Poster #82

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

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RATIONALE

- Approximately 70% of children with peanut allergy have a concomitant food allergy (CFA)[1]
- CFAs are associated with an increased risk of severe reactions, decreased quality of life, and more nutritional deficits,[2-4] highlighting the need for an available treatment option for young patients with peanut allergy with and without CFAs
- 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 patch (VP250) containing 250 µg (~1/1000 of 1 peanut) of peanut allergen to intact skin to induce desensitization
- The phase 3 EPITOPE (NCT03211247) study demonstrated that 12 months of daily EPIT with VP250 was statistically superior to placebo in desensitizing peanut-allergic young children aged 1 to <4 years with peanut allergy, with treatment responder rates of 67% (VP250 group) vs 33.5% (placebo group) (difference: 33.4%; 95% CI: 22.4, 44.5 [*P*<0.001])[5]

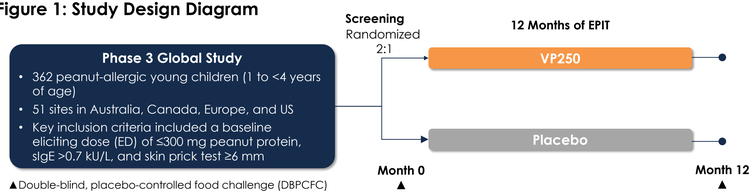
OBJECTIVE

- To assess if the efficacy and safety of EPIT with VP250 in peanut-allergic young children aged 1 to <4 years is influenced by CFA

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 young children aged 1 to <4 years (**Figure 1**)

Figure 1: Study Design Diagram



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

- DBPCFCs were conducted per PRACTALL guidelines[6] at Month 0 and Month 12 and were ended when sufficient signs or symptoms met the prespecified stopping criteria
- The primary efficacy endpoint was the percent difference in treatment responders between VP250 and placebo after 12 months, as defined in **Table 1**

Table 1: Definition of Treatment Responder (Primary Efficacy 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 young children with and without CFA

RESULTS

BASELINE CFA

- At baseline, 242 (66.9%) participants had CFA and 120 (33.1%) participants did not
- Further baseline characteristics are shown in **Table 2**

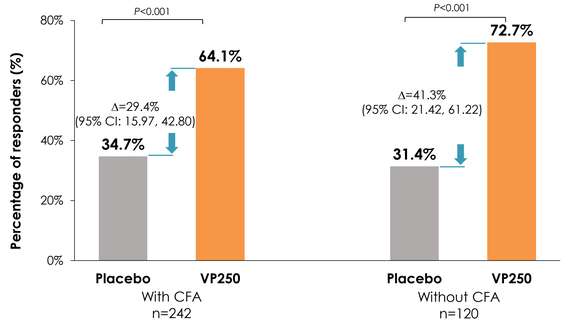
Table 2: Baseline Demographics

	VP250		Placebo	
	Ongoing Medical History of Food Allergy Other Than Peanut			
	No	Yes	No	Yes
Age, n	83	161	37	81
Median (Q1, Q3)	2.5 (1.90, 3.20)	2.6 (1.65, 3.30)	2.7 (2.20, 3.30)	2.2 (1.60, 3.00)
Baseline IgE peanut (kU/L), n	83	161	37	81
Median (Q1, Q3)	7.84 (3.83, 42.79)	15.85 (4.08, 84.88)	12.7 (3.08, 36.91)	17.97 (5.49, 53.85)
Baseline IgG_4 (mg/L), n	79	158	36	81
Median (Q1, Q3)	0.28 (0.10, 0.85)	0.46 (0.16, 1.40)	0.22 (0.09, 0.66)	0.51 (0.19, 1.11)
Baseline mean wheal diameter (mm), n	83	161	37	81
Median (Q1, Q3)	10 (8.00, 12.00)	10 (8.00, 13.00)	10.5 (8.00, 12.50)	10 (8.00, 12.75)
Sex				
Female, n (%)	37 (44.58)	42 (26.09)	14 (37.84)	20 (24.69)
Male, n (%)	46 (55.42)	119 (73.91)	23 (62.16)	61 (75.31)
Ongoing MH of rhinitis				
No, n (%)	70 (84.34)	125 (77.64)	32 (86.49)	63 (77.78)
Yes, n (%)	13 (15.66)	36 (22.36)	5 (13.51)	18 (22.22)
Ongoing MH of asthma				
No, n (%)	70 (84.34)	135 (83.85)	30 (81.08)	61 (75.31)
Yes, n (%)	13 (15.66)	26 (16.15)	7 (18.92)	20 (24.69)
Ongoing MH of eczema				
No, n (%)	27 (32.53)	23 (14.29)	9 (24.32)	13 (16.05)
Yes, n (%)	56 (67.47)	138 (85.71)	28 (75.68)	68 (83.95)

MH, medical history; n, number of participants.

TREATMENT RESPONSE

Figure 2: Treatment Responder Rates at Month 12 DBPCFC



- **Figure 2** shows treatment responder rates among participants at Month 12
  - CFA: 64.1% (VP250) vs 34.7% (placebo) (difference: 29.4%; 95% CI: 15.97, 42.80 [*P*< 0.001]); isolated peanut allergy: 72.7% (VP250) vs 31.4% (placebo) (difference: 41.3%; 95% CI: 21.42, 61.22 [*P*<0.001])
  - Interaction effect between baseline CFA and randomized intervention was not statistically significant (*P*=0.18), indicating treatment effect was not significantly different by CFA

SAFETY

- Serious treatment-emergent adverse events (TEAEs) related to VP250: 1(1.2%) participant with isolated peanut allergy and no participant with CFA (**Table 3**)
- TEAEs leading to permanent study discontinuation: 2 (2.4%) VP250 participants with isolated peanut allergy and 6 (3.7%) VP250 participants with CFA (**Table 3**)

Table 3: Overall Summary of TEAEs by Ongoing Medical History of Food Allergy Other Than Peanut

Adverse Event Category, n (%)	VP250 (N=244)		Placebo (N=118)	
	With CFA (n=161)	Without CFA (n=83)	With CFA (n=81)	Without CFA (n=37)
Any TEAEs	161 (100)	83 (100)	81 (100)	36 (97.3)
Considered related to IMP	161 (100)	83 (100)	77 (95.1)	35 (94.6)
Any Serious TEAEs	10 (6.2)	11 (13.3)	1 (1.2)	2 (5.4)
Considered related to IMP	0	1 (1.2)	0	0
Any TEAEs leading to permanent study treatment discontinuation	6 (3.7)	2 (2.4)	0	0
Any mild TEAEs	159 (98.8)	83 (100)	81 (100)	36 (97.3)
Any moderate TEAEs	148 (91.9)	77 (92.8)	67 (82.7)	24 (64.9)
Any severe TEAEs	38 (23.6)	25 (30.1)	8 (9.9)	4 (10.8)
Considered related to IMP	34 (21.1)	23 (27.7)	8 (9.9)	3 (8.1)
Any IMP-induced local TEAEs	160 (99.4)	83 (100)	77 (95.1)	34 (91.9)
Severe	34 (21.1)	21 (25.3)	8 (9.9)	2 (5.4)
Any local TEAESI	25 (15.5)	23 (27.7)	11 (13.6)	1 (2.7)
Any systemic TEAESI	18 (11.2)	4 (4.8)	4 (4.9)	1 (2.7)
Reported as anaphylactic reaction	13 (8.1)	4 (4.8)	2 (2.5)	1 (2.7)
Reported as systemic hypersensitivity reaction	4 (2.5)	0	3 (3.7)	0
Considered related to IMP	3 (1.9)	1 (1.2)	0	0
Reported as anaphylactic reaction	3 (1.9)	1 (1.2)	0	0
Any TEAEs leading to an epinephrine intake	20 (12.4)	5 (6)	8 (9.9)	0
Considered related to IMP	2 (1.2)	1 (1.2)	0	0
Any TEAEs leading to systemic or inhaled corticosteroid use	46 (28.6)	23 (27.7)	27 (33.3)	8 (21.6)
Any TEAEs leading to topical corticosteroid use	152 (94.4)	82 (98.8)	55 (67.9)	20 (54.1)

AE, adverse event; IMP, investigational medicinal product; n, number of participants; SAE, serious adverse event; TEAESI, treatment-emergent adverse event of special interest.
Note: AEs related to accidental peanut consumption and SAEs elicited during symptoms/reactions elicited during the DBPCFCs are excluded.

CONCLUSIONS

- Twelve months of treatment with EPIT with a patch containing 250 µg peanut protein was effective in desensitizing peanut-allergic young children aged 1 to <4 years, reducing the risk of reaction to accidental ingestion, irrespective of whether participants were allergic to other foods or solely peanuts at study entry (**Figure 2**)
  - Consistent with these data, a previous subgroup analysis of peanut-allergic children aged 4-11 years enrolled in the PEPITES trial demonstrated that the responder rate in those receiving VP250 was greater regardless of whether participants had other atopic conditions[7]
- Safety and tolerability profiles were similar in peanut-allergic young children randomized to VP250 with peanut allergy alone or peanut allergy with CFA

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Viaskin (VP250) is an investigational agent, and it has not yet been approved by the US FDA or any other regulatory authority.