



DBV TECHNOLOGIES

Corporate Presentation | September 2025

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As of the date of this presentation, EPIT and DBV's VIASKIN® patch are investigational and have not yet been approved by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or any other regulatory agencies. Some of the information contained herein regarding EPIT or Viaskin is or may be under review by FDA, EMA and other regulatory agencies as part of a biologics license application (or equivalent) and is subject to change based on such review.

VIASKIN is a registered trademark of DBV Technologies.

Summary Overview of DBV Technologies



Our Mission is to Develop Novel Treatments for Pediatric Food Allergy



Global, late-stage, biopharmaceutical company



Committed to transforming lives of children & families living with the daily burden of food allergy



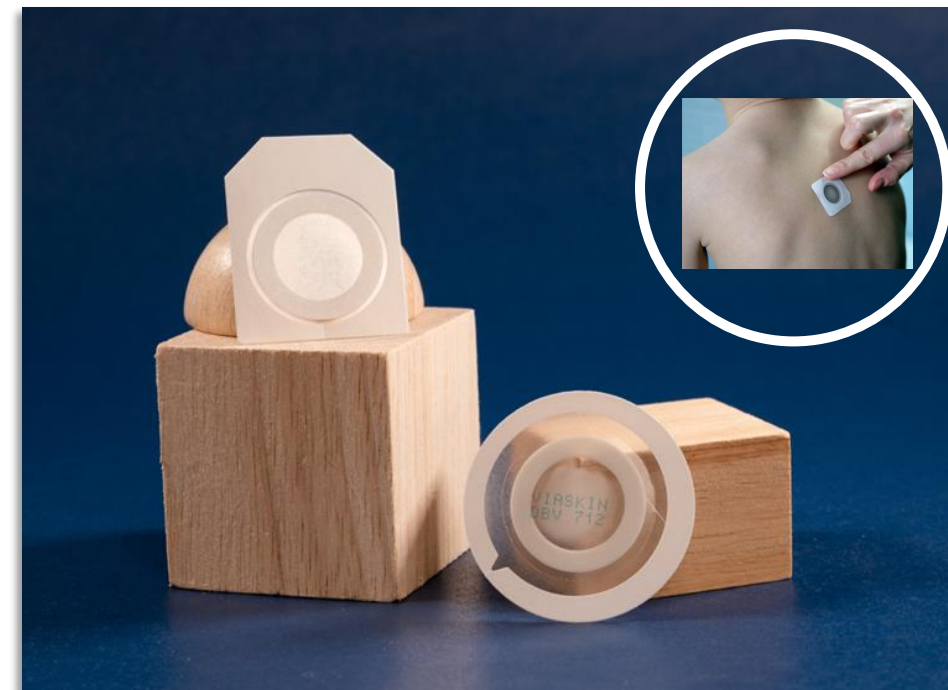
Pioneered VIASKIN® patch technology
DBV's novel approach to epicutaneous immunotherapy



VIASKIN® peanut patch as lead product, with two candidates: one in 1-3 YO & one in 4-7 YO
(~1M patches administered to 1300 children ages 1-7 YO)



Science-driven leadership team with deep regulatory & commercial experience



Purposely designed to meet treatment goals of patients, caregivers & clinicians



Investment Highlights (US)

Two Distinct Opportunities for VIASKIN® Peanut Patch

One BLA in 4-7 YO



One BLA in 1-3 YO



Clear Clinical Pathway for Both Programs

Ongoing, fully-enrolled 12-month Phase 3 pivotal trial (VITESSE) in 4–7-YO for potential BLA submission in children¹



The successful EPITOPE Phase 3 study to be supported by 6-month supplemental safety trial² (COMFORT Toddlers; Initiated June 2025³)



Anticipated Clinical & Regulatory Milestones

- Topline results for VITESSE anticipated in **4Q25**⁴
- BLA submission anticipated for **1H26**⁵ (eligible for priority review)[†]



- Completion of enrollment for COMFORT Toddlers & topline data
- BLA submission anticipated for **2H26** under a formalized Accelerated Approval pathway⁶



Cash Position

\$103.2 M
of Cash and Cash Equivalents
as of June 30, 2025⁷



Additional aggregate of up to \$181.4 million⁸ in gross proceeds to be received if all warrants are exercised (subject to VITESSE topline results)



DBV Technologies Press Release. September 23, 2024; 2. DBV Technologies Press Release. April 19, 2023; 3. DBV Technologies Press Release. June 25, 2025; 4. DBV Technologies Press Release. October 22, 2024; 5. DBV Technologies Press Release. March 24, 2025; 6. DBV Technologies Press Release. December 11, 2024; 7. DBV Technologies Press Release. July 29, 2025; 8. DBV Technologies Press Release. March 27, 2025. [†]VIASKIN® Peanut patch has breakthrough designation.



Financing (Closed in April) Provides Runway Through Potential Approval & Launch of VIASKIN® Peanut Patch

March 2025 Financing

Financing led by several large dedicated healthcare funds¹

Upfront	\$125.5 M
Proceeds from exercise of all warrants following release of VITESSE topline data (anticipated in Q4 2025)	\$181.4 M
Total Financing	\$306.9 M



DBV is sufficiently funded through the expected Biologics License Application (BLA) submission for the VIASKIN® Peanut patch in 4-7 YO & commercial launch, if approved



Significant Market Opportunity for VIASKIN® Peanut Patch

~670K Children Aged 1-7 Years Have Peanut Allergy in US¹⁻³



1-3 years old

280,000 Toddlers¹⁻³



4-7 years old

390,000 Children¹⁻³

VIASKIN® Peanut Patch – A Potential Treatment for Peanut Allergy That Can Be Easily Incorporated into the Busy Lives of Families



Potential Benefits of Epicutaneous Immunotherapy with VIASKIN® Peanut Patch

- ✓ Applied at home, once a day onto child's back
- ✓ No treatment escalation requiring frequent doctor's appointments
- ✓ No interruptions to daily routines*
- ✓ No increased risk of side effects due to illness, missed sleep, or stress
- ✓ No oral peanut ingestion required
- ✓ No injection required
- ✓ Potentially disease modifying therapy¹⁻³

*In DBV's Phase 3 efficacy trials, there were no restriction on daily activities (e.g., exercise/sports, swimming or bathing).



VIASKIN® Peanut patch harnesses the powerful immune properties of the skin to progressively desensitize patients to peanut allergen

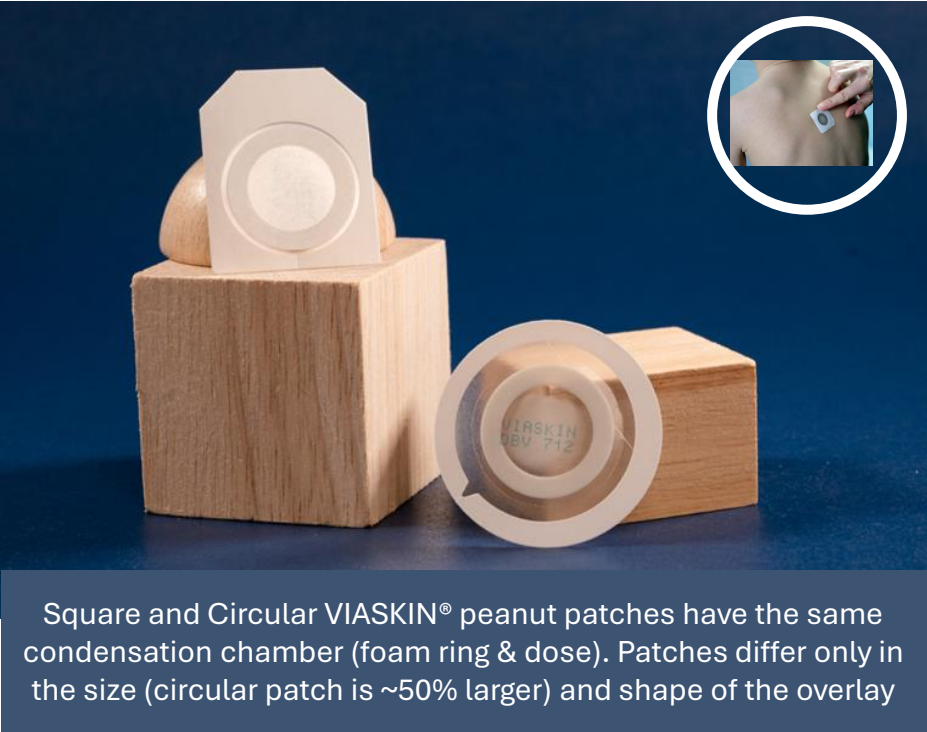


Daily exposure = 250 µg peanut protein
(~1/1000th of a peanut kernel)



Square & Circular VIASKIN[®] Peanut Patches Are Separate Product Candidates – Two Distinct Opportunities in US

Independent Clinical & Regulatory Paths for VIASKIN[®] Peanut Patch in Toddlers 1–3 YO & Children 4–7 YO

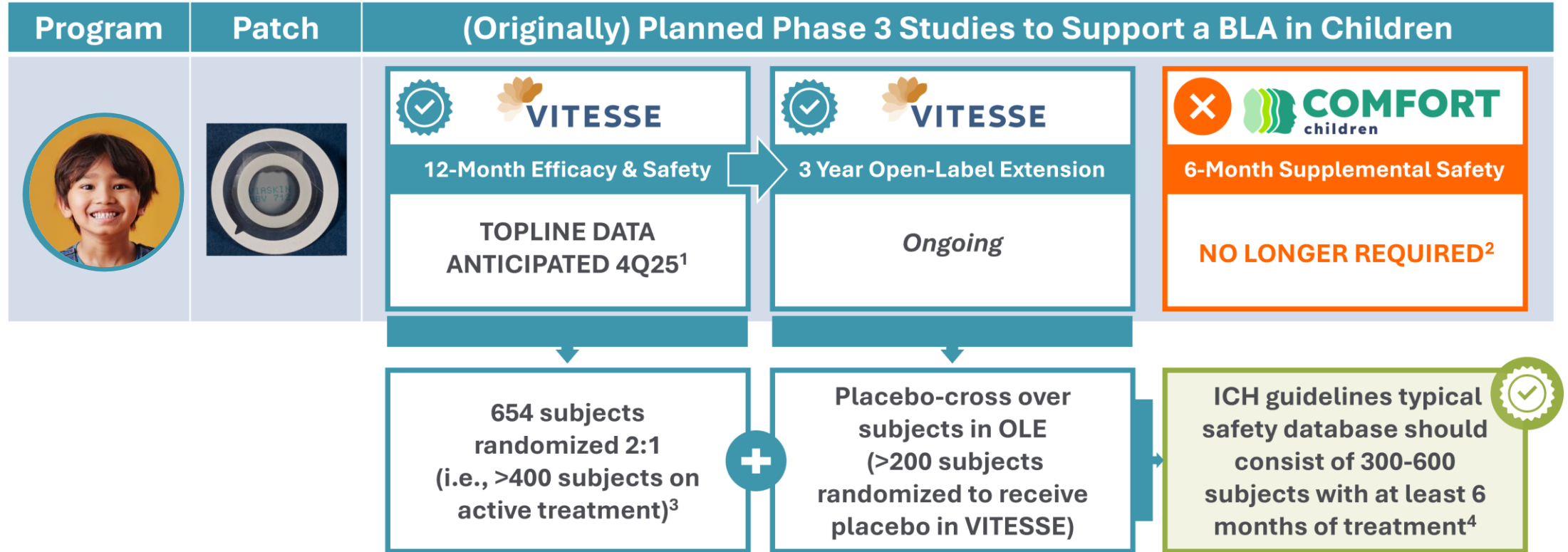


	Square Patch	Circular Patch
Target Age	1-3 YO 	4-7 YO 
Overlay Size	34 mm/side	44 mm diameter
Dose (Peanut Allergen Extract)	250 µg	250 µg
Anticipated BLA SUBMISSION	 2H 2026 ¹	 1H 2026 ²
	Under Accelerated Approval Pathway ¹	ACCELERATED Timeline for BLA Submission ²



Accelerated Timeline for VIASKIN Peanut in Children, Ages 4 –7 YO

Agreement with FDA on Safety Exposure Data for BLA Filing, Obviating Need for COMFORT Children Trial



Anticipated BLA submission in 1H26²; BLA may be eligible for priority review*



DBV anticipates this path may accelerate potential launch, if approved by FDA, by ~1 year²



US Regulatory Pathway for VIASKIN Peanut in Toddlers, Ages 1 –3 YO

Alignment with FDA on an Accelerated Approval (AA) Pathway for Toddlers Program¹



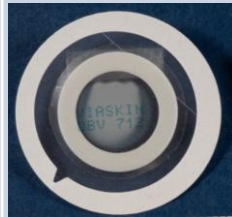
BLA for 1-3 YO under AA pathway is anticipated to be submitted in 2H26¹



EMA Provided Guidance for Marketing Authorization Application (MAA) for the Circular VIASKIN® Peanut Patch in 1-7 Year Olds

The unmet need for peanut allergy in Europe is significant:

- Estimated that 615,000 children ages 1 – 7 YO in the EU have peanut allergy¹
- Incidence of new diagnosis of ~81,000 a year¹

Program	Patch	EMA Guidance for an MAA Submission for a 1-7 YO Indication to Consist of 3 Studies ² :				
 1-7		1  Results from successful EPITOPE Phase 3 efficacy & safety trial in 1-3 YO	+	2  Positive result in the ongoing VITESSE Phase 3 efficacy & safety trial in 4-7 YO	+	3 A new safety study with circular modified patch in 1-3 YO

3

DBV plans to seek formal EMA scientific advice on safety study design elements



There Are Multiple Unmet Needs Concerning the Management of Peanut Allergy

For Many Families, Avoidance Is Not Enough

- Accidental exposures still happen despite families' best efforts¹
- In a follow-up, prospective study, approximately 41% of peanut-allergic children reported an accidental exposure within 3 years of diagnosis²

Reactions Are Unpredictable

- Reactions to peanut are more likely to be severe than in other food allergies³
- Many factors — such as exercise, infection, asthma, NSAID usage, and stress — contribute to reaction severity, making it unpredictable⁴

Peanut Allergy Directly Impacts Quality of Life

- Patients and their families have reported experiencing increased anxiety and healthcare costs, and decreased quality of life due to fear of life-threatening reactions^{5,6}
- Approximately 35% of caregivers and 42% of children report that their peanut allergy interferes with their daily life⁷
- Nearly 80% of peanut-allergic children report that fear of accidental exposure impacts their emotional well-being⁷

1. Capucilli P, et al. *Ann Allergy Asthma Immunol.* 2020;124:459-465; 2. Kansen HM, et al. *J Allergy Clin Immunol.* 2020;145:705-707.e7; 3. Gupta RS, et al. *Pediatrics.* 2018;142:e20181235; 4. Turner PJ, et al. *Allergy.* 2016;71:1241-1255; 5. Shaker MS, et al. *Curr Opin Pediatr.* 2017;29:497-502; 6. Blaiss MS, et al. *J Manag Care Spec Pharm.* 2021;27:516-527; 7. Nowak-Węgrzyn A, et al. *World Allergy Organ J.* 2021 Feb 15;14(2):100512.

Current Treatment Options Are Often Not Ideal for Patients & Their Families¹⁻⁴



Oral Immunotherapy (Approved[†] & Non-Proprietary)



Complex dose escalation schedule, requiring multiple visits to an allergist's office that can each last >1 hour



Avoidance of certain activities (sports, strenuous physical activities & hot showers/baths) within 3 h of dose



Increased risk of an allergic reaction to OIT dose if patient is ill (e.g., viral infection), very tired or missing sleep, stressed, or exercising



Requirement to eat peanut every day at the same time regardless of potential fear of ingesting peanut or aversion to taste

Non-proprietary OIT refers to in-house methods conducted by some OIT allergists; [†]PALFORZIA® is an FDA approved version of OIT and is approved in children aged 1-17 YO.



Omalizumab (anti-IgE Monoclonal Antibody)[#]



Fear of injection:

- Requires injection(s) 1-2 times per month^{4,5}
- Potentially painful injection site reactions



Not disease modifying⁴

- Patient needs to continue therapy indefinitely



Long-term immunological effects of blocking IgE in young children are currently unknown

- Approval in children (1-17 YO) based on one study where 45 children (1-5 YO) were on active treatment (versus 23 children on placebo)⁶

[#]XOLAIR (Omalizumab) was approved by the FDA in Feb 2024 for children and adults (aged 1-55 YO) with one or more food allergies.



90% of allergists see the need for additional options in the treatment of pediatric peanut allergy⁷



Treatment Must Be Effective, Safe, and Practical to Use to Achieve Outcomes with Immunotherapy



Peanut Allergy Treatment Must Balance 3 Key Elements¹⁻⁴

Reduces likelihood of an allergic reaction in case of accidental exposure

Low risk of a serious reaction caused by the treatment & low risk of side effects

Accepted by caregiver & child



Purposely Designed to Meet the Outcome Objectives of Immunotherapy

1

✓ Clinical study results show statistically significant treatment effect after 12 months⁵⁻⁷ & with further gains in desensitization through 36 months⁸⁻¹⁰

2

✓ Daily exposure to 1/1000th of a peanut kernel
✓ Consistently favorable safety & tolerability profile⁵⁻¹¹ with ~1M patches administered to >1300 children

3

✓ Applied once a day at home; no treatment escalation; no restriction on activities in trials
✓ High Tx compliance across trials (93% out to 5 years¹²)

1. Greenhawt M, et al. *Ann Allergy Asthma Immunol.* 2018;120:620-625. doi:10.1016/j.anai.2018.03.001; 2. Based on primary market research conducted on behalf of DBV among 100 allergists in the United States. Survey question: If a new peanut allergy desensitization treatment for children 4 to 11 years of age became FDA-approved and available for use, what would be the importance of each of the following attributes to you? Please use a 0- to 7-point scale where 0 means "not at all important to me" & 7 means "very important to me"; 3. Anagnostou A, et al. *J Allergy Clin Immunol Pract.* 2020;8:46-51; 4. Ravindran M, et al. *Allergy* 2025;80(1):63-76; 5. Greenhawt M, et al. *N Engl J Med.* 2023; 388:1755-1766; 6. DBV Technologies Press Release. April 19, 2023; 7. Fleischer DM, et al. *JAMA.* 2019;321:946-955; 8. Greenhawt M, et al. *J Allergy Clin Immunol Pract.* 2025;13:1176-1187; 9. Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: Results After 3 Years of Treatment – Matthew Greenhawt, MD. Presented at The Eastern Food Allergy & Comorbidity Conference. January 9-12, 2025; 10. Fleischer DM, et al. *J Allergy Clin Immunol.* 2020;146(4):863-874; 11. Pooled Safety Data from Phase 3 Studies of Epicutaneous Immunotherapy for Peanut Allergy in Children Aged 4-11 Years – Rachel Robison, MD. Presented at AAAAI Annual Meeting, February 2022; 12. Long-term Efficacy Results of Epicutaneous Immunotherapy with VIASKIN® Peanut Patch in Peanut-Allergic Children Ages 4-11 Years in the Phase 3 PEOPLE Study – David M. Fleischer, MD. Presented at AAAAI, March 3, 2025.



Anticipated Near-Term Milestones

Upcoming Milestones & Catalysts Anticipated Over Next 18 Months



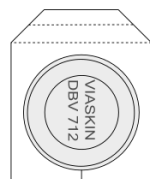
CHILDREN (4-7 years)



VITESSE topline data anticipated in Q4 2025



BLA submission for 4-7 YO anticipated in 1H 2026¹



TODDLERS (1-3 years)



Completion of enrollment of COMFORT Toddlers safety trial



COMFORT Toddlers Topline Data



BLA submission for 1-3 YO anticipated in 2H 2026¹

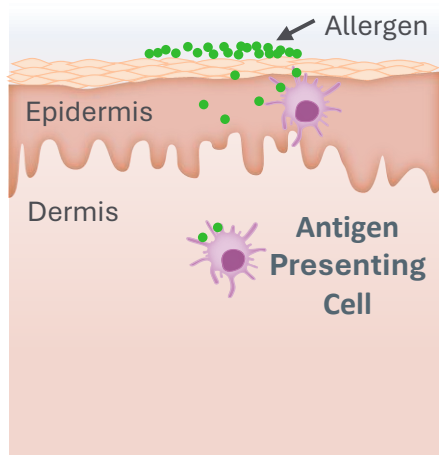


A microscopic view of various cells, including a prominent red one on the left and several purple ones on the right. A trail of small, glowing blue-green particles connects the red cell to the purple cells, suggesting a signal or communication pathway. The background is a teal color with diagonal lines.

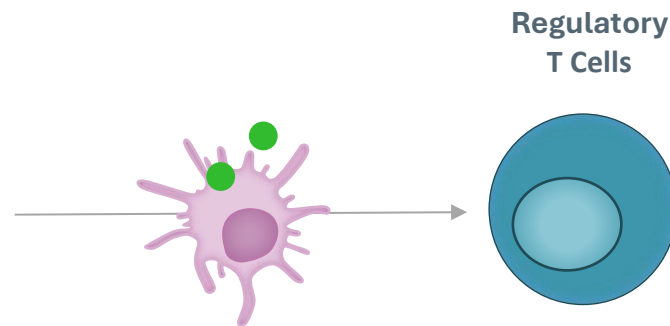
THE SCIENCE OF EPICUTANEOUS IMMUNOTHERAPY (EPIT)

Epicutaneous Immunotherapy (EPIT) Aims to Re-educate the Immune System Thus Suppressing the Allergic Response¹⁻⁷

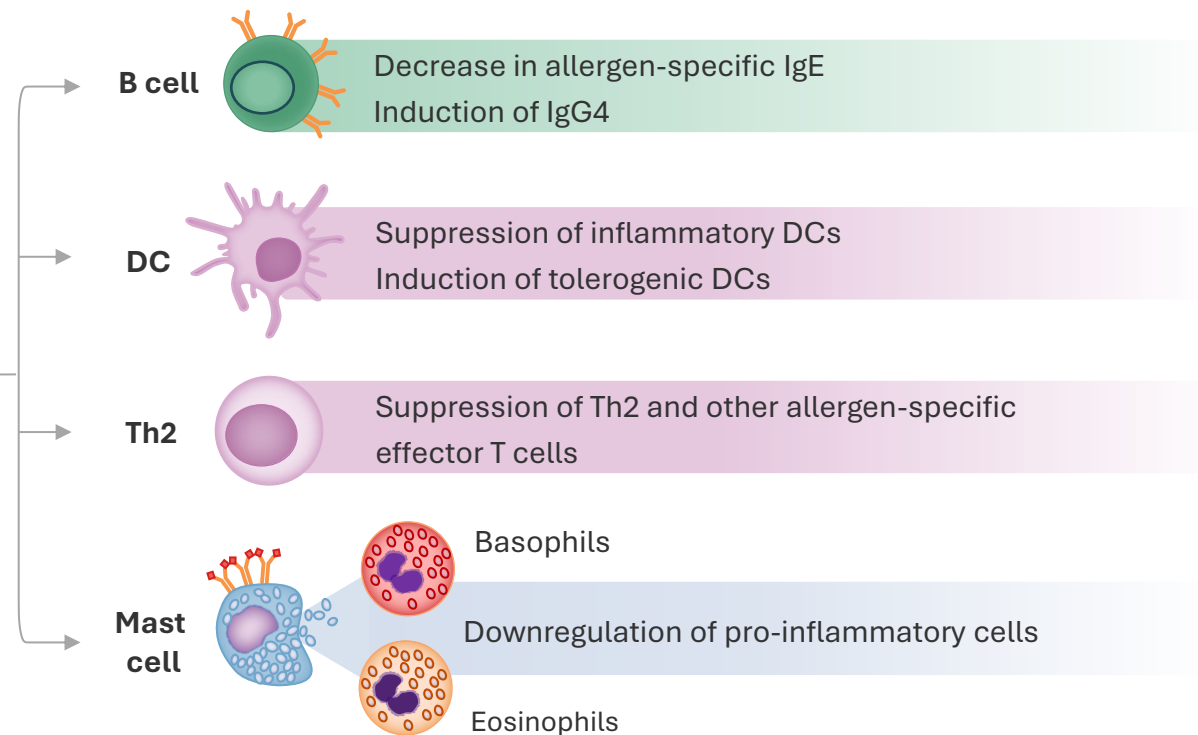
EPIT delivers allergen to the skin



Antigen Presenting Cells capture allergen and induce unique Regulatory T Cells



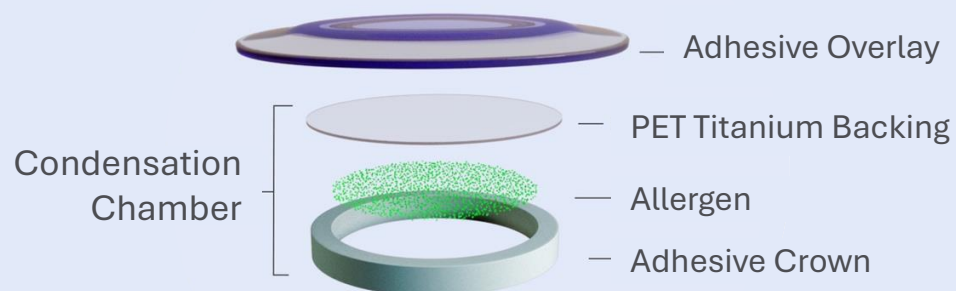
Regulatory T Cells act on the immune system to suppress the allergic response



DC=dendritic cell; IgE=immunoglobulin E; IgG4=immunoglobulin G4; Th2=T-helper 2 cell.

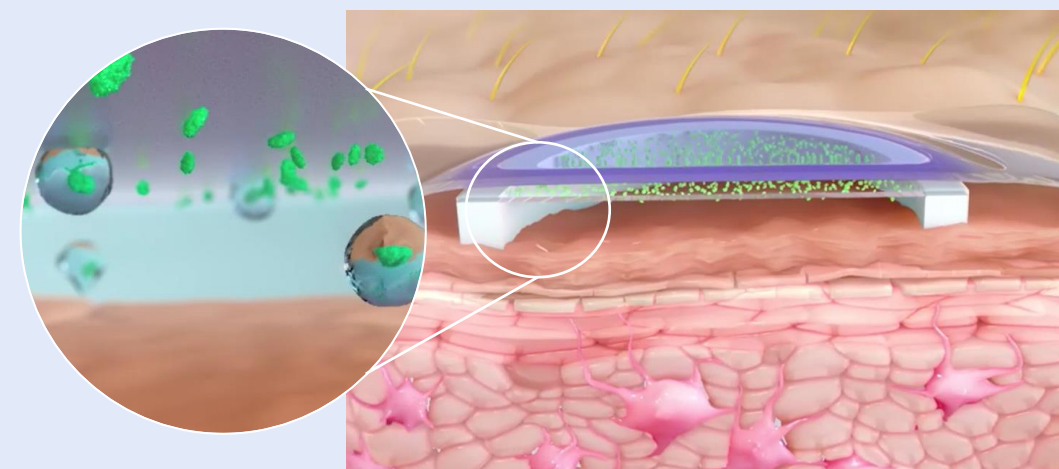
VIASKIN® Patch: Our Innovative Approach to Epicutaneous Immunotherapy¹⁻³

A Novel Drug-Device Combination for Delivering Allergen Immunotherapy



Condensation Chamber

formed by adhesive crown, allergen and titanium backing, secured by adhesive overlay



Allergen Solubilization

Occurs within condensation chamber when natural epidermal water loss solubilizes dry antigen on titanium backing

VIASKIN® Patch Uses Minimal Amounts of Allergen to Induce Desensitization¹⁻³

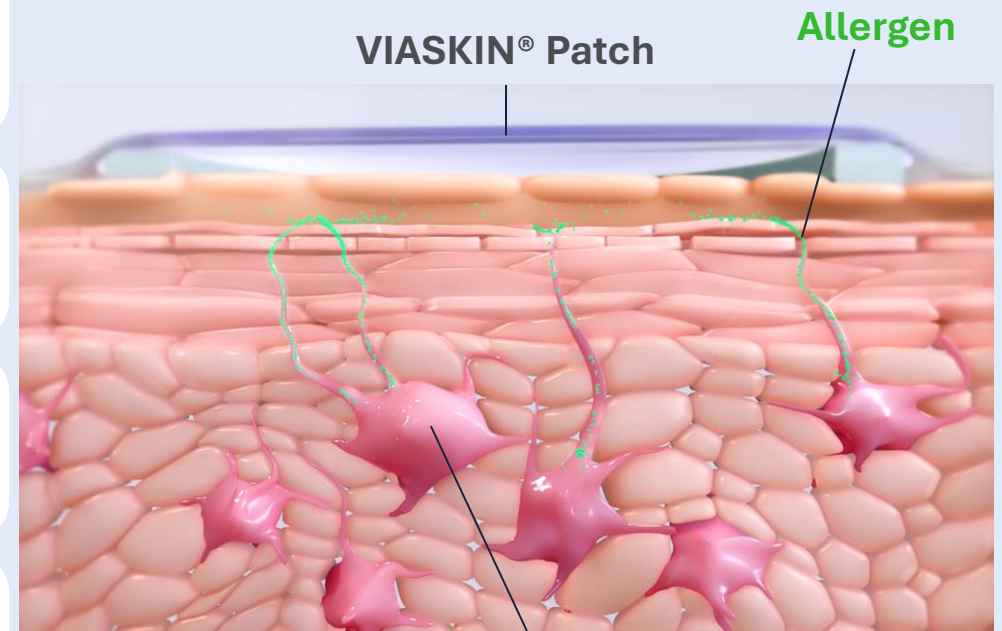
1/1000th of a peanut is applied daily to the skin

3 years of treatment with VIASKIN® Peanut patch (250 µg) is equivalent in exposure amount to 1 peanut kernel

Solubilized allergen is captured by specialized Antigen Presenting Cells (**Langerhans cells**) in the epidermis

Langerhans cells process allergen, migrate to lymph nodes where they present fragments of allergen to T-cells, leading to a specific immune response that suppresses the allergic reaction

Allergen delivered via VIASKIN is **not detected in the bloodstream** in animal models

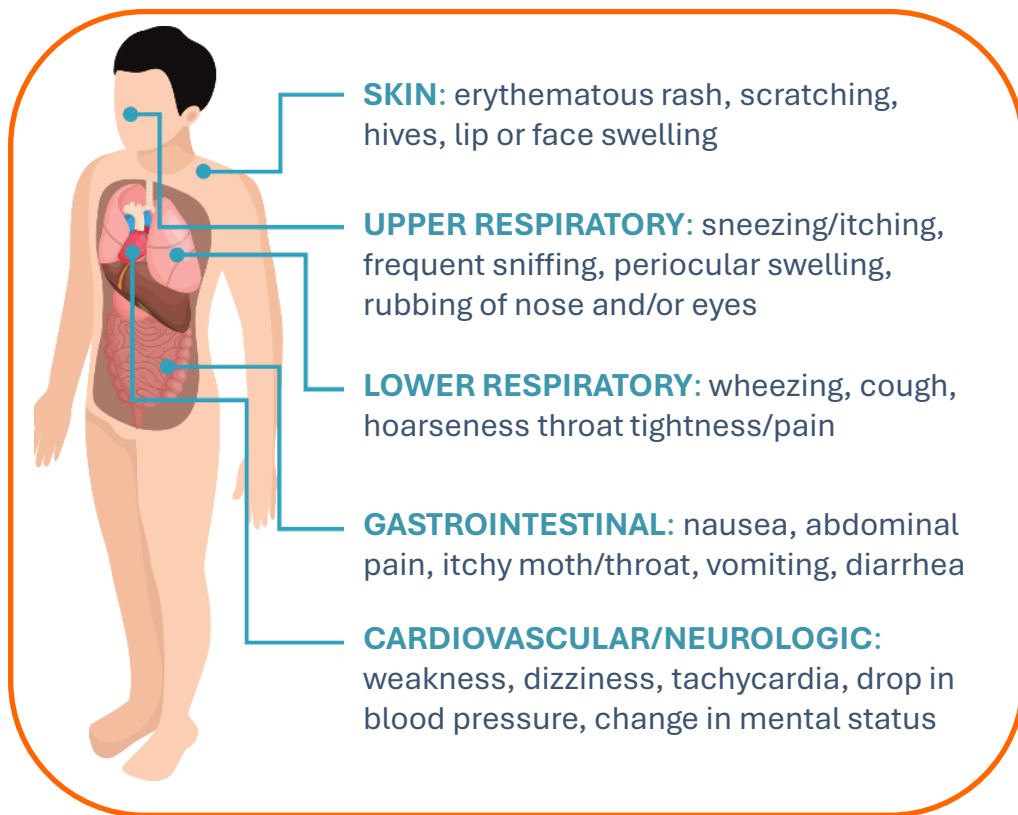


Langerhans Cell

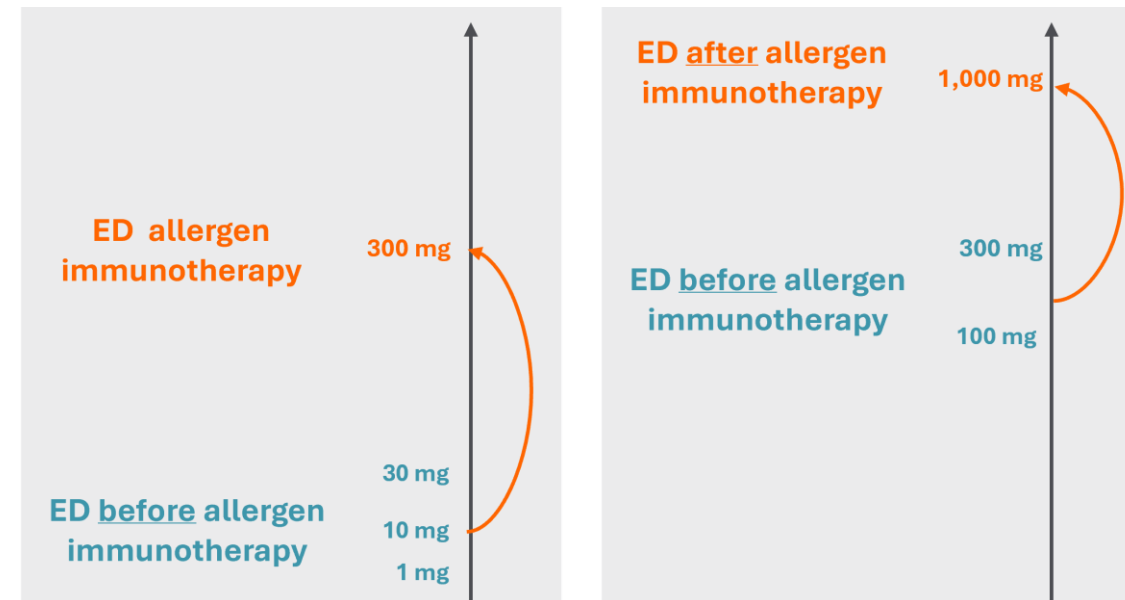
(capturing allergen in the outer layer of the epidermis)

Desensitization is Measured by Increases in Eliciting Dose (ED)

ED = the amount of allergen that induces allergic symptoms¹:



Decrease in Reaction Risk with Increased ED Following Allergen Immunotherapy



Modeling* data suggest increasing a patient's ED decreases the risk of an allergic reaction¹

Increasing a patient's eliciting dose from **1**, **10**, or **30 mg** to **300 mg** or **100** or **300 mg** to **1,000 mg** via allergen immunotherapy is predicted to reduce their risk of an allergic reaction by **≥99%**

VIASKIN® Peanut Patch Program in Children Ages 4-7 Years Old





VITESSE Study Design

- Fully enrolled since end of Q3 2024¹ → 654 subjects ages 4-7 YO (vs target enrollment of 600²)
- Largest immunotherapy clinical trial for this patient population¹

Global Phase 3 Trial

Randomized, double-blind, placebo-controlled

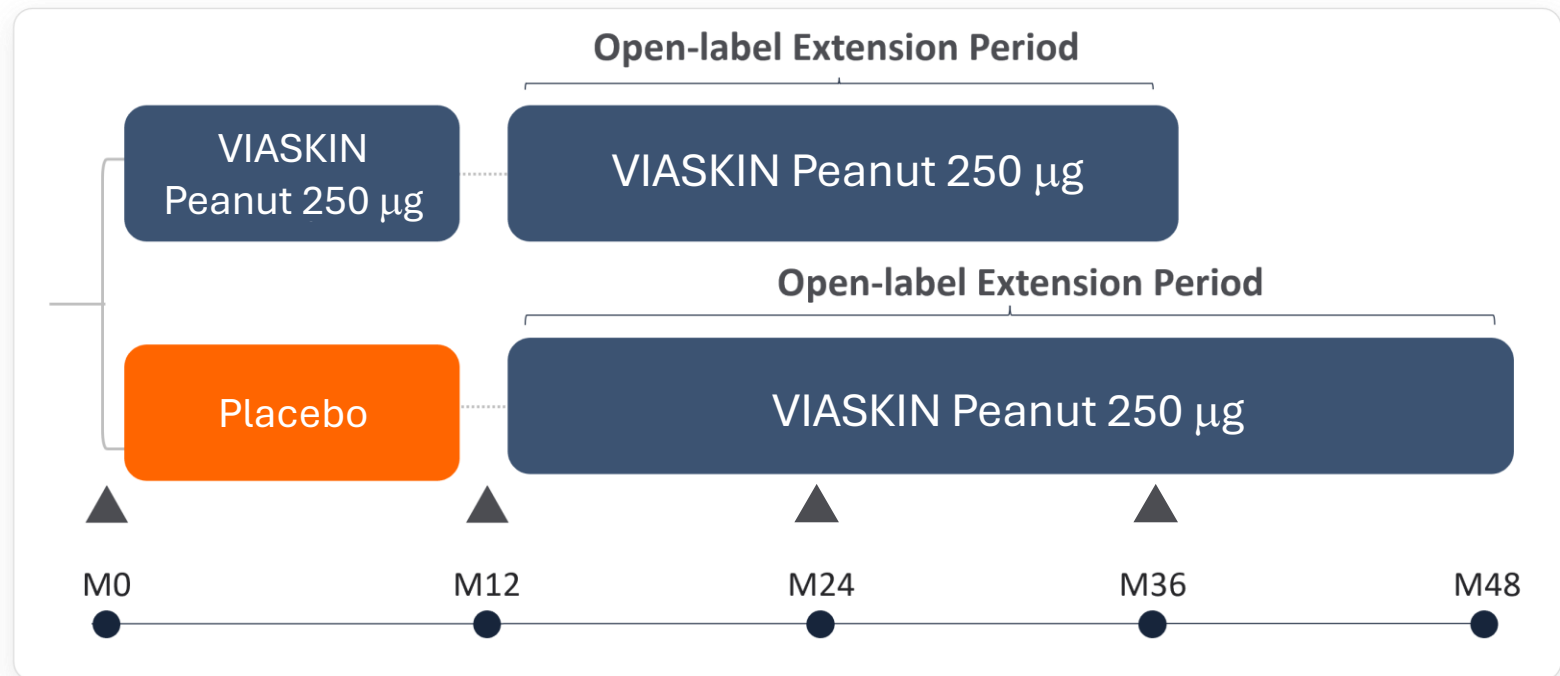
- **654 subjects** Randomized 2:1
- Inclusion Criterion Baseline ED ≤ 100 mg
- **86 sites in US, Canada, Europe, Australia**

Primary endpoint:

Difference between % of treatment responders in the active vs. placebo group after 12 months

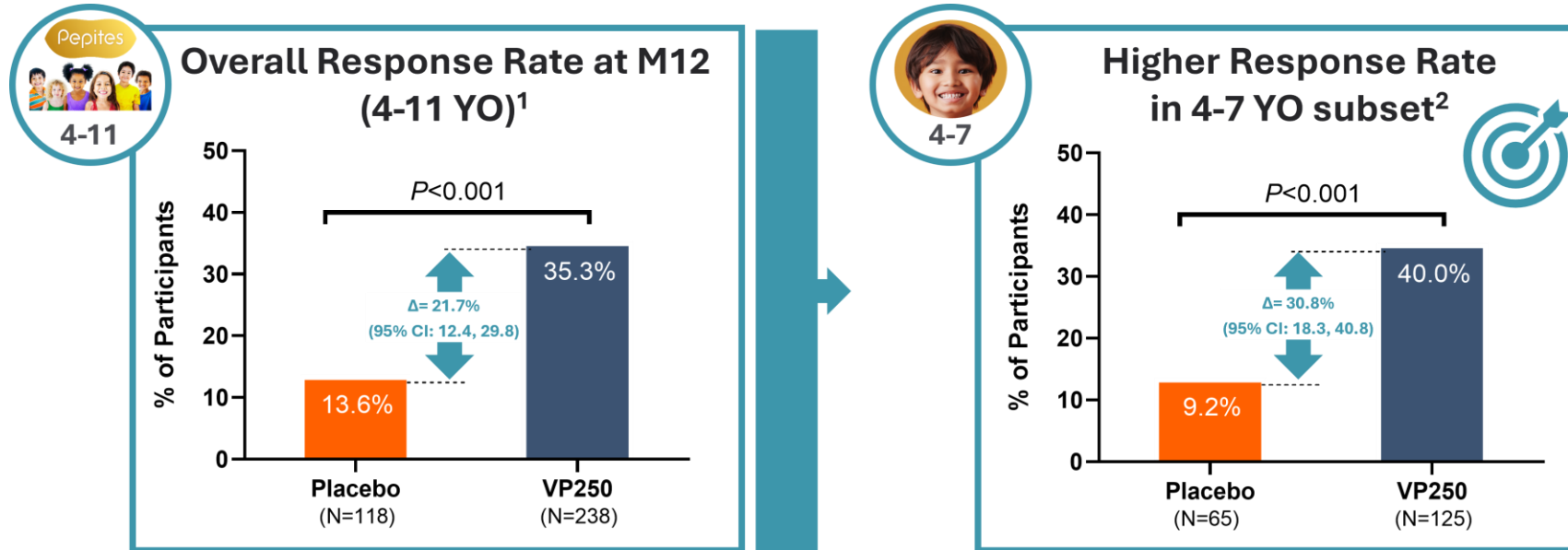
Treatment responder (assessed by DBPCFC) defined as:

If ED ≤ 30 mg at baseline, responder if ED ≥ 300 mg at M12
If ED = 100 mg at baseline, responder if ED ≥ 600 mg at M12



▲ DBPCFC=Double-Blind Placebo-Controlled Food Challenge

VITESSE Study Design Informed by Prior Phase 3 PEPITES (4-11 YO)^{1,2}



VITESSE targets younger & more sensitive patients who are also some of the highest risk patients



Targeting a younger population than prior indication (4-11 YO)³



Lowered baseline entry OFC to 100 mg (Prior DBV Phase 3 studies used 300 mg)



More malleable immune systems that can be more easily re-educated with immunotherapy^{2,4}



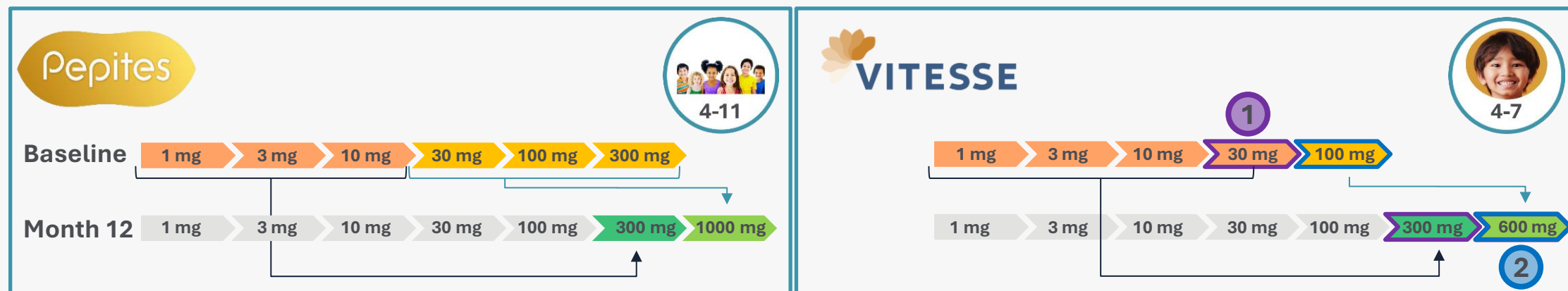
More sensitive subjects (lower ED) tend to have a higher responder rate^{1,5}

Other inclusion criteria remain largely unchanged³ (e.g., SPT, sIgE)



Statistical Definition of a Responder Reflects a More Sensitive Population Enrolled in VITESSE

Responder Criteria Changed to Reflect a Younger, More Sensitive Population



Two Key Differences in VITESSE Responder Criteria

1

Subjects with baseline ED of 30 mg will be considered as responders if Month 12 ED ≥ 300 mg
 → DBV's prior Phase 3 studies required the 30 mg baseline ED group to reach a Month 12 ED of ≥ 1000 mg

2

600 mg ED criterion added
 → Subjects with a baseline ED of 100 mg must reach an ED of ≥ 600 mg to be considered as a responder
 → DBV's prior Phase 3 studies required the 100 mg baseline ED group to reach a Month 12 ED of ≥ 1000 mg



VITESSE Study Fully Enrolled as of August, 2024¹



DBV's original statistical calculations had at least 90% power with 600 randomized subjects



654 subjects enrolled²: power >90%



**57% of enrolled subjects are aged 4-5 YO³
(43% of cohort = 6-7 YO)**



Younger patients tend to respond better³



Overall randomized population has lower than expected specific IgE (39.2 kU_A/L)³



Patients with lower baseline IgE tend to respond better⁴

Both factors, younger age and lower sIgE are associated with more robust treatment effects with VIASKIN Peanut patch^{4,5}

A woman with long dark hair, wearing a light-colored patterned dress, is holding a toddler. The toddler is wearing a light blue short-sleeved shirt and olive green shorts. They are standing outdoors in a park-like setting with trees and a playground in the background. The woman is looking down at the child with a gentle expression.

epitope

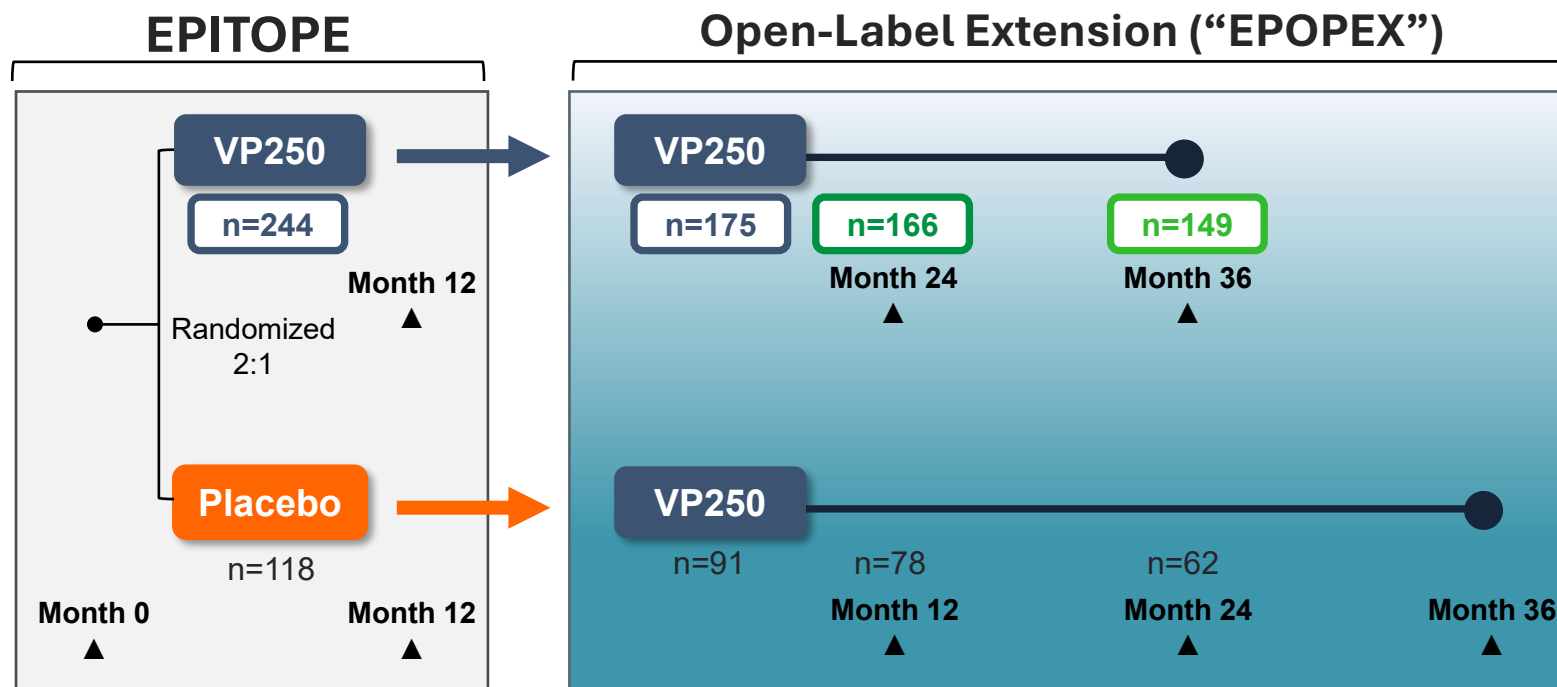
 **COMFORT**
toddlers

**VIASKIN® Peanut Patch
Program in Toddlers
(Ages 1–3-Years Old)**



Phase 3 EPITOPE: VIASKIN® Peanut Patch in Toddlers 1-3 Years of Age

Study Design for EPITOPE Pivotal Global Study¹ & Open-Label Extension (OLE) to EPITOPE Study²



High % of subjects opted to stay on VP250 after Year 1 EPITOPE through 36 Months^{3,4}

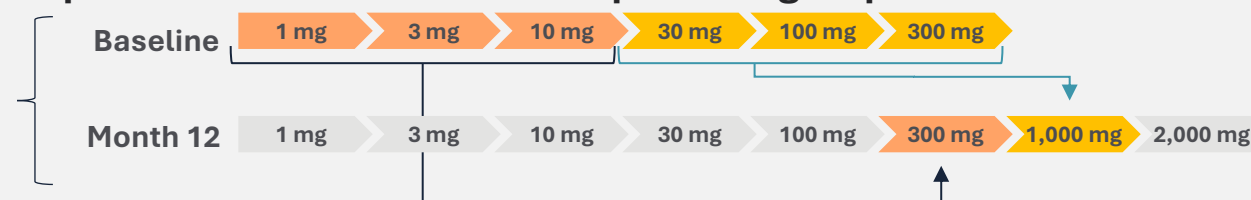
➤ 95% of VP250 subjects who entered OLE underwent DBPCFC at Month 24

➤ 85% of VP250 subjects who entered OLE underwent DBPCFC at Month 36

▲ DBPCFC = Double-Blind Placebo-Controlled Food Challenge

Primary endpoint = difference between % of treatment responders in the active versus placebo group after 12 months:

Treatment responder (assessed by DBPCFC) defined as:
 If ED ≤ 10 mg at baseline, responder if ED ≥ 300 mg at Month 12
 If ED > 10 mg at baseline, responder if ED ≥ 1,000 mg at Month 12



VP250=VIASKIN® Peanut patch 250 µg; ED=eliciting dose.

1. Greenhawt M, et al. Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy. *N Engl J Med*. 2023;388:1755-1766; 2. Greenhawt M, et al. EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: 1-year Open-Label Extension to EPITOPE. Oral Presentation at ACAAI Meeting Nov 2023; 3. DBV Technologies Press Release. January 8, 2025; 4. Greenhawt M, et al. EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: Results After 3 Years of Treatment. Presentation at Eastern Food Allergy & Comorbidity Conference. January 9-12, 2025.



Positive Month 12 Results from Phase 3 EPITOPE Study with Primary Endpoint Met & with a Favorable Safety & Tolerability Profile



PRIMARY ENDPOINT MET ¹⁻³



67.0% of participants on VP250 were responders vs 33.5% on placebo (p<0.001)



95% CI lower bound of 22.4% ≥ 15% → Primary endpoint met



OTHER ENDPOINTS ¹⁻³

64.2% of participants reached an ED of ≥1000 mg (equivalent of 3 peanuts; ≥8x more than the typical amount consumed upon accidental exposure³ vs 29.6% on placebo)

Shift towards reduction in symptom severity following 12 months of VP250 treatment relative to placebo (p<0.001)



≥95% compliance



SAFETY ¹⁻³

VP250 was well-tolerated, consistent with other trials with VP250

Serious treatment-related AEs occurred in 0.4% of subjects treated with VP250 vs 0% in the placebo group

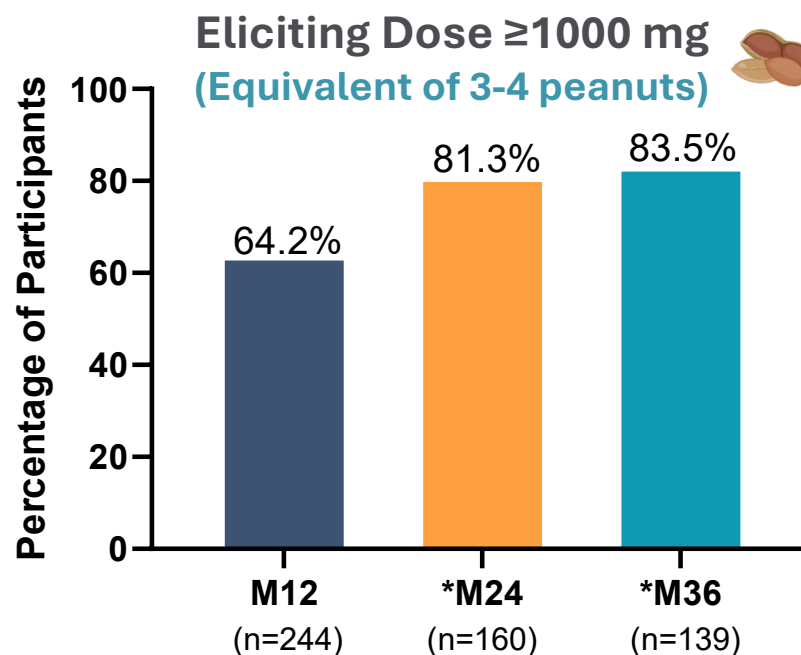
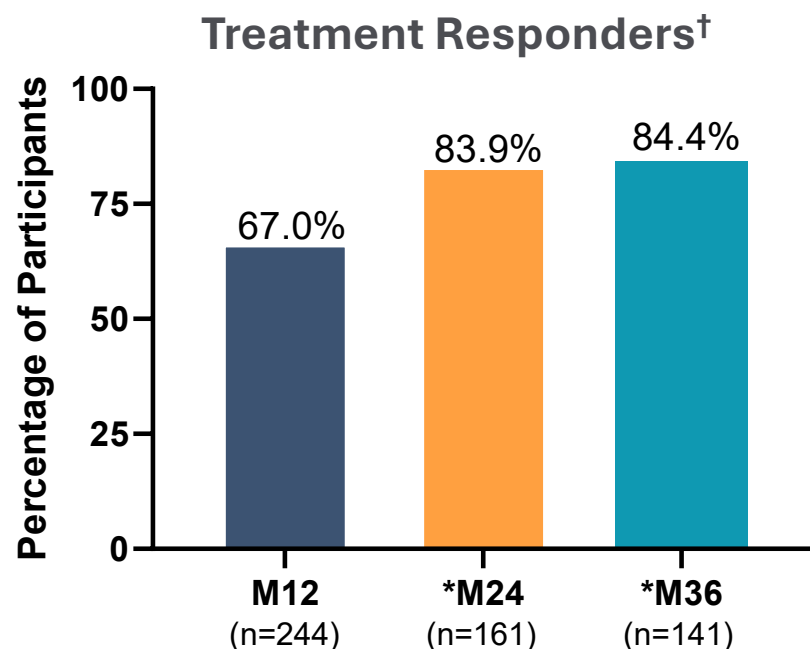
Treatment-related anaphylaxis occurred in 1.6% in the VP250 group and none in the placebo group

VP250=VIASKIN® Peanut patch 250 µg; CI=confidence interval; ED=eliciting dose; AE=adverse event.



EPITOPE Open-Label Extension Shows Continued Improvement in Treatment Response in Toddlers Through 36 MO¹⁻⁴

- 175 subjects entered OLE study (out of 244 randomized to receive VP250 in EPITOPE)
- 166 subjects (95%) of those in the OLE underwent DBPCFC at Month 24
- 149 subjects (85%) underwent DBPCFC at Month 36



In EPITOPE placebo participants who received treatment with VP250 in the OLE study (2-4 YO), efficacy was consistent with results seen after 12 and 24 months of VP250 treatment in EPITOPE²

[†]In EPITOPE, a treatment responder (assessed by DBPCFC) was defined as: If ED ≤ 10 mg at baseline, responder if ED ≥ 300 mg at M12; If ED > 10 mg at baseline, responder if ED ≥ 1000 mg at M12.

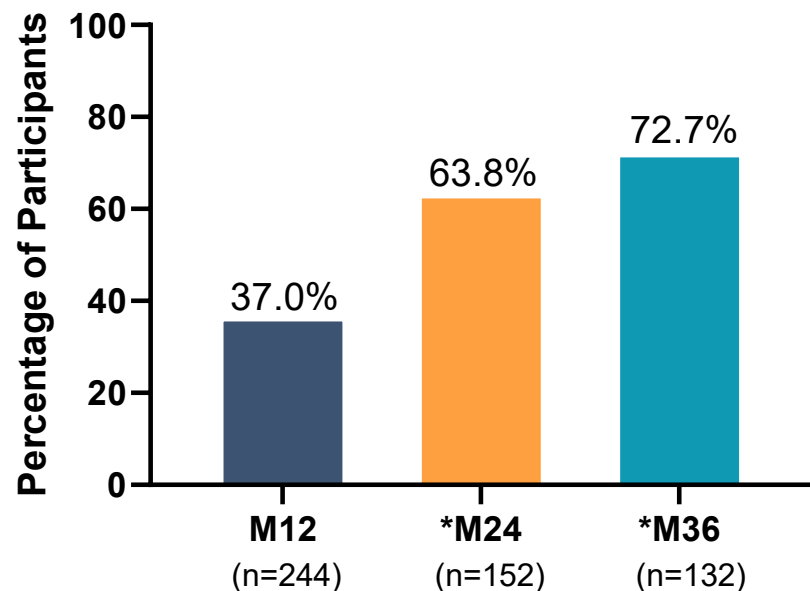
*Number of subjects with non-missing food challenge endpoint. VP250=VIASKIN® Peanut patch 250 μ g; OLE=Open Label Extension; DBPCFC=Double-Blind Placebo-Controlled Food Challenge.

1. Greenhawt M, et al. Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy. *N Engl J Med*. 2023;388:1755-1766; 2. Greenhawt M, et al. Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Toddlers: Open-Label Extension to EPITOPE. *J Allergy Clin Immunol Pract*. 2025;13:1176-1187; 3. DBV Technologies Press Release. January 8, 2025; 4. Greenhawt M, et al. EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: Results After 3 Years of Treatment. Presentation at Eastern Food Allergy & Comorbidity Conference. January 9-12, 2025.



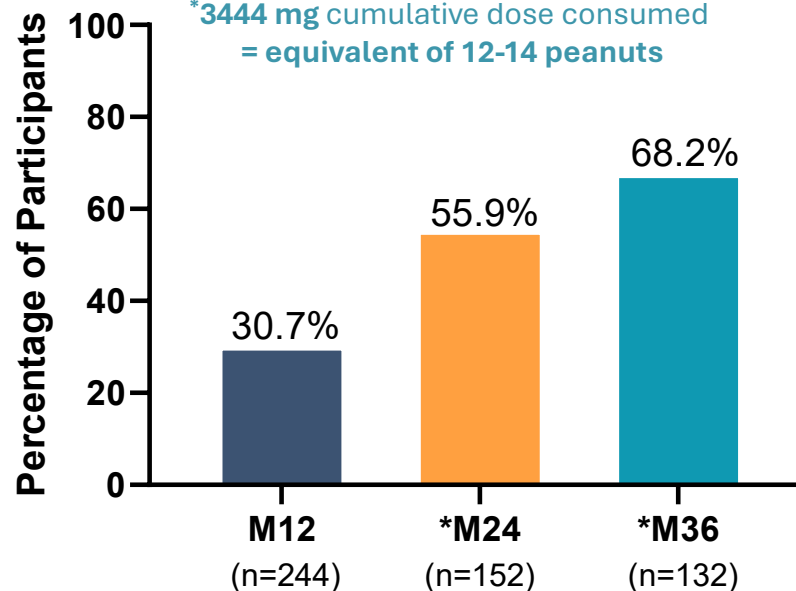
Data from EPITOPE Open-Label Extension Show Continued Improvement in Treatment Response in Toddlers Through 36 MO¹⁻³

Eliciting Dose ≥ 2000 mg
(Equivalent of 6-8 peanuts)



Completed Food Challenge* Without Meeting Stopping Criteria

*3444 mg cumulative dose consumed
= equivalent of 12-14 peanuts



In EPITOPE placebo participants who received treatment with VP250 in the OLE study (2-4 YO), efficacy was consistent with results seen after 12 and 24 months of VP250 treatment in EPITOPE²

[†]In EPITOPE, a treatment responder (assessed by DBPCFC) was defined as: If ED ≤ 10 mg at baseline, responder if ED ≥ 300 mg at M12; If ED > 10 mg at baseline, responder if ED ≥ 1000 mg at M12.

*Number of subjects with non-missing food challenge endpoint. VP250=VIASKIN® Peanut patch 250 μ g; OLE=Open Label Extension; DBPCFC=Double-Blind Placebo-Controlled Food Challenge.

1. Greenhawt M, et al. Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy. *N Engl J Med*. 2023;388:1755-1766; 2. Greenhawt M, et al. Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Toddlers: Open-Label Extension to EPITOPE. *J Allergy Clin Immunol Pract*. 2025;13:1176-1187; 3. DBV Technologies Press Release. January 8, 2025; 4. Greenhawt M et al. EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: Results After 3 Years of Treatment. Presentation at Eastern Food Allergy & Comorbidity Conference. January 9-12, 2025.



Study Results of VIASKIN® Peanut Patch Consistently Demonstrate a Favorable Safety & Tolerability Profile in Toddlers¹⁻⁴

Frequency of Treatment-Related Local Skin Reactions Are Further Reduced After 3 Years of Treatment

- Consistent with other studies⁵, local application site reactions were the most reported AE; however, the **frequency of reactions reduced over 36 months**
- **Frequency of treatment-related TEAEs was reduced at Year Two and even further reduced at Year Three**
- **No subjects had treatment-related serious TEAEs during second or third year of treatment (vs 1% in Year One), no treatment-related permanent study discontinuations occurred in Year 3**
- **No treatment-related anaphylaxis was observed during the second or third year of treatment with VP250**

	Year 1 [†] (EPITOPE) (N=175)	Year 2 (OLE) (N=175)	Year 3 (OLE) (N=165)
Adverse Event Category, n (%)			
TEAEs	175 (100%)	172 (98.3%)	145 (87.9%)
Treatment-related TEAEs	175 (100%)	161 (92.0%)	113 (68.5%)
Treatment-related serious TEAEs	1 (0.6%)	0	0
TEAEs leading to treatment discontinuation	0	1 (0.6%)	0
Treatment-related local TEAEs	175 (100%)	161 (92.0%)	111 (67.3%)
Severe treatment-related local TEAEs	37 (21.1%)	10 (5.7%)	3 (1.8%)
Treatment-emergent local AESI	40 (22.9%)	26 (14.9%)	14 (8.5%)
Treatment-related anaphylactic reaction	3 (1.7%)	0	0
Treatment-related TEAE leading to Epinephrine use	2 (1.1%)	0	0

VP250=VIASKIN® Peanut patch 250 µg; OLE=Open-Label Extension to EPITOPE; AE=adverse event; TEAEs=treatment-emergent adverse events. AESI=Adverse event of special interest.

[†]175 subjects entered OLE study (out of 244 randomized to receive VP250 in EPITOPE).



Accelerated Approval Pathway for VIASKIN[®] Peanut Patch in Toddlers

FDA Accelerated Approval Pathway to Licensure Designed to Facilitate & Expedite Promising Therapies

Current FDA Guidance for Accelerated Approval (AA)
Includes 3 Qualifying Criteria:

1

Product treats a serious disease



FDA states it is met²

2

**Generally provides a meaningful advantage
over available therapies[†]**



FDA states it is met²

3

**Demonstrates an effect on an intermediate
clinical endpoint (ICE) that is reasonably likely to
predict clinical benefit**



**FDA states it is met via
Written Response Letter¹**

- ✓ FDA confirmed that efficacy data from Phase 3 study EPITOPE can serve as an ICE
- ✓ Endpoint confirmed to be reasonably likely to predict efficacy in the post-marketing confirmatory study^{††}



1. DBV Technologies Press Release. December 11, 2024.

2. DBV Technologies Press Release. October 22, 2024.

[†] PALFORZIA and XOLAIR are FDA-approved for the treatment of peanut allergy.

^{††} Post-marketing study will also provide adhesion data to support DBV Technologies' proposed labeling strategy.



SUMMARY:

VIASKIN Peanut – A Novel Drug-Device with Blockbuster Potential



High Unmet Need: Medical Consequence of Accidental Peanut Consumption plus the Ever-Present Impact on Child and Family's Quality of Life



Significant Market Size in BOTH indications



Designed to meet outcome objectives of Immunotherapy: Efficacy, Safety, and Practicality



**Topline Data for VITESSE Anticipated in 4Q25 with BLA Submission Anticipated in 1H26
BLA Submission for Toddlers Anticipated in 2H26**



Actionable Market: Parents & Allergists Want Additional Approved Treatment Alternatives and Like VIASKIN Peanut's Profile



Manufacturing Capacity at Scale to Support Commercialization



❖ **VIASKIN Pipeline**

❖ **Manufacturing**

❖ **Intellectual Property**

Our Long-Term Vision is to Realize the Full Potential of the VIASKIN® Patch Technology

Program	Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3
VIASKIN® Milk Patch (DBV135) – Cow's Milk Allergy; MILES: Ages 2-17 years ¹					
VIASKIN® Milk Patch (DBV135) – Eosinophilic Esophagitis; SMILEE: Ages 4-17 years ²					
Autoimmune and Inflammatory Disorders					
Vaccines					



EPIT=epicutaneous immunotherapy; MILES=VIASKIN Milk Efficacy and Safety; SMILEE=Study of Efficacy and Safety of VIASKIN Milk for Milk-induced EoE

Robust Intellectual Property Portfolio

IP Protection in Various Countries, Encompassing:

Core patch technology	Condensation chamber
Mechanism of action	Epicutaneous immunotherapy (EPIT) activates the immune system by allowing the antigen to penetrate the upper layer of the epidermis (intact skin)
Manufacturing	Electrospray patch manufacturing allows for precise antigen deposits without adjuvants
Disease Areas	Peanut allergy, cow's milk allergy, EoE
Broad Geographic Coverage	Various protection across US, European nations, Australia, and Canada (and others)
Potential for Key Patent to Expire	2034 [†]
Patent	Innovation-driven patent lifecycle management

Patch Manufacturing Capabilities

Integrated End-to-End Patch Manufacturing in Place



Source Material

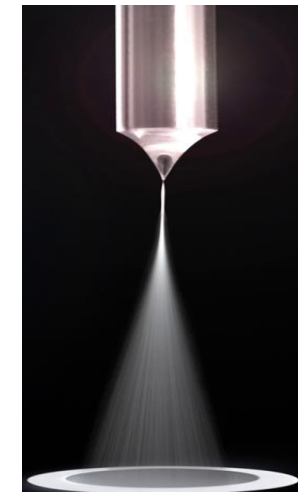


Active Pharmaceutical Ingredient (API)



Final Product Process

Proprietary electrospray technology
deposits a precise antigen dose without
any adjuvant on a PET titanium backing film

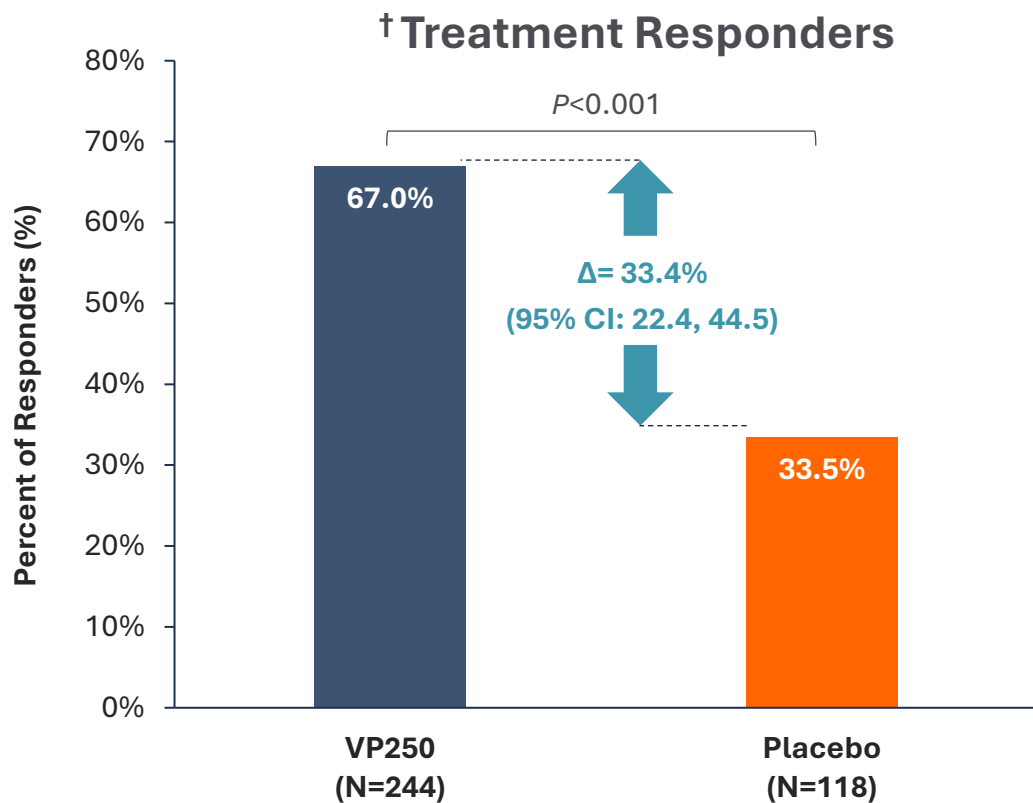




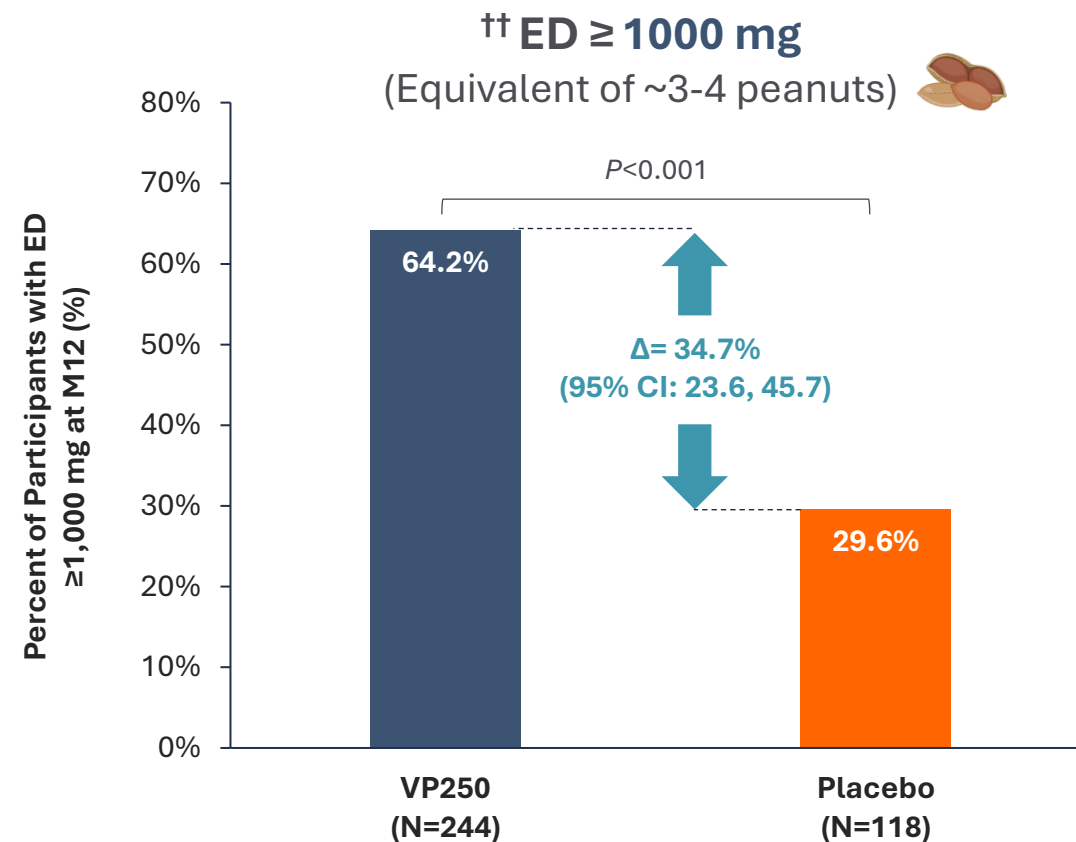
**VIASKIN® Peanut Patch Program
in Toddlers (1–3-Years Old)**



VIASKIN® Peanut Patch Demonstrated a Statistically Significant Treatment Effect in Toddlers After 12 Months^{1,2}



95% CI lower bound of 22.4% $\geq$ 15% $\rightarrow$
Primary endpoint is met



†† Versus 100 mg = Median ED at baseline
125 mg = Median dose of peanut protein consumed at accidental consumption³



Proposed Labeling Approach to FDA Based on Early Wear-Time Experience in 1–3-Year-Old Subjects in EPITOPE



Question was raised by FDA during dialogue re. COMFORT Toddlers' protocol:
What should prescribers tell their patients if there is day-to-day variability in patch wear time?

I.e., What will the label look like, if VIASKIN® Peanut patch is approved?



To address this question, DBV proposed draft labeling information for prescribers for the 1-3 YO indication, based on *post-hoc* analysis of EPITOPE efficacy & wear-time experience¹



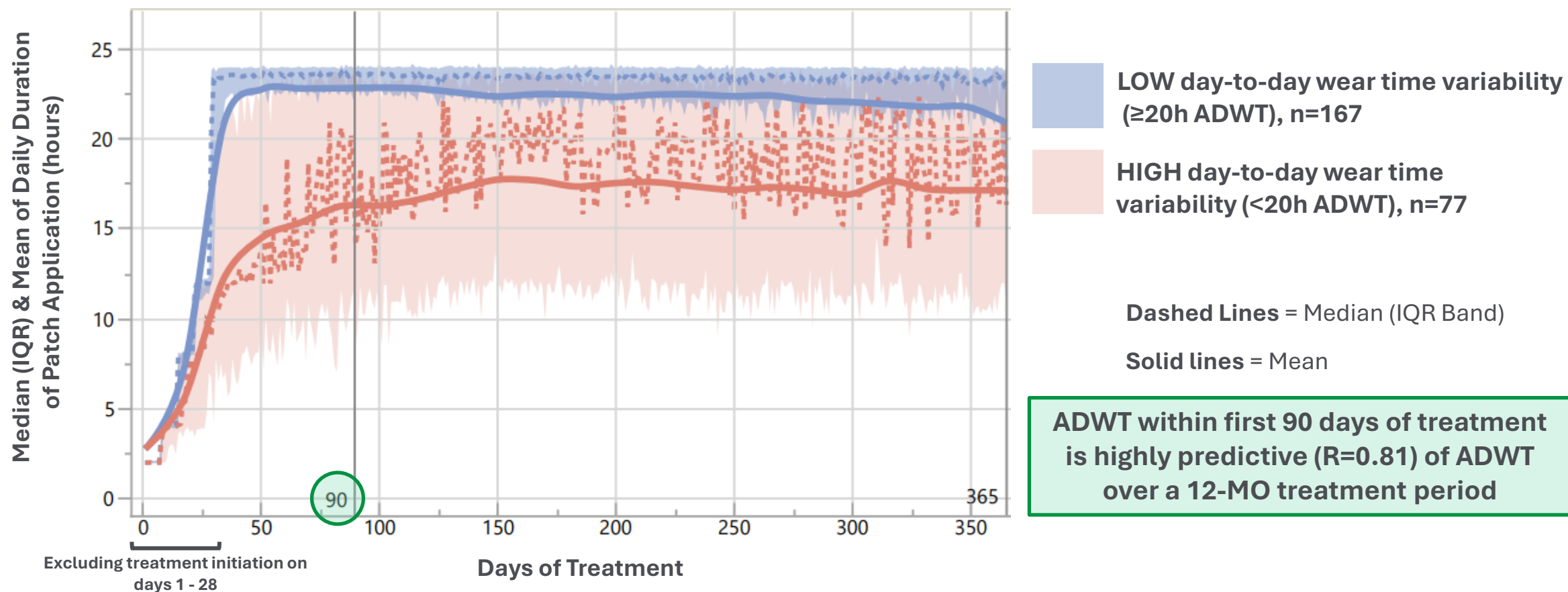
Identifies patients who would have the highest potential clinical benefit at Month 12 based on wear-time experience in the first 90 days of treatment

→ Data indicate that patient-specific factors (i.e., “tolerability to itch”) impact a patient’s wear-time experience / Average Daily Wear-Time (ADWT)²



Two Groups of Subjects Are Distinguished by This Labeling Approach

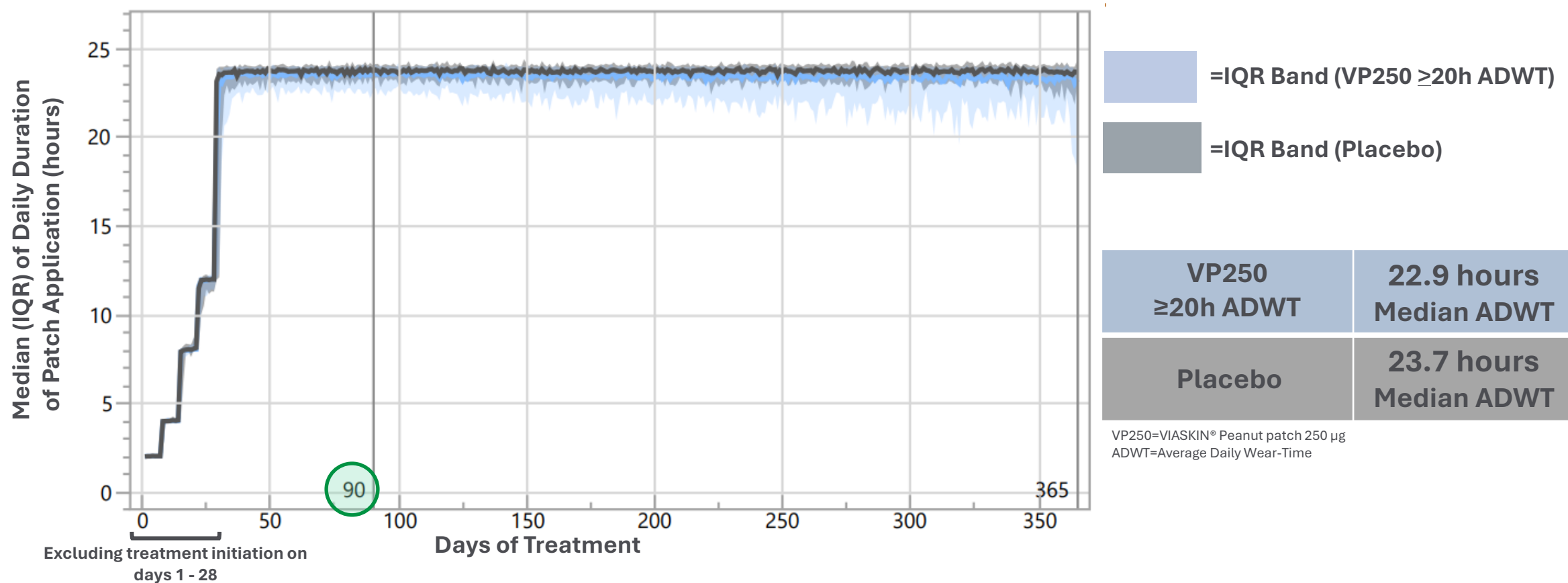
~70% of Subjects Experienced LOW Day-to-Day Variability Consistently Achieving ≥ 20 Hours ADWT Versus
~30% of Participants with HIGH Day-to-Day Variability (< 20 Hours ADWT)^{1,2}





Similar Wear-Time Experience Observed in Participants Achieving ≥ 20 hours ADWT as Placebo Subjects^{1,2}

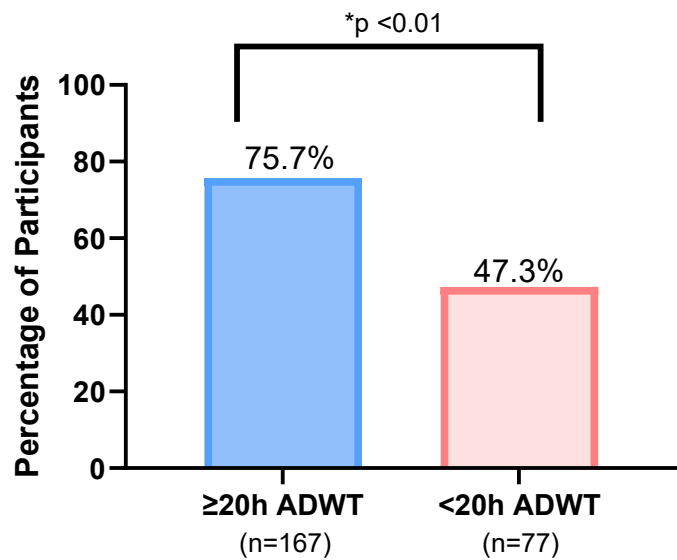
Higher Tolerability to Peanut Allergen in Those Subjects Achieving ADWT ≥ 20 hours





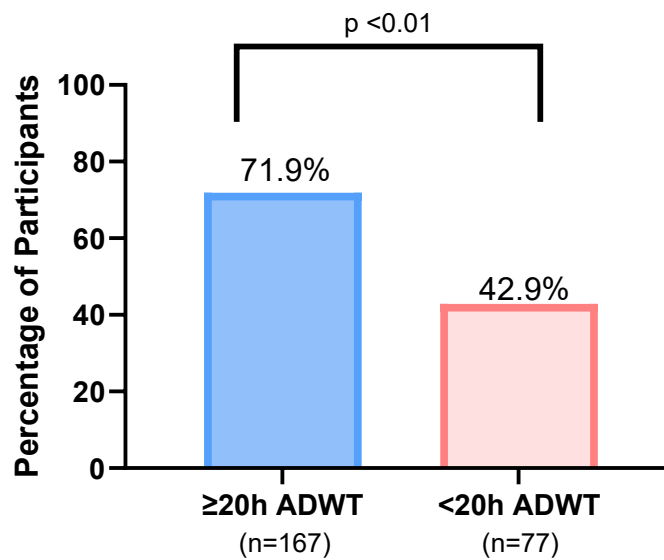
Subjects with Higher Average Daily Wear-Time (ADWT ≥ 20 Hours) Are Better Responders at Month 12 ^(1,2)

Responder Primary Analysis

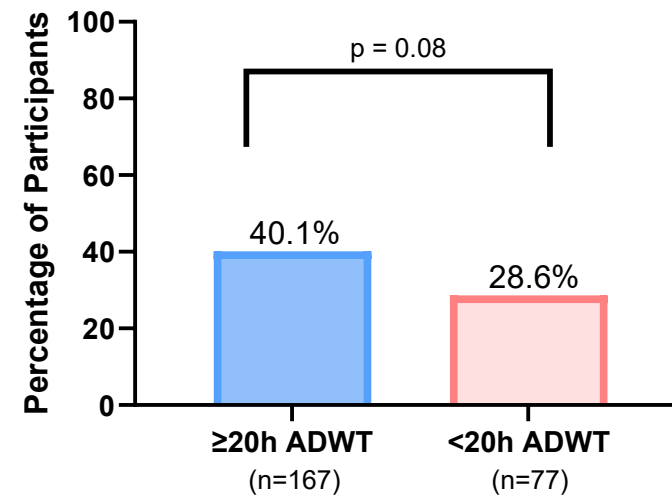


Versus 67.0% responder rate of ALL subjects (non-segregated) at Month 12 ⁽³⁾
[slide 40]

Eliciting Dose ≥ 1000 mg (Equivalent of 3-4 peanuts)



Eliciting Dose ≥ 2000 mg (Equivalent of 6-8 peanuts)





Similar Baseline Characteristics Between the Two Groups of Subjects at Treatment Initiation Regardless of ADWT

Lower Tolerability to Peanut Allergen (“More Itchiness”) Observed in Subjects with ADWT <20h¹⁻²

Baseline characteristics & in-study factors which may influence system wear time & adhesion	≥20h ADWT (n=167)	<20h ADWT (n=77)
Baseline sIgE, median (mean)	13.3 (66.1)	13.9 (50.8)
Baseline Ara h 2, median (mean)	8.1 (38.9)	9.6 (32.7)
Baseline ED, median	100 mg	100 mg
Baseline SCORAD, median	3.9	3.7
Eczema at baseline (%)	77.8%	83.1%
% systems scored *2 or 3, median	13.4	32.0
Scratching as system detachment reason (n) median (mean)	10 (26.9)	22.5 (63.6)
% days with local skin reaction, median (mean)	93 (83.7)	89.8 (81.4)
Related AEs leading to topical corticosteroid use, median (mean)	7.0 (13.6)	6.0 (13.9)

sIgE=peanut-specific IgE; Ara h 2=a major peanut allergen; ED=Eliciting Dose; SCORAD=SCORing Atopic Dermatitis; AEs=Adverse events.

*Score of 2=partially detached; score of 3=detached



Lower Rate of Key Safety Outcomes in Subjects with ADWT ≥ 20 Hours Versus Subjects with ADWT of ≤ 20 Hours^{1,2}

12-MO Safety Outcomes in VP250 Subjects According to ADWT During First 90 Days of Treatment

TEAE, n (%)	ADWT ≥ 20 h (n=167)	ADWT < 20 h (n=77)
TEAEs (mean)	45.0	44.7
Treatment-related TEAEs leading to temporary discontinuation	16 (9.6%)	15 (19.5%)
Treatment-related TEAEs leading to permanent discontinuation	1 (0.6%)	6 (7.8%)
Treatment-related TEAE leading to epinephrine use	1 (0.6%)	2 (2.6%)
Treatment-related anaphylaxis events	1 (0.6%)	3 (3.9%)
Treatment-related severe TEAEs (mean)	1.3	0.9
Systemic AESI	17 (10.2%)	8 (10.4%)
Serious systemic AESI	3 (1.8%)	2 (2.6%)

VP250=VIASKIN® Peanut patch 250 µg; ADWT=Average Daily Wear-Time.

TEAEs=treatment-emergent adverse events.

AESI=Adverse event of special interest.



SUMMARY – Optimizing Patch User Experience Based on Patch Wear-time in Toddlers, Ages 1-3 YO

Post-hoc analyses showed that in EPITOPE, participants could be readily distinguished based on Average Daily Wear Time (ADWT)^{1,2}



HIGH ADWT
≥20 hours



LOWER ADWT
<20 hours

Despite this, subjects with ADWT of ≥20 hours vs ADWT <20 hours have highly comparable baseline immunological profiles AND a similar incidence & severity of local site reactions^{1,2}



Reported more scratching leading to patch detachment – suggesting these toddlers experience lower tolerability (more “itchiness”) to peanut-induced local skin immune response

Subjects with LOW day-to-day ADWT variability (~70% of subjects in Year One) have a very similar wear time experience to placebo patients^{1,2}



Median ADWT
= 22.9 hours



Median ADWT
= 23.7 hours

Placebo

- ADWT within the first 90 days of treatment is highly predictive of clinical efficacy at month 12:
 - 75.7% of subjects with an ADWT ≥20h were treatment responders (vs 67.0% of all EPITOPE subjects)³
 - 47.3% of subjects with an ADWT <20h were treatment responders vs 33.5% of placebo subjects
- ADWT within the first 90 days is also highly predictive of ADWT over a 12-month treatment period

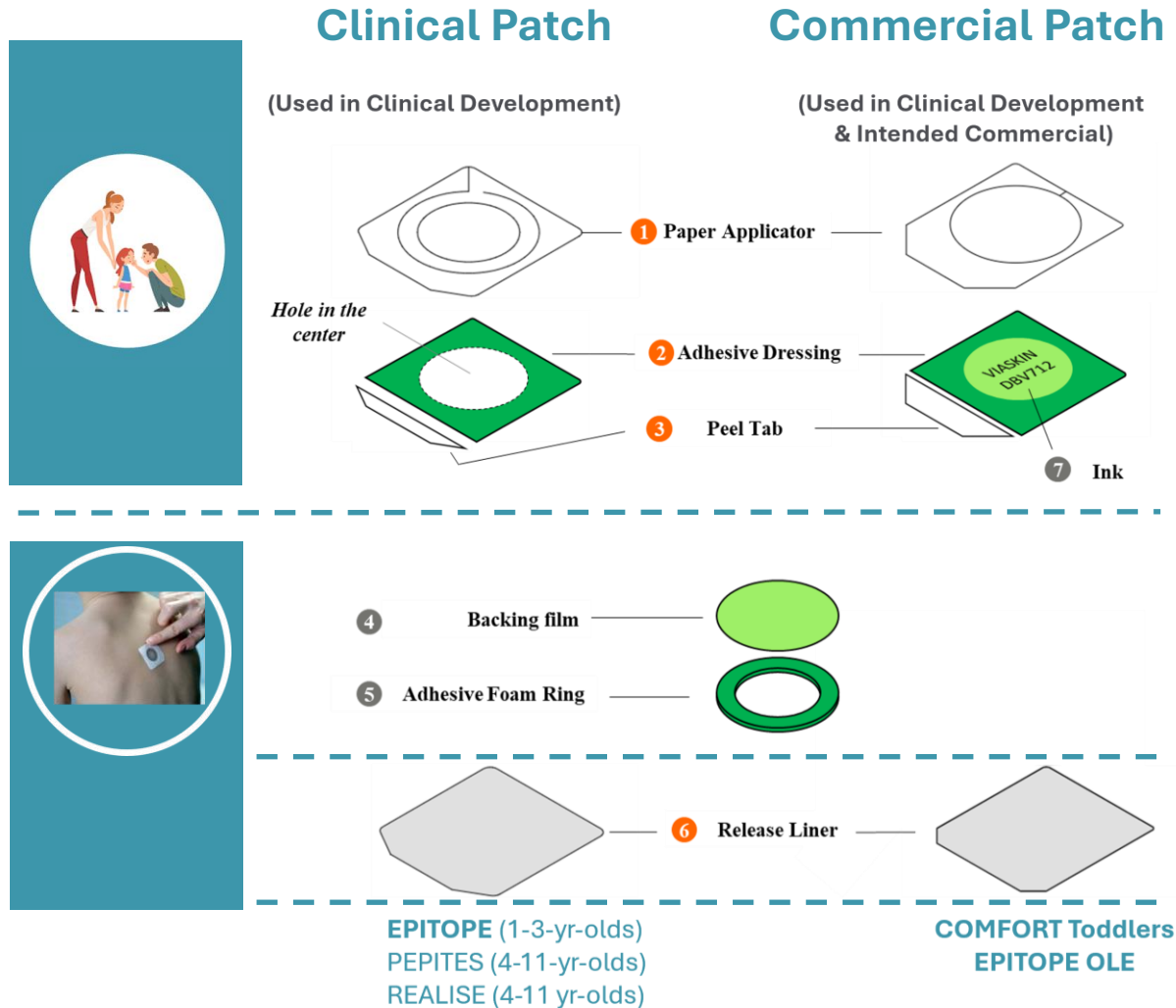
ADWT is a practical approach that could be adopted to guide shared decision-making & optimal use of VIASKIN® Peanut patch, if approved

1. Kim, E et al. VP250 Average Daily Wear Time: Impact on Efficacy and Safety in the Phase 3 EPITOPE Study. Presentation at Eastern Food Allergy & Comorbidity Conference, January 9-12, 2025.
2. DBV Technologies Press Release. January 8, 2025.
3. Greenhawt M, et al. *N Engl J Med*. Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy. 2023;388:1755-1766.



Minor Alterations to EPITOPE Patch to Evolve Towards Commercialization

FDA Views the Clinical Patch (Used in EPITOPE) Versus Commercial Patch as Two Different Products



Legacy VIASKIN® Peanut Patch Program in Children Ages 4-11 Years Old



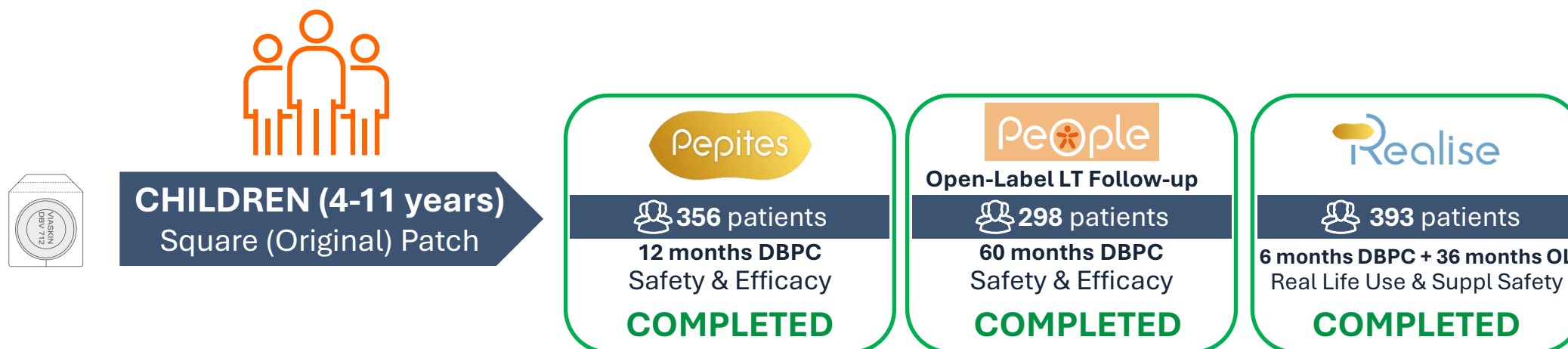
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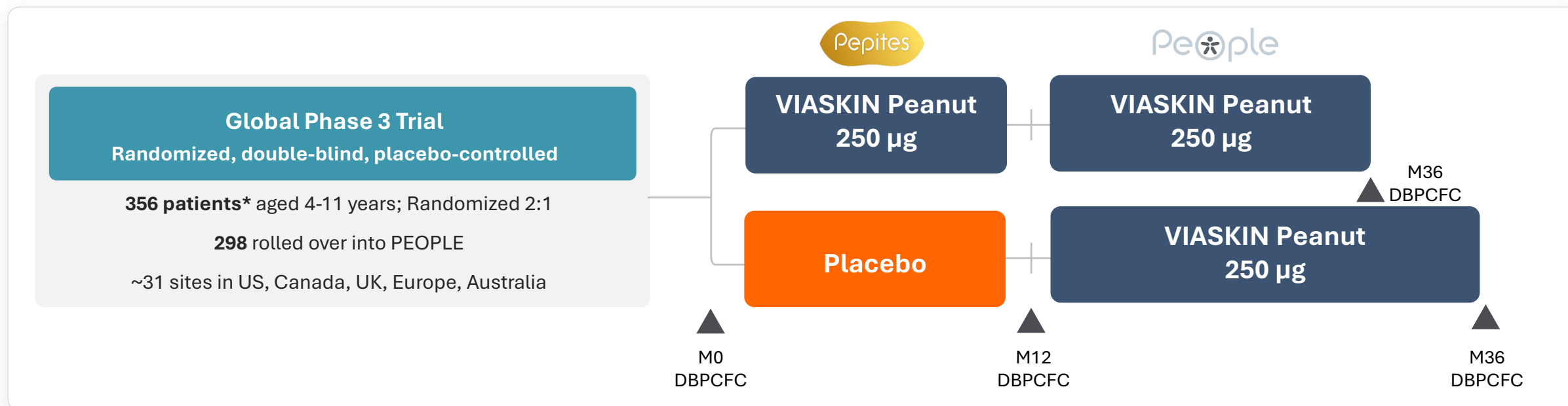
VIASKIN® Peanut Patch Clinical Development Program in 4–11-Year-Olds

Efficacy & Safety Data From Completed Phase 3 Studies in Children Aged 4-11 Years
Supported Progression of Program to Younger Age Groups



Phase 3 PEPITES/PEOPLE: VIASKIN® Peanut Patch 250 µg in Children 4–11 YO

Results Published in JAMA (PEPITES)¹ & Journal of Allergy & Clinical Immunology (PEOPLE)²



PEPITES Primary efficacy endpoint: difference between the percentage of treatment responders in the active vs. placebo group after 12 months

Treatment responder (assessed by DBPCFC) defined as:

- If ED ≤10 mg at baseline, responder if ED ≥300 mg at M12
- If ED >10 mg at baseline, responder if ED ≥1,000 mg at M12

PEOPLE Primary outcome measures: % of subjects originating from the active arm of PEPITES reaching an ED ≥1,000 mg after 24 months of additional treatment in PEOPLE

*Confirmed peanut allergy by SPT ≥6 mm for 4- to 5-year-olds or ≥8 mm for 6- to 11-year-olds and sIgE levels (>0.7 kUA/L).

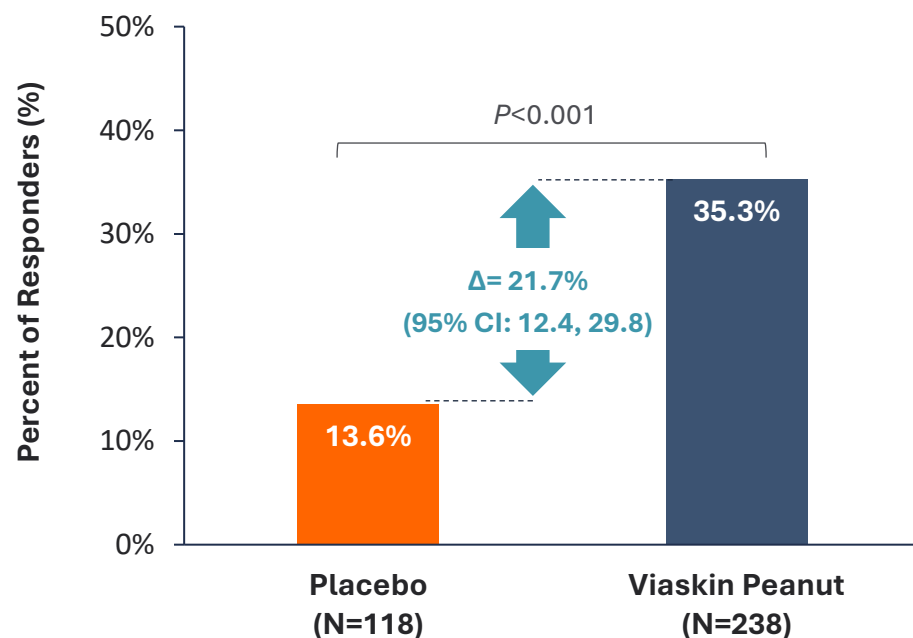
DBPCFC=Double-Blind Placebo-Controlled Food Challenge; ED=Eliciting Dose.

1. Fleischer DM, et al. Effect of Epicutaneous Immunotherapy vs Placebo on Reaction to Peanut Protein Ingestion Among Children With Peanut Allergy: The PEPITES Randomized Clinical Trial. *JAMA*. 2019;321:946-955; 2. Fleischer DM, et al. Long-term, open-label extension study of the efficacy and safety of epicutaneous immunotherapy for peanut allergy in children: PEOPLE 3-year results. *J Allergy Clin Immunol*. 2020;146:863-874.

VIASKIN® Peanut Patch Treatment Achieved Clinically Meaningful Changes in Eliciting Dose (ED) After 1 Year

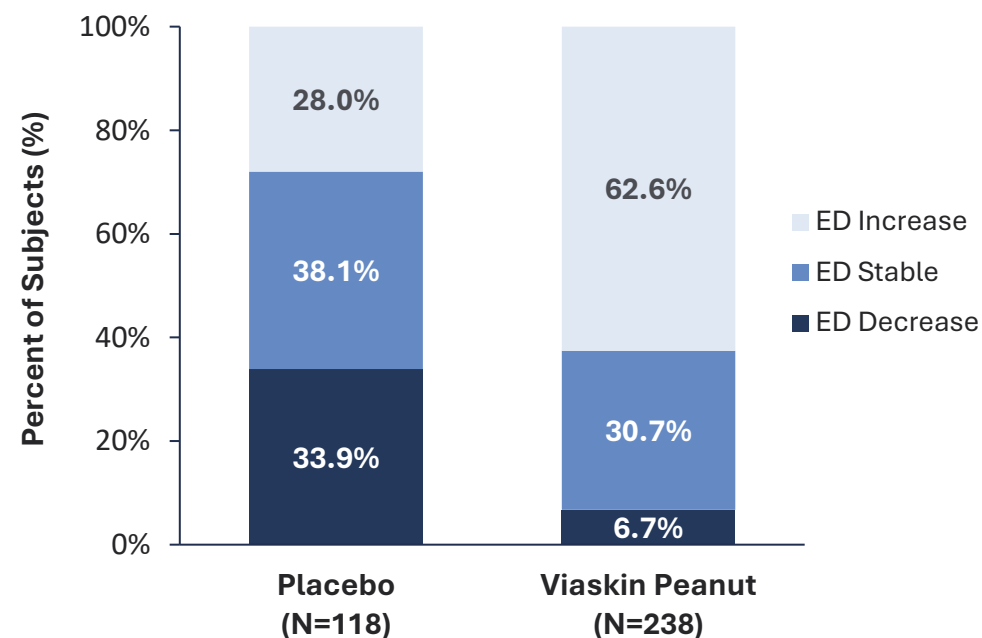
Primary Efficacy Outcome Showed Statistically Significant Treatment Benefit

Response Rate after 12 Months



The prespecified 15% lower bound of the 95% CI of the difference between treatment groups was not met. The clinical relevance of this is not known.

Change in Eliciting Dose after 12 Months*

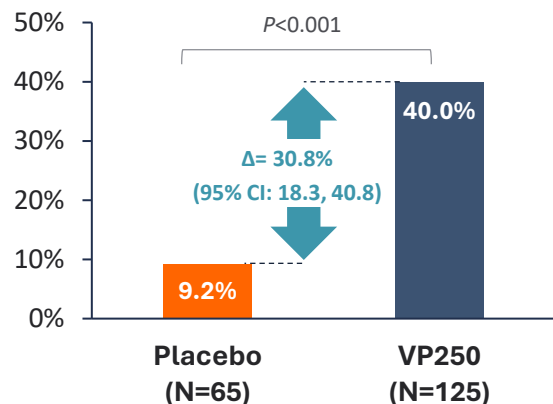


An increase in ED was >4 times more likely to occur in the VIASKIN® Peanut patch group compared with placebo

Post-Hoc Analysis of PEPITES Data Supports Concept That Greater Gains in Desensitization May Be Achieved in Younger Versus Older Children¹

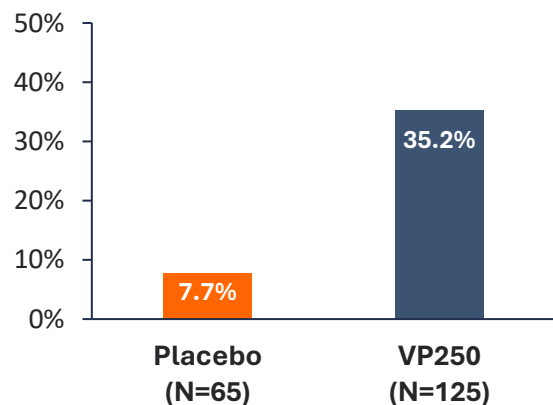
Treatment Responders

Children Ages 4-7 Years



ED $\geq 1,000$ mg at Month 12

Children Ages 4-7 Years



By *post hoc* analysis, a larger treatment effect in subjects aged 4–7 years who received VIASKIN® Peanut patch 250 µg (VP250) versus placebo was demonstrated

- **40.0% of subjects in the VIASKIN® Peanut patch 250 µg arm were responders compared with 9.2% in the placebo arm, with a risk difference of 30.8% (95% CI: 18.3–40.8; $P < 0.001$)**
- In comparison, the difference in the proportion of treatment responders between VIASKIN® Peanut patch and placebo subjects aged 8–11 years was 11.2% (95% CI: -3.4–23.4)
- **Furthermore, among subjects aged 4–7 years, 35.2% in the VIASKIN® Peanut patch 250 µg arm versus 7.7% in the placebo arm reached an ED of ≥ 1000 mg at Month 12**

The **safety profile** in the subgroup of children aged 4–7 years was consistent with that observed in the overall 4 to 11-year-old PEPITES population

Pooled Safety Data from Phase 3 Studies of VIASKIN® Peanut Patch¹

749 Subjects Included in the Overall Pooled Safety Analyses, Including
630 Subjects Treated with VIASKIN® Peanut Patch 250 µg for up to 36 Months

749 Subjects from Months 0–6 (Randomized Double-Blind Placebo-Controlled Treatment Period)

- Serious TEAEs were experienced by 1.1% of VIASKIN® Peanut patch 250 µg subjects and 1.8% of placebo subjects
- TEAEs leading to permanent discontinuation occurred in 1.1% of patients treated for 6 months with VIASKIN® Peanut patch versus 0% with placebo

630 Subjects Treated with VIASKIN® Peanut patch for Up to 36 Months

- Treatment with VIASKIN® Peanut patch 250 µg for up to 36 months in peanut-allergic children was generally safe and well tolerated
- Most adverse events (AEs) were mild to moderate in both the VIASKIN® Peanut patch and placebo groups
- The most common treatment-related AEs were local application site reactions
- Low occurrence of systemic allergic* AEs (5.3 events per 100 subject years [SY]) and anaphylactic reactions (3.7/100 SY)

Conclusion

“A well-tolerated treatment approach with a favorable benefit-risk profile could afford those with peanut allergy a valuable therapeutic option for managing this serious condition”¹

REALISE: Study Design and Results from Long-term Safety Study

Children 4–11 Years Old

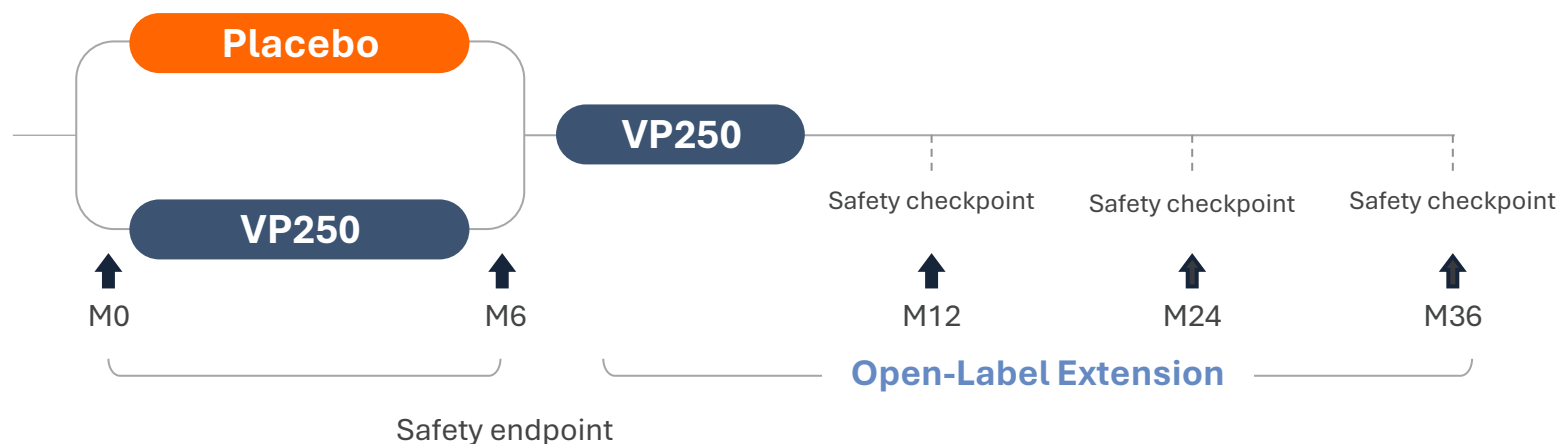
REALISE Phase 3

Randomized, double-blind,
placebo-controlled

393 patients aged 4–11 years with history of IgE-mediated reactions to peanut, including those with severe anaphylaxis

32 centers in the US and Canada

Confirmed peanut allergy by SPT (≥ 8 mm), and sIgE levels (≥ 14 kU/L)



- REALISE met its primary endpoint in the 6-month blinded portion of the study, demonstrating that VIASKIN® Peanut patch was tolerated with no new or unexpected AEs¹
- 36-month data show similar long-term safety profile in peanut-allergic children consistent with previous clinical trials²

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