REALISE (Real-life Use and Safety of EPIT) Study: 3 Year Results in Peanut-Allergic Children

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ACAAI 2021 Annual Scientific Meeting

Disclosures

- DBV Technologies: principal investigator, consultant, Clinical / Medical Advisory Board

The Burden of Peanut Allergy

Peanut allergy is the most common food allergy[1]

2.2% of children in the US are allergic to peanut

In some patients, reactions can occur after exposure to low doses of peanut[2,3]

Standard of care for peanut allergy is strict avoidance plus personalized medical intervention plans[4]

However, despite practicing strict avoidance, accidental exposure often occurs and commonly leads to allergic reactions[5-7]

The management of peanut allergy remains a challenge for patients, families, and healthcare providers due to[8-10]:

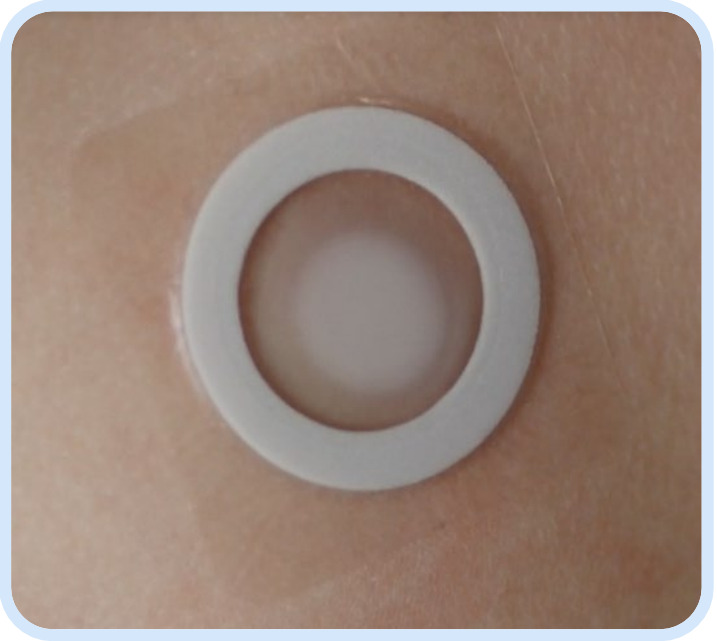
- Concerns about unintentional exposure
- Unpredictability of severe reactions
- Relatively high risk of anaphylaxis

1. Gupta RS, et al. *Pediatrics*. 2018; 142(6):e20181235. **2.** Al-Muhsen S, et al. *CMAJ*. 2003;168:1279-1285. **3.** Deschildre A, et al. *Clin Exp Allergy*. 2016;46:610-620. **4.** Jones SM, Burks AW. *N Engl J Med*. 2017;377:1168-1176. **5.** Green TD, et al. *Pediatrics*. 2007;120:1304-1310. **6.** Cherkaoui S, et al. *Clin Transl Allergy*. 2015;5:16. **7.** Neuman-Sunshine DL, et al. *Ann Allergy Asthma Immunol*. 2012;108:326-331. **8.** Chan ES, et al. *Ann Allergy Asthma Immunol*. 2020;124(5):479-86. **9.** Leickly FE, et al. *J Pediatr*. 2018;192:223-8.e1. **10.** Pettersson ME, et al. *Allergy*. 2018;73(7):1532-40.

Investigational Epicutaneous Immunotherapy for the Management of Peanut Allergy

Viaskin™ Peanut 250 µg (DBV712)[1,2]

- Single, daily-dose patch
  - Applied to the back
- Dose: 250 µg
  - **~1/1000 of a peanut[3]**
- 2-week at-home treatment initiation leading to 24-hour wear time
- No restrictions based on illness or daily activities required



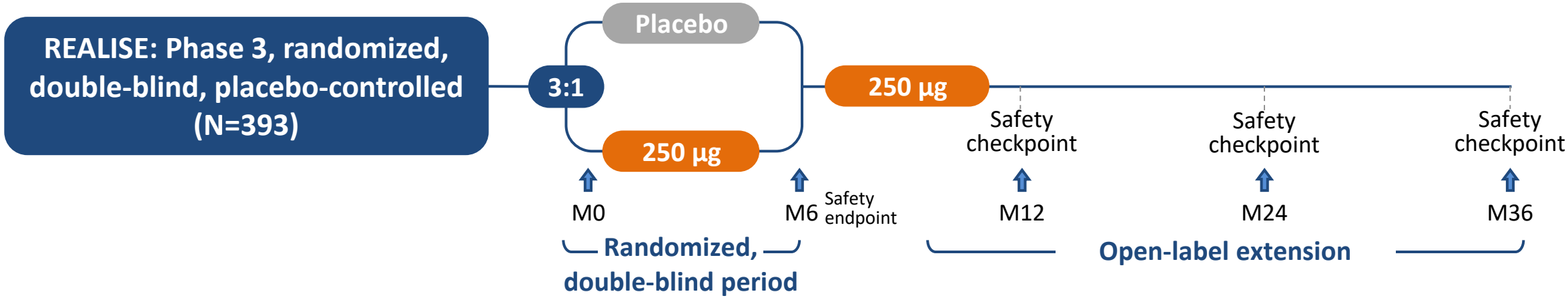
1. Sampson HA, et al. *JAMA*. 2017;318:1798-1809. **2.** Tilles SA, et al. *Ann Allergy Asthma Immunol*. 2018;121:145-149. **3.** Parrish CP. *Am J Manag Care*. 2018;24:S419-S427.

Study Objective

- Efficacy and safety of epicutaneous immunotherapy with Viaskin Peanut has been previously studied in a phase 3 randomized controlled trial in children[1,2]
- **We further examined its safety over 3 years in REALISE, a phase 3 study approximating anticipated real-world use**

1. Fleischer DM, et al. *JAMA*. 2019;321:946-955. **2.** Fleischer DM, et al. *J Allergy Clin Immunol*. 2020;146:863-874.

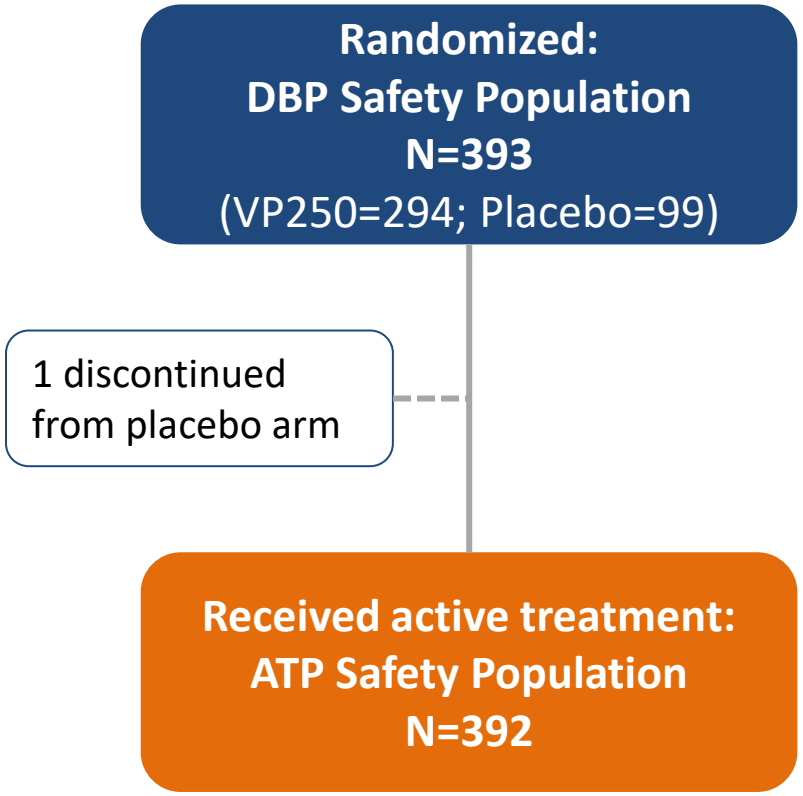
REALISE Study Design and Methods



- Children aged 4–11 years with physician-diagnosed peanut allergy (well-documented clinical history, SPT ≥8 mm, and peanut-specific IgE ≥14 kUA/L) were enrolled
- **Entry food challenges were not required**
- Subjects with a history of severe peanut anaphylaxis were eligible
- Subjects initially randomized to 6 months VP250 or placebo were offered VP250 for a total of 3 years in an open-label extension
- Safety and compliance data were collected

IgE=immunoglobulin E; M=month; SPT=skin-prick test; VP250=Viaskin Peanut 250 µg.

Subject Disposition and Baseline Characteristics



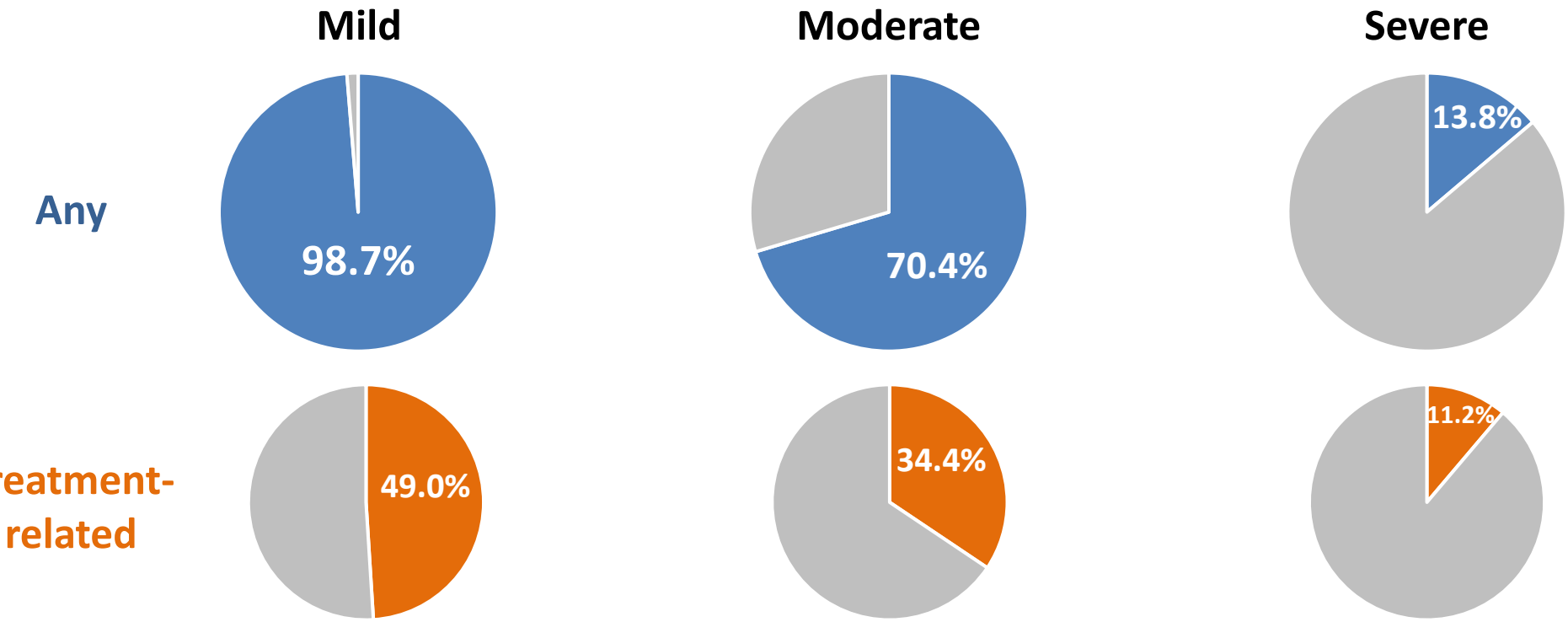
	Active Treatment Period (ATP) Safety Population N=392
Sex, n (%) Male Female	 229 (58.4%) 163 (41.6%)
Median age, years	7.0
Median peanut-specific IgE, kU/L (range)	95.5 (14.5–1515.0)
Median SPT wheal size, mm (IQR)	10.5 (9.0–14.0)
History of severe anaphylaxis, n (%)	14 (3.6%)
Median treatment exposure to VP250, days	1093.0
Mean compliance, %	96.4%

DBP=double-blind period; IQR=interquartile range; SPT=skin-prick test; VP250=Viaskin Peanut 250 µg.

The Majority of TEAEs Were Mild or Moderate

- Most subjects (98.7%) treated with VP250 experienced at least 1 TEAE

Severity of TEAEs in subjects who experienced ≥1 TEAE (Total ATP Safety Population [N=392])



ATP=active treatment period; TEAE=treatment-emergent adverse event; VP250=Viaskin Peanut 250 µg.

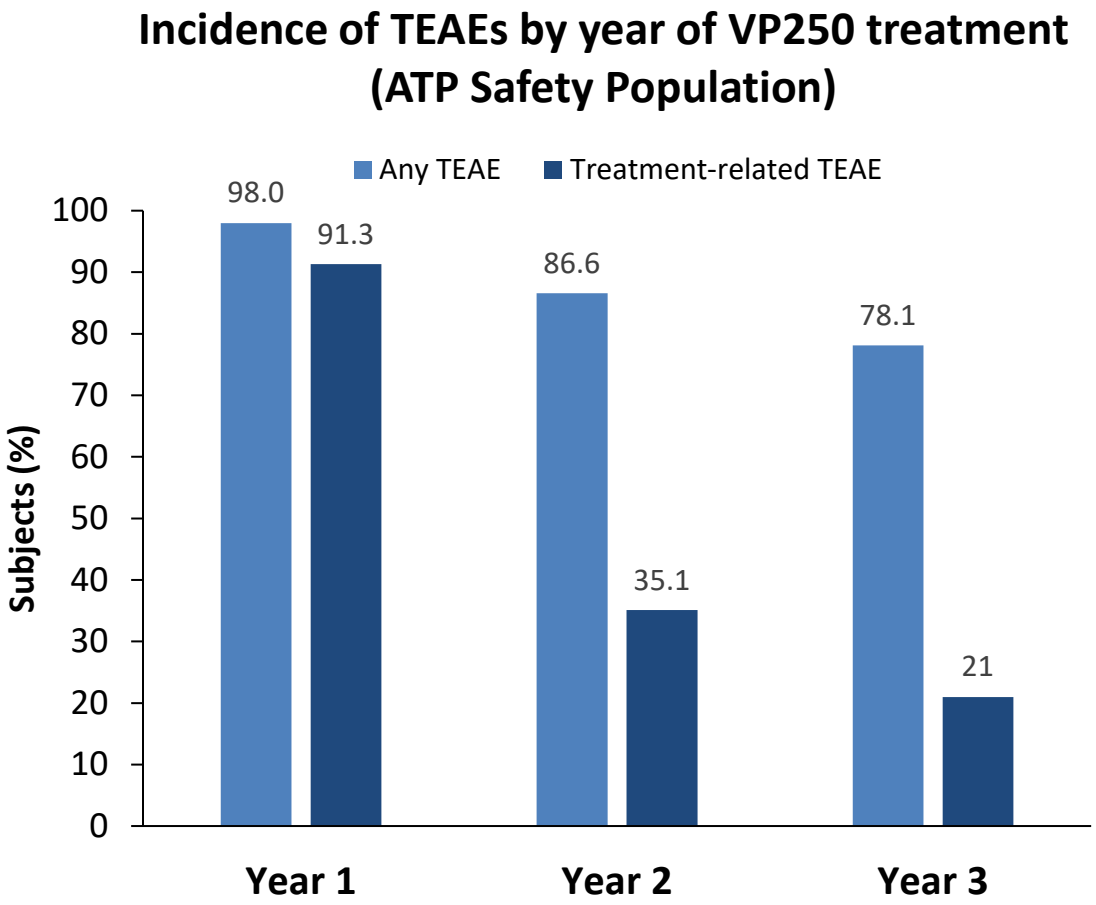
Most Treatment-related TEAEs Were Local Application Site Reactions

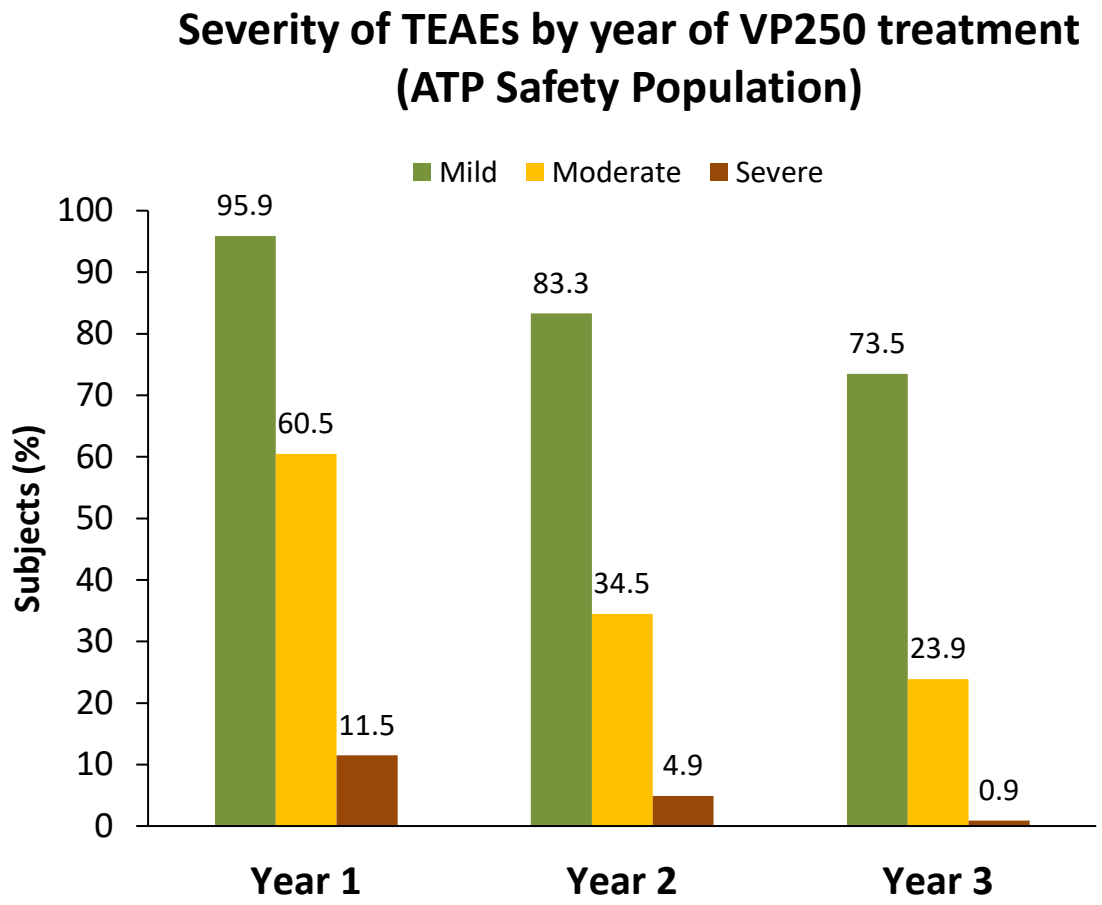
Most Frequent Treatment-related TEAEs Occurring in ≥10% of Subjects (ATP Safety Population)

Preferred Term, n (%)	VP250 N=392
Any Treatment-related TEAE	**371 (94.6%)**
Administration Site Conditions	**358 (91.3%)**
Application site erythema	297 (75.8%)
Application site pruritus	259 (66.1%)
Application site swelling	148 (37.8%)
Application site papules	57 (14.5%)
Application site eczema	55 (14.0%)
Application site urticaria	40 (10.2%)
Skin and subcutaneous tissue disorders	47 (12.0%)

ATP=active treatment period; TEAE=treatment-emergent adverse event; VP250=Viaskin Peanut 250 µg.

Incidence and Severity of TEAEs Decreased Over Time





ATP=active treatment period; TEAE=treatment-emergent adverse event; VP250=Viaskin Peanut 250 µg.

Rates of Treatment-Related Anaphylactic Reactions Observed

Anaphylactic Reactions

- 16 (4.1%) subjects experienced 17 anaphylactic reactions deemed related to VP250
  - None were severe*
  - In total, 2 serious VP250-related TEAEs (both anaphylaxis):
    - Both were considered medically important events
    - 1 event led to permanent study discontinuation
  - 12 subjects temporarily discontinued and 3 subjects (including the SAE) permanently discontinued treatment due to VP250-related anaphylactic reactions
  - 10 events in 9 subjects (**2.3% of total population**) required epinephrine administration due to VP250-related anaphylactic reactions
- 2 additional subjects received epinephrine for non-anaphylaxis VP250-related events

*As assessed by the Investigator based on a protocol-specified staging system for anaphylaxis.

SAE=serious adverse event; TEAE=treatment-emergent adverse event; VP250=Viaskin Peanut 250 µg.

Summary

- In a study designed to mimic potential real-world use, over 36 months, **Viaskin Peanut was generally well tolerated** by peanut-allergic children aged 4–11 years
- The **frequency and intensity** of local and systemic **treatment-related TEAEs decreased over time**
- **Compliance was high** throughout the duration of the study
- **No specific safety concerns** arose in subjects with **history of severe peanut anaphylaxis**