Efficacy and Safety of Epicutaneous Immunotherapy for Peanut Allergy in Subjects Aged 1 Through 3 Years With and Without Concomitant Asthma in the EPITOPE Study

George Du Toit,[1] Juan Trujillo,[2] Nicolette JT Arends,[3] Christian Vogelberg,[4] Paul Turner,[5] Timothée Bois,[6] Dianne E. Campbell,[6,7] Hugh A. Sampson,[6,8] A. Wesley Burks[9]

[1]Guy's and Saint Thomas' NHS Foundation Trust, London, United Kingdom; [2]Department of Paediatrics and Child Health, University College Cork, Cork, Ireland; [3]Department of Pediatrics, Sophia Children's Hospital, Erasmus MC University Medical Centre, Rotterdam, The Netherlands; [4]Department of Pediatrics, University Hospital Dresden, Dresden, Germany; [5]National Heart & Lung Institute, Imperial College London, London, United Kingdom; [6]DBV Technologies SA, Montrouge, France; [7]Children's Hospital at Westmead, Westmead, NSW, Australia; [8]Icahn School of Medicine at Mount Sinai, The Elliot and Roslyn Jaffe Food Allergy Institute, New York, NY, USA; [9]Division of Pediatric Allergy and Immunology, Department of Pediatrics, University of North Carolina School of Medicine, Chapel Hill, NC, USA

RATIONALE

- Asthma and food allergy commonly coexist; food allergies can develop in the first year of life and precede the development of asthma[1]
- The development of allergic rhinitis and asthma after atopic dermatitis is known as atopic march[2]; children with peanut allergy (PA) have high rates of concomitant asthma[3]
- A patch-based technology platform is currently being investigated for the treatment of PA. This novel approach to epicutaneous immunotherapy (EPIT) involves the administration of a patch, Viaskin Peanut (VP250), containing 250 µg (~1/1000 of 1 peanut) of peanut allergen to intact skin in order to induce desensitization
- The phase 3 trial EPITOPE (NCT03211247) demonstrated that 12 months of daily EPIT with VP250 was statistically superior to placebo in desensitizing peanut-allergic children aged 1 through 3 years with PA, 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])[4]
- Given the significance of asthma as a comorbidity in patients with food allergy, it's important to understand how participants with asthma will respond to EPIT

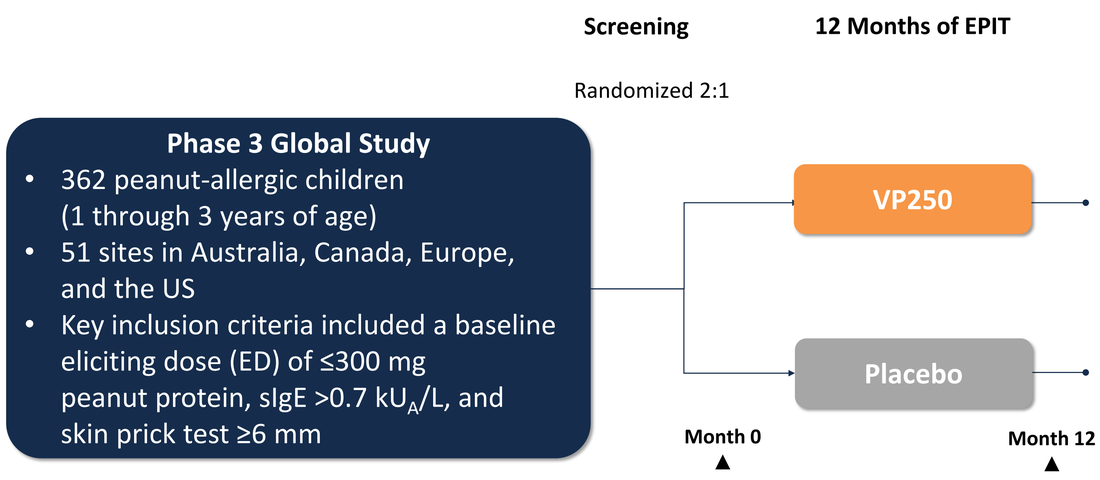
OBJECTIVE

- Assess the efficacy and safety of EPIT with VP250 in peanut-allergic children aged 1 through 3 years with and without asthma

METHODS

- EPITOPE was a multicenter, randomized, double-blind, placebo-controlled phase 3 trial designed to evaluate the efficacy and safety of EPIT with VP250 among toddlers aged 1 through 3 years (**Figure 1**)
  - 362 participants were randomized 2:1 to receive either the VP250 patch or the placebo patch daily for 12 months
- Ongoing baseline asthma assessed by Investigators at study entry

Figure 1: Study Design Diagram



▲Double-blind, placebo-controlled food challenge (DBPCFC)

- DBPCFCs were conducted per the PRACTALL guidelines[5] using a standardized, blinded food matrix at Month 0 (baseline) and Month 12, and were ended when sufficient signs or symptoms met the prespecified stopping criteria
- Inclusion criteria included a baseline ED, defined as the dose at which allergic reaction signs/symptoms resulted in ending the DBPCFC, ≤300 mg peanut protein (approximately 1 peanut)
- The primary outcome was percentage of responders, defined as change in ED from baseline to Month 12 DBPCFC, as shown in **Table 1**

Table 1: Responder Criteria Based on EDs at Month 0 and Month 12 – Primary Endpoint

ED at Month 0	ED at Month 12 required for responder status
≤10 mg	≥300 mg
>10 to ≤300 mg	≥1000 mg

- Efficacy and safety outcomes were assessed in children with and without ongoing asthma (as specified by site investigator) at study entry

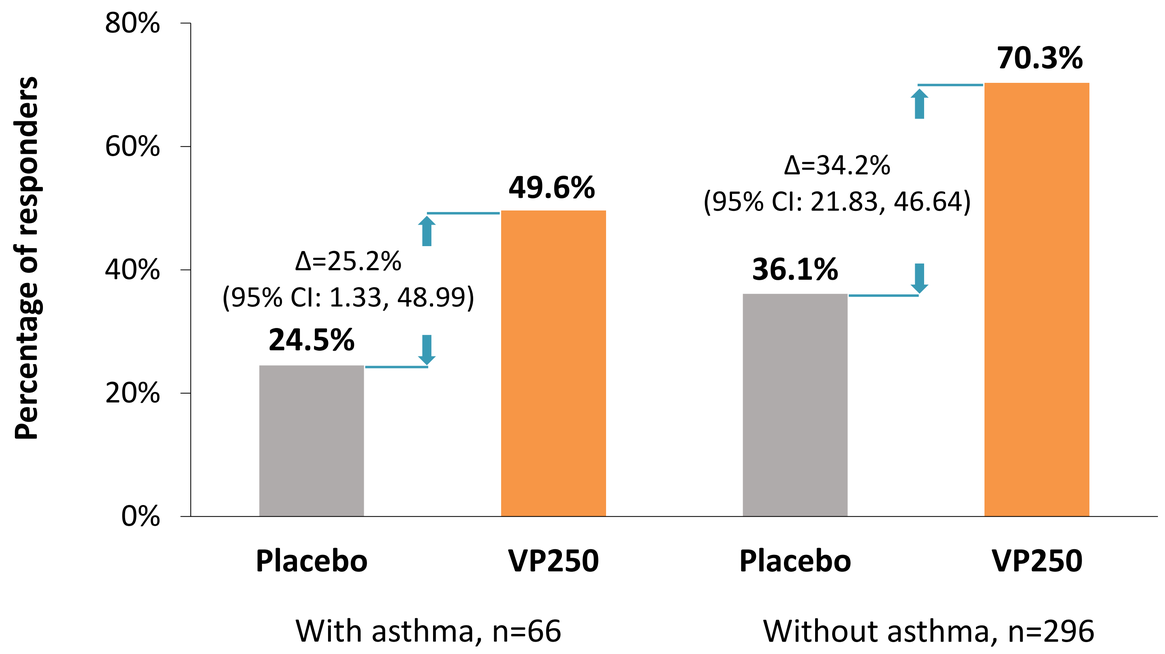
RESULTS

- 66 participants (18.2%) had asthma and 296 (81.8%) did not

Treatment Response

- In subjects with asthma at study entry, the responder rate was 49.6% vs 24.5% in the VP250 group vs placebo, respectively, with a risk difference of 25.2% (95% CI: 1.33, 48.99) (**Figure 2**)
- In subjects without asthma, the responder rate was 70.3% vs 36.1% in the VP250 group vs placebo, respectively, with a risk difference of 34.2% (95% CI: 21.83, 46.64) (**Figure 2**)

Figure 2: Treatment Responder Rates at Month 12 DBPCFC



- Interaction effect between baseline asthma and treatment was not significant (*P*=0.72)

Safety

- Serious treatment-emergent adverse events (TEAEs) assessed as related to VP250 in those receiving VP250 occurred in 1 (0.5%) subject without asthma and no subjects with asthma (**Table 2**)
- TEAEs leading to permanent study discontinuation occurred in 8 participants receiving VP250: 5 (2.4%) participants without asthma, and 3 (7.7%) participants with asthma

Table 2: Safety Profile

	Asthma		No asthma	
	VP250 (n=39)	Placebo (n=27)	VP250 (n=205)	Placebo (n=91)
Any TEAE	100%	100%	100%	98.9%
Any IMP-related TEAE	100%	92.6%	100%	95.6%
SAE	0%	0%	0.5%	0%
Anaphylaxis	2.6%	0%	1.5%	0%
Epinephrine use	0%	0%	1.5%	0%
TEAE leading to discontinuation	7.7%	0%	2.4%	0%

IMP, investigational medicinal product; SAE, serious adverse event.

CONCLUSIONS

- These results suggest that EPIT with VP250 could be a potential treatment option in peanut-allergic children both with and without asthma, a common comorbid condition in this patient population
  - The interaction effect between baseline asthma and treatment was not significant (*P*=0.72)
- Safety and tolerability profiles were similar between the groups with and without baseline asthma

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

REFERENCES: 1. Foong RX et al. *Front Pediatr*. 2017;5:89. 2. Bantz SK et al. *J Clin Cell Immunol*. 2014;5(2):202. 3. Fleischer DM et al. *JAMA*. 2019;321(10):946-955. 4. Greenhawt M et al. *N Engl J Med*. 2023;388(19):1755-1766. 5. Sampson HA et al. *J Allergy Clin Immunol*. 2014;134(5):1016-1025.e43.

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