Poster #85

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

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RATIONALE

- Atopic dermatitis (AD) is the strongest and most established risk factor for the development of food allergy, particularly in children[1]
- There is a high occurrence of AD in patients with peanut allergy, with a reported prevalence rate of ~60%-70%[2]
- 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 study (NCT03211247) 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% in the VP250 group vs 33.5% in the placebo group (difference: 33.4%; 95% CI: 22.4, 44.5 [*P*<0.001])[3]

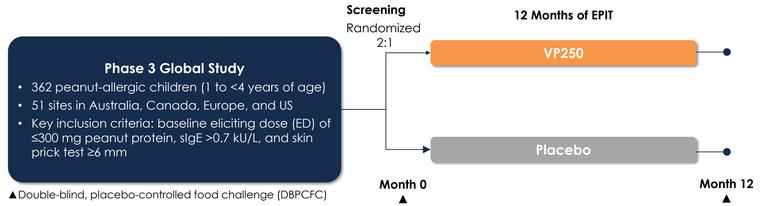
OBJECTIVE

- Given the high prevalence of AD in young children with peanut allergy, we aimed to assess whether the treatment response or safety of EPIT with VP250 in peanut-allergic young children aged 1 to <4 years is influenced by baseline AD

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



- DBPCFCs were conducted per PRACTALL guidelines[4] at Month 0 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, of ≤300 mg peanut protein (approximately 1 peanut)
- 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 AD (including eczema)

RESULTS

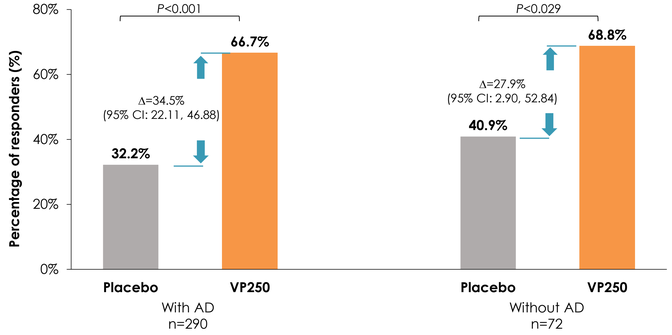
BASELINE AD

- At baseline, 290 (80.1%) participants had AD while 72 (19.9%) did not

TREATMENT RESPONSE

- In participants with AD at study entry, the response rate was 66.7% vs 32.2% in the VP250 group vs placebo, respectively, with a risk difference of 34.5% (95% CI: 22.11, 46.88 [*P*<0.001]) **(Figure 2)**
- In participants without AD, the response rate was 68.8% vs 40.9% in the VP250 group vs placebo, respectively, with a risk difference of 27.9% (95% CI: 2.90, 52.84 [*P*<0.029]) **(Figure 2)**

Figure 2: Treatment Responder Rates at Month 12 DBPCFC



- Interaction effect between baseline AD and randomized treatment was not significant (*P*=0.42)

SAFETY

- No change was observed in SCORing Atopic Dermatitis (SCORAD) scores over time, regardless of presence of AD or treatment group **(Table 2)**
- No difference in overall safety was observed between the AD and non-AD groups **(Table 3)**
- Serious treatment-emergent adverse events (TEAEs) assessed as related to VP250 did not occur in any participant with AD and in one (2%) participant without AD
- Treatment-related TEAEs leading to permanent study discontinuation occurred in 6 (3.1%) participants with AD and 2 (4.0%) participants without AD
- Rates of local VP250-induced TEAEs (any and severe) were similar between VP250 participants with and without AD (99.5% vs 100%; 23.2% vs 20%), respectively

Table 2: SCORAD Over Time by Ongoing Medical History of Eczema/AD

	Ongoing Medical History of Eczema			
	No		Yes	
	Placebo	VP250	Placebo	VP250
SCORAD Baseline, n	0	10	62	122
Median (min-max)	-	4.2 (0-16.8)	11.7 (0-42)	11.0 (0-43.8)
SCORAD Month 6, n	5	13	33	95
Median (min-max)	3.9 (0-7.6)	8.2 (3.7-24.3)	15.1 (0-62.7)	14.1 (1.4-43.3)
SCORAD Month 12, n	3	8	40	76
Median (min-max)	4.8 (0-15.3)	8.9 (0.2-17.6)	12.6 (3.7-36.1)	13.7 (0-40.3)

Table 3: Overall Summary of TEAEs by Ongoing Medical History of Eczema/AD

Adverse Event Category, n (%)	VP250 (N=244)		Placebo (N=118)	
	With AD (n=194)	Without AD (n=50)	With AD (n=96)	Without AD (n=22)
Any TEAEs	194 (100)	50 (100)	95 (99)	22 (100)
Considered related to IMP	194 (100)	50 (100)	90 (93.8)	22 (100)
Any serious TEAEs	19 (9.8)	2 (4)	3 (3.1)	0
Considered related to IMP	0	1 (2)	0	0
Any TEAEs leading to permanent treatment discontinuation	6 (3.1)	2 (4)	0	0
Any mild TEAEs	192 (99)	50 (100)	95 (99)	22 (100)
Any moderate TEAEs	177 (91.2)	48 (96)	74 (77.1)	17 (77.3)
Any severe TEAEs	52 (26.8)	11 (22)	8 (8.3)	4 (18.2)
Considered related to IMP	47 (24.2)	10 (20)	7 (7.3)	4 (18.2)
Any IMP-induced local TEAEs	193 (99.5)	50 (100)	90 (93.8)	21 (95.5)
Severe	45 (23.2)	10 (20)	6 (6.3)	4 (18.2)
Any local AESI	36 (18.6)	12 (24)	10 (10.4)	2 (9.1)
Any systemic AESI	19 (9.8)	3 (6)	5 (5.2)	0
Reported as anaphylactic reaction	15 (7.7)	2 (4)	3 (3.1)	0
Considered related to IMP	4 (2.1)	0	0	0
Reported as anaphylactic reaction	4 (2.1)	0	0	0
Any TEAEs leading to an epinephrine intake	22 (11.3)	3 (6)	8 (8.3)	0
Considered related to IMP	3 (1.5)	0	0	0
Any TEAEs leading to topical corticosteroid use	185 (95.4)	49 (98)	61 (63.5)	14 (63.6)

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

CONCLUSIONS

- Twelve months of EPIT treatment with VP250 resulted in a significant response compared to placebo, irrespective of ongoing AD status 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 compared to placebo, regardless of whether participants had other atopic conditions[5]
- Baseline AD was common among study participants, as is often seen with the peanut-allergic pediatric population
- Safety and tolerability profiles were similar in peanut-allergic young children randomized to VP250 with or without AD at baseline
- Treatment with VP250 for 1 year does not appear to result in a change in AD severity
- Efficacy and safety results support a potential role for EPIT with VP250 in desensitizing peanut-allergic young children aged 1 to <4 years, irrespective of whether they have AD prior to treatment

REFERENCES

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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.