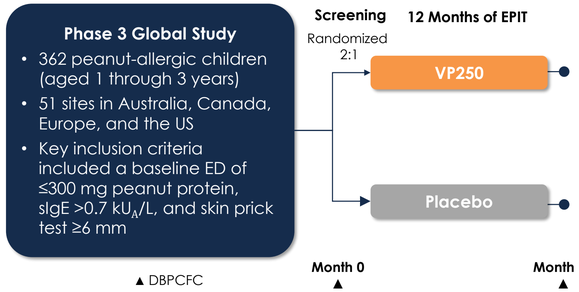
OBJECTIVE

- 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**)

Figure 2: Study Design Diagram

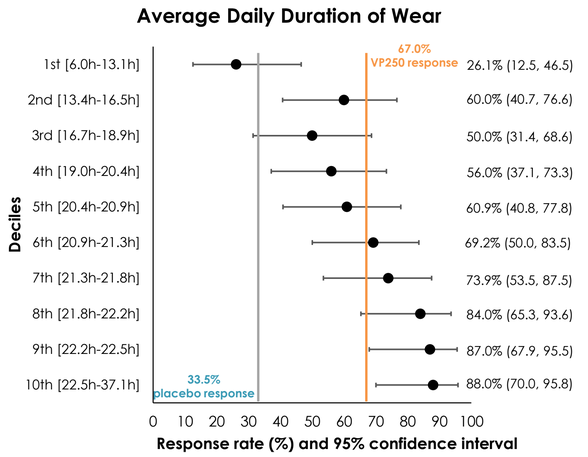


- Mean daily wear time was determined by the difference between time of patch application and time of patch removal averaged over the days of patch wear
- The primary responder outcome (using missing=failure imputation) was assessed by deciles of average daily duration of wear (**Figure 3**), and (for participants with non-missing outcome data) according to mean daily wear time, categorized by integer hours (**Figure 4**)

RESULTS

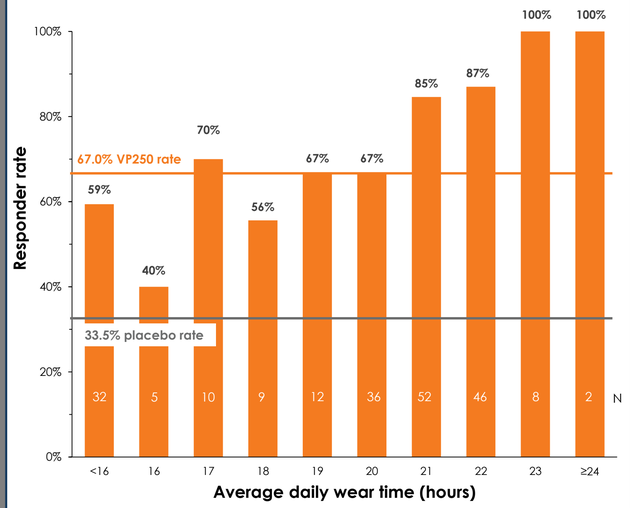
- The median average daily wear times in the EPITOPE study were 22.2 hours (VP250) and 23.7 hours (placebo)
- The results of the study showed a strong association between duration of wear and efficacy (**Figures 3 and 4**)

Figure 3: Responder Rate by Average Daily Duration of Wear



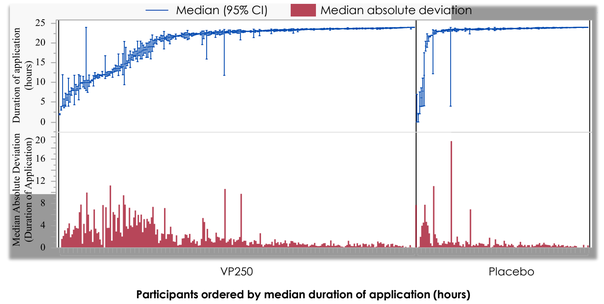
- Among participants with <20 hours of average daily wear time, a responder rate of 60.3% was observed, increasing to 67%, 85%, 87%, and 100% for those with mean durations of 20, 21, 22, and ≥23 hours, respectively (**Figure 4**)

Figure 4: Responder Rate by Average Daily Duration of Wear



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



CONCLUSIONS

- EPITOPE analyses demonstrated high treatment responder rates and high mean daily wear times for the majority of participants using VP250
- Mean daily wear time was strongly associated with treatment response
- Low mean daily wear times were observed in a small proportion of participants using VP250, and these participants could be identified early in treatment
- These results support the continued investigation of EPIT with VP250 in peanut-allergic young children

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

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