



**DBV TECHNOLOGIES**

**Corporate Presentation | January 2026**

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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.

# 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**



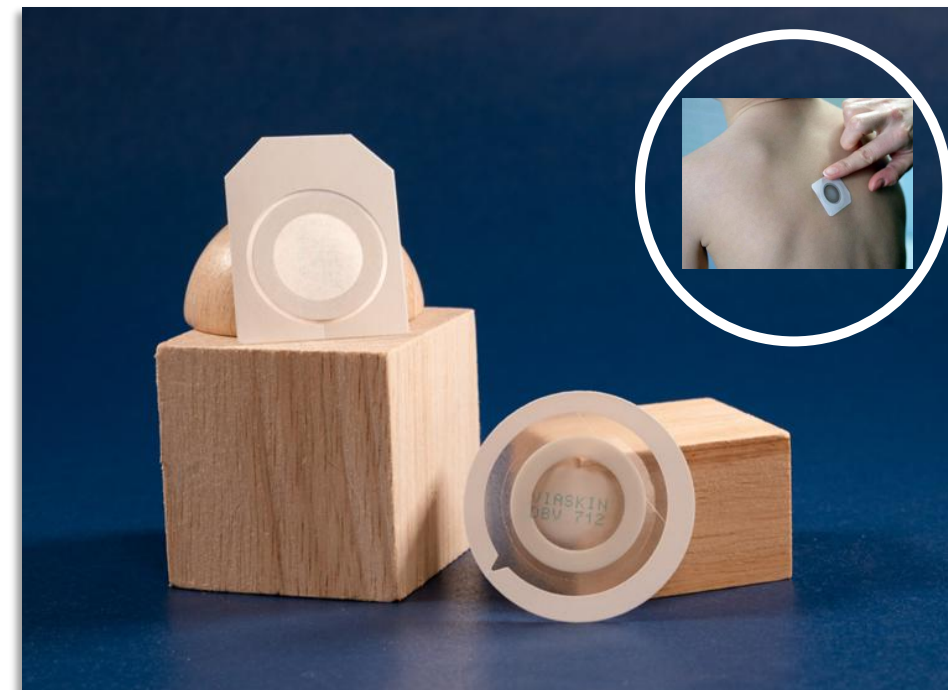
**Pioneered VIASKIN® patch technology**  
DBV's novel approach to epicutaneous immunotherapy



**VIASKIN® peanut patch as lead product, with two candidates: 1-3 YO & 4-7 YO**  
(1.1M+ patches administered to 1,600+ children ages 1-7 YO)



**Science-driven leadership team with deep regulatory & commercial experience**



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



# Regulatory Overview (US)

## Two Distinct Opportunities for VIASKIN® Peanut Patch

### One BLA in 4-7 YO



### One BLA in 1-3 YO



## Clear Regulatory Pathway for Both Programs

The **successful VITESSE Phase 3 study**, will support a BLA submission in children 4–7-YO<sup>1</sup>



The **successful EPITOPE Phase 3 study** to be supported by 6-month supplemental safety trial<sup>2</sup> (COMFORT Toddlers; Initiated June 2025<sup>3</sup>)



## Anticipated Clinical & Regulatory Milestones

- BLA submission anticipated for **1H26**<sup>4</sup> (eligible for priority review)<sup>†</sup>
- Completion of enrollment for COMFORT Toddlers & topline data
- BLA submission anticipated for **2H26** under a formalized Accelerated Approval pathway<sup>5</sup>







# Significant Market Opportunity for VIASKIN® Peanut Patch

~670K Children Aged 1-7 Years Have Peanut Allergy in US<sup>1-3</sup>



**1-3 years old**

**280,000 Toddlers<sup>1-3</sup>**



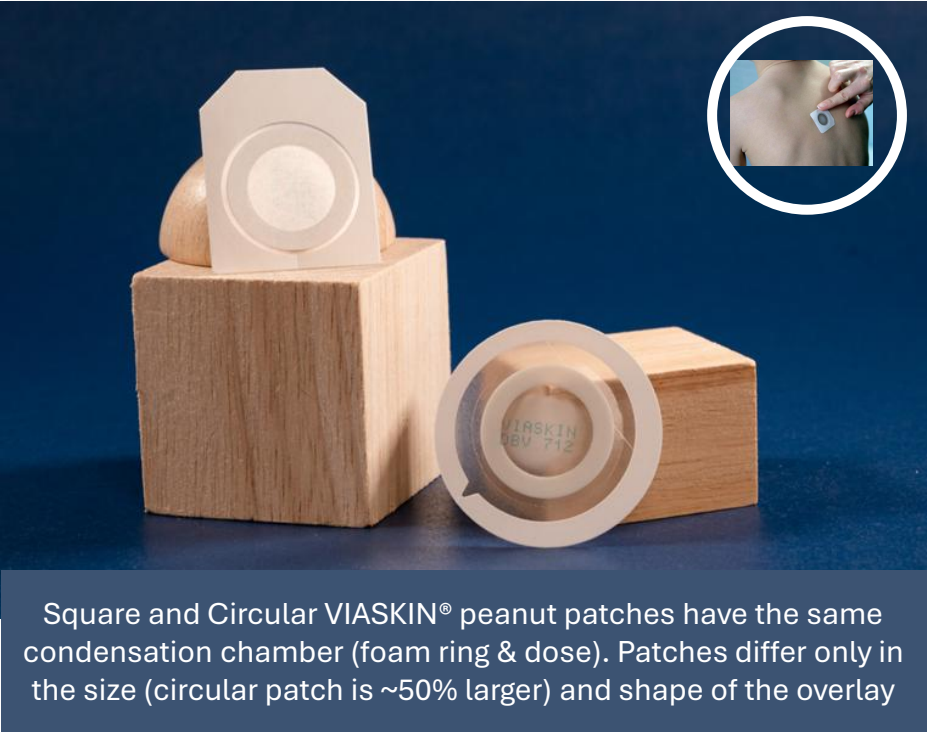
**4-7 years old**





**390,000 Children<sup>1-3</sup>**



# Square & Circular VIASKIN<sup>®</sup> Peanut Patches Are Separate Product Candidates – Two Distinct Opportunities in US

Independent Clinical & Regulatory Paths for VIASKIN<sup>®</sup> 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 <sup>1</sup>	 1H 2026 <sup>2</sup>
	Under Accelerated Approval Pathway <sup>1</sup>	Accelerated Timeline for BLA Submission <sup>2</sup>

# Anticipated Near-Term Milestones

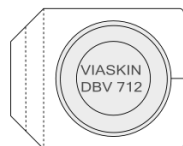
## Upcoming Milestones & Catalysts Anticipated in 2026



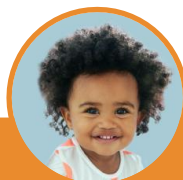
### CHILDREN (4-7 years)



**BLA submission for 4-7 YO anticipated in 1H 2026<sup>1</sup>**  
Eligible for Priority Review (~8 Months Total Vs ~12 months Total with Standard Review)



### 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 2026<sup>1</sup>**











# 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 allergy<sup>1</sup>
- Incidence of new diagnosis of ~81,000 a year<sup>1</sup>

Program	Patch	EMA Guidance for an MAA Submission for a 1-7 YO Indication to Consist of 3 Studies <sup>2</sup> :		
 1-7		<div>1</div> <div></div> <div>Results from successful EPITOPE Phase 3 efficacy &amp; safety trial in 1-3 YO</div>	+	<div>2</div> <div></div> <div>Results from successful VITESSE Phase 3 efficacy &amp; safety trial in 4-7 YO</div>
			+	<div>3</div> <div></div> <div>A new safety study with circular modified patch in 1-3 YO</div>

3

DBV has ongoing dialogue with EMA for scientific advice on safety study design elements





**U.S. COMMERCIAL  
OPPORTUNITY  
VIASKIN® PEANUT PATCH**



# The Peanut Allergy Epidemic

OFTEN A LIFELONG BURDEN STARTING AT AN EARLY AGE

“

***“...mass explosion  
of food allergy...”***

- Dr. Marty Makary, FDA  
Commissioner 11/17/25<sup>1</sup>

**92%**

of peanut allergy cases  
emerge by age of 7<sup>2</sup>; ~80%  
are lifelong<sup>3</sup>

**41%**

have an accidental exposure  
within 3 years of diagnosis<sup>4</sup>

- ✓ Reactions unpredictable and can be life-threatening
- ✓ Annual economic impact \$25B<sup>5</sup>; impact to quality of life for caregivers/children<sup>6</sup>
- ✓ Limited options in pediatric age range which is the optimal time to desensitize and when caregivers have the greatest motivation to seek treatment

# Current Treatment Options Are Often Not Ideal for Patients & Their Families<sup>1-4</sup>



## Oral Immunotherapy (Approved<sup>†</sup> & 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; <sup>†</sup>PALFORZIA® is an FDA approved version of OIT and is approved in children aged 1-17 YO.



## Omalizumab (anti-IgE Monoclonal Antibody)<sup>#</sup>



### Fear of injection:

- Requires injection(s) 1-2 times per month<sup>4,5</sup>
- Potentially painful injection site reactions<sup>5</sup>



### Not disease modifying<sup>4</sup>

- 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)<sup>6</sup>

<sup>#</sup>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 allergy<sup>7</sup>**

# 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 therapy<sup>1-3</sup>

\*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  
(~1/1000<sup>th</sup> of a peanut kernel)



# PEANUT ALLERGY MARKET DYNAMICS



## The Patients

**670K Children**

ages 1 to 7 years old <sup>1,2</sup>

DBV will leverage its strong relationships with Advocacy Groups



## The Prescribers

**4,500 Allergists**

in the US<sup>1,2</sup>

50 to 70-person specialty sales force  
can cover 90% of Allergists



## The Payers

**50 Payers**

cover +85% of lives

8 – 10 account managers can build strong managed care access

# PEANUT ALLERGY MARKET DYNAMICS

## Pediatricians



**60K**  
**Pediatricians**  
in the US

**PEDs overwhelmingly follow the AAP guidance to refer families to an Allergist for immunotherapy**

- DBV will partner with the American Academy Pediatrics (AAP) to educate Pediatricians (PEDs) on the benefits of Viaskin Peanut treatment
- Call-to-action will be to urgently refer patients to an Allergist

## Parents



**7.2M**  
**Millennials**  
born between 1981 and  
1996

**Most millennials turn to digital spaces for health information and advice**

- DBV will launch a digital and social-media campaign to activate parents
- Call-to-action will be to initiate a shared-decision making conversation with their child's Allergist about Viaskin Peanut treatment

# External Engagements: HCP Interactions Designed to Activate, Learn, and Inform

HCP engagement, driven by the MSL team, is aimed at educating and gathering expert insights through 1:1 meetings, congress activities, and advisory boards



## 2026 Advisory Boards

Insights gathering across geographies and specialties



## ACAAI 2025

Record-breaking Product Theater attendance

### 2026 Regional Advisory Board Series

**VIASKIN Peanut Patch: Expert Allergy Forum**  
Hear from regional experts in the allergy and immunology space to inform launch strategy

**Description**

- Coordinate up to 12 advisory board meetings
  - Assumes meetings will be planned to occur at 2026 regional congresses
  - Assumes up to 11 regional meetings with allergist MD/DOs – 1 per MSL region
  - Assumes up to 1 APP meeting with allergist NPs/PAs
- Utilize the 2025 analytics outputs to identify 8-10 **regional leaders** (MDs/DOs/NPs/PAs) in the allergy and immunology space
- Understand community and regional practice patterns and how best to integrate VIASKIN peanut patch into clinical practice

**Core Benefits**

- Expand HCP reach beyond key KOLs to include more clinical focused HCPs (MDs/DOs/NPs/PAs) and regional clinical leaders and leverage regional insights and practice patterns to optimize the integration of VIASKIN peanut patch into clinical practice
- Learn from regional leaders about how best to inform their peers and hopefully encourage utilization of VIASKIN peanut patch in patients upon FDA approval




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### Assembling a Launch Excellence Advisory Board

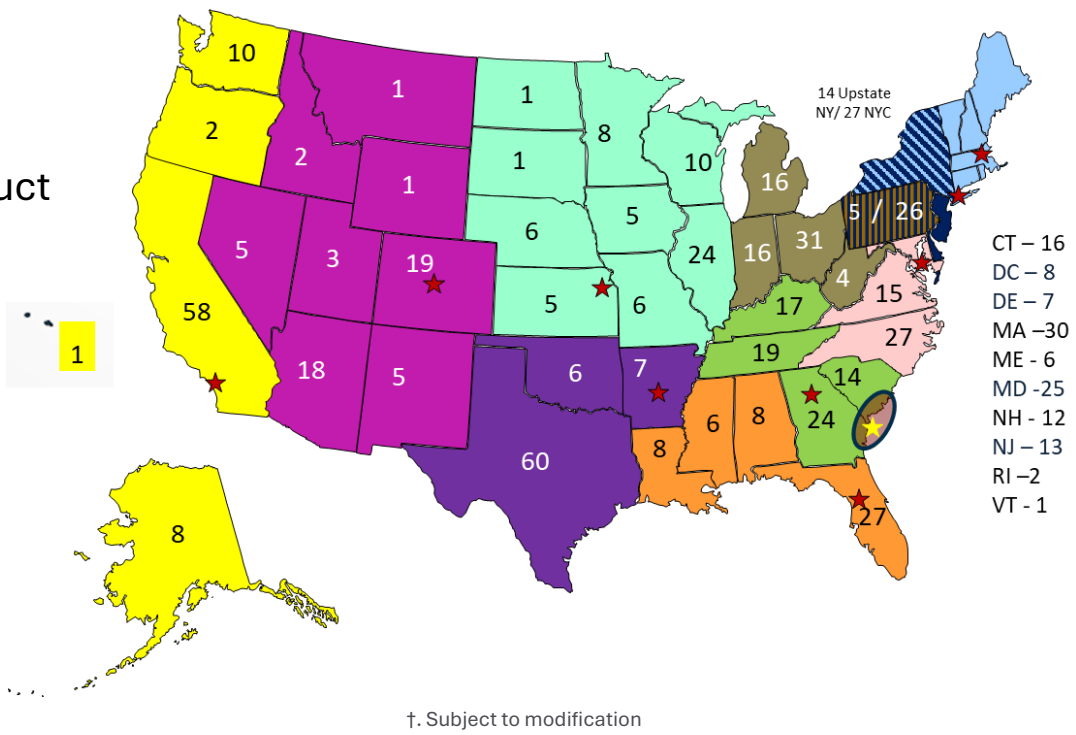
**Advisory Board Objectives**

- Identify clinical goals/objectives for the successful integration of VIASKIN peanut patch into clinical practice
- Gain insights on drivers and barriers for integrating VIASKIN peanut patch into clinical practice
- Discuss how to overcome the barriers and ensure optimal utilization and a successful launch of VIASKIN peanut patch
- Obtain feedback on data gaps for VIASKIN peanut patch



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## MSL Territory Mapping†



# VIASKIN Peanut is a breakthrough patch with the potential to revolutionize treatment in a large market with significant unmet need

## DIFFERENTIATION:

Ability to address peanut allergy with a non-invasive patch that creates sustainable differentiation

## SIZEABLE MARKET AT LAUNCH:

Launch momentum in 1-7 YO will be driven by ~670k children, the majority are currently not desensitizing; avoid + epi

## INTENT FOR BROAD UTILIZATION:

Allergists see a significant role for VP, as a complement with avoidance and epi to desensitize EARLY in a child's life

## ALLERGIST Writing & PED Referral:

Nearly 60% of peanut allergic children are cared for by allergists today and pediatricians follow guidance to refer

## STRONG POTENTIAL FOR PAYER ADOPTION:

Payer dynamics and early research suggest favorable access and value potential for VIASKIN Peanut



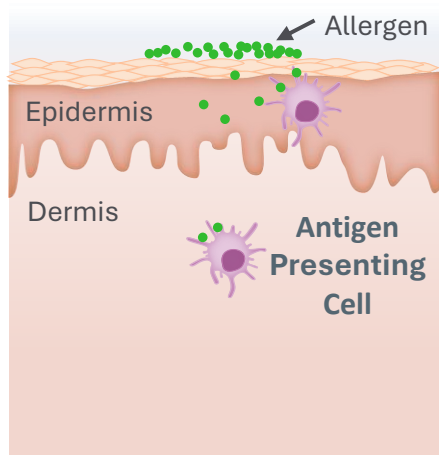


A detailed microscopic illustration of immune cells. A central cell with a bright red nucleus and a textured, brownish-yellow surface is surrounded by several other cells. Some cells are purple with a bumpy texture, while others are pinkish-white with a more granular appearance. A trail of small, glowing blue-green particles extends from the central cell towards the upper right, suggesting a signal or interaction. The background is a deep teal with diagonal light blue streaks.

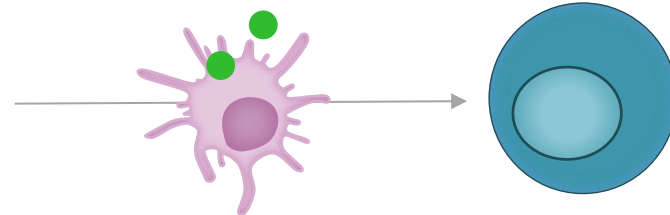
# THE SCIENCE OF EPICUTANEOUS IMMUNOTHERAPY (EPIT)

# Epicutaneous Immunotherapy (EPIT) Aims to Re-educate the Immune System Thus Suppressing the Allergic Response<sup>1-7</sup>

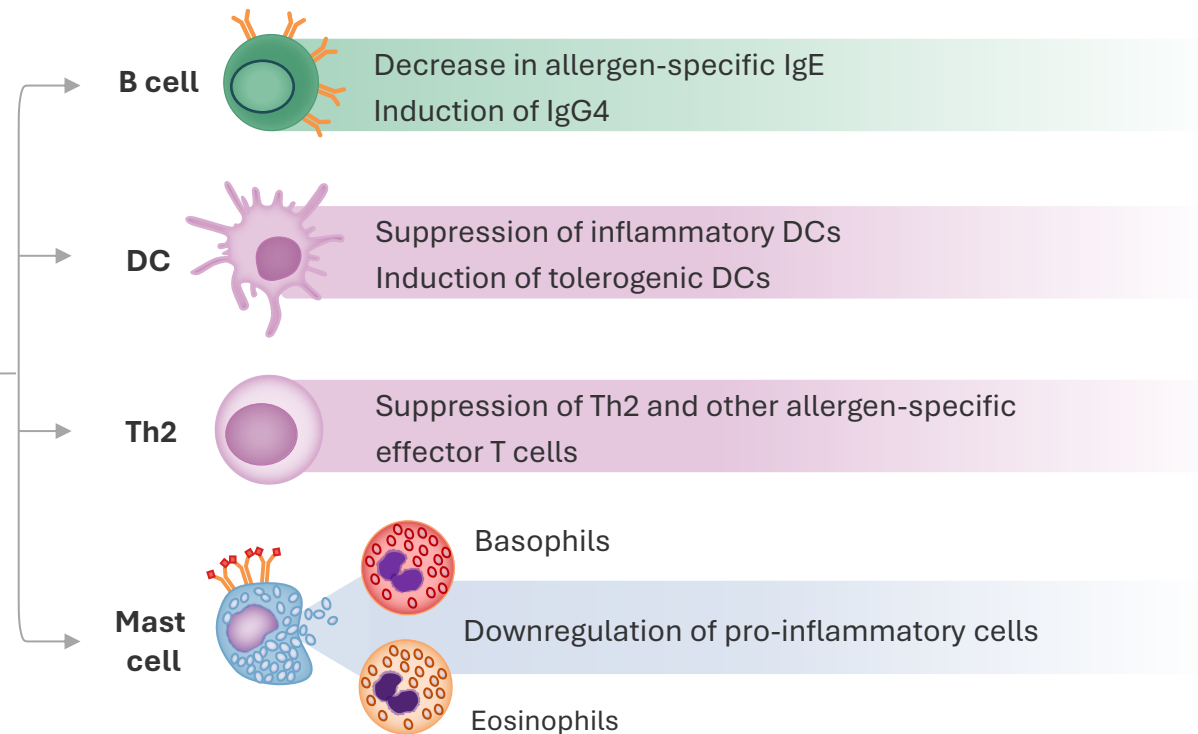
EPIT delivers allergen to the skin



Antigen Presenting Cells capture allergen and induce unique Regulatory T Cells



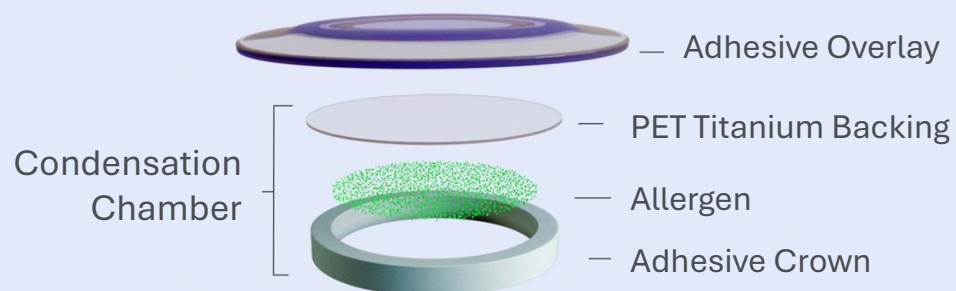
Regulatory T Cells act on the immune system to suppress the allergic response



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

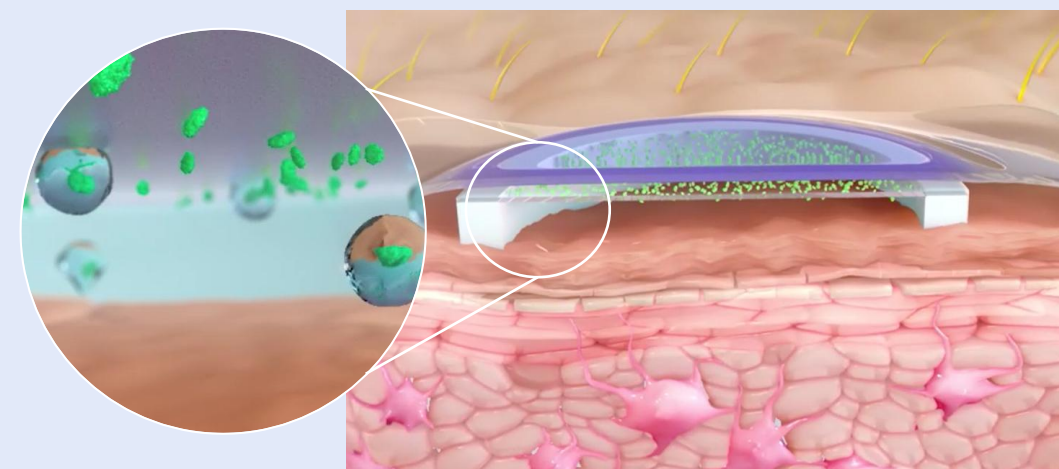
# VIASKIN® Patch: Our Innovative Approach to Epicutaneous Immunotherapy<sup>1-3</sup>

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 Desensitization<sup>1-3</sup>

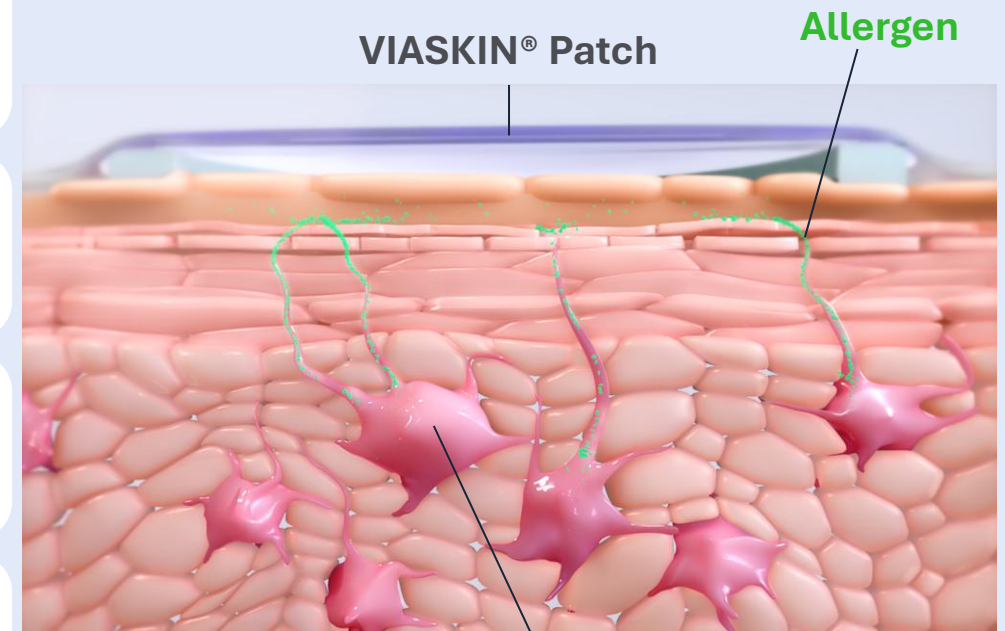
**1/1000<sup>th</sup> of a peanut is applied daily to the skin**

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



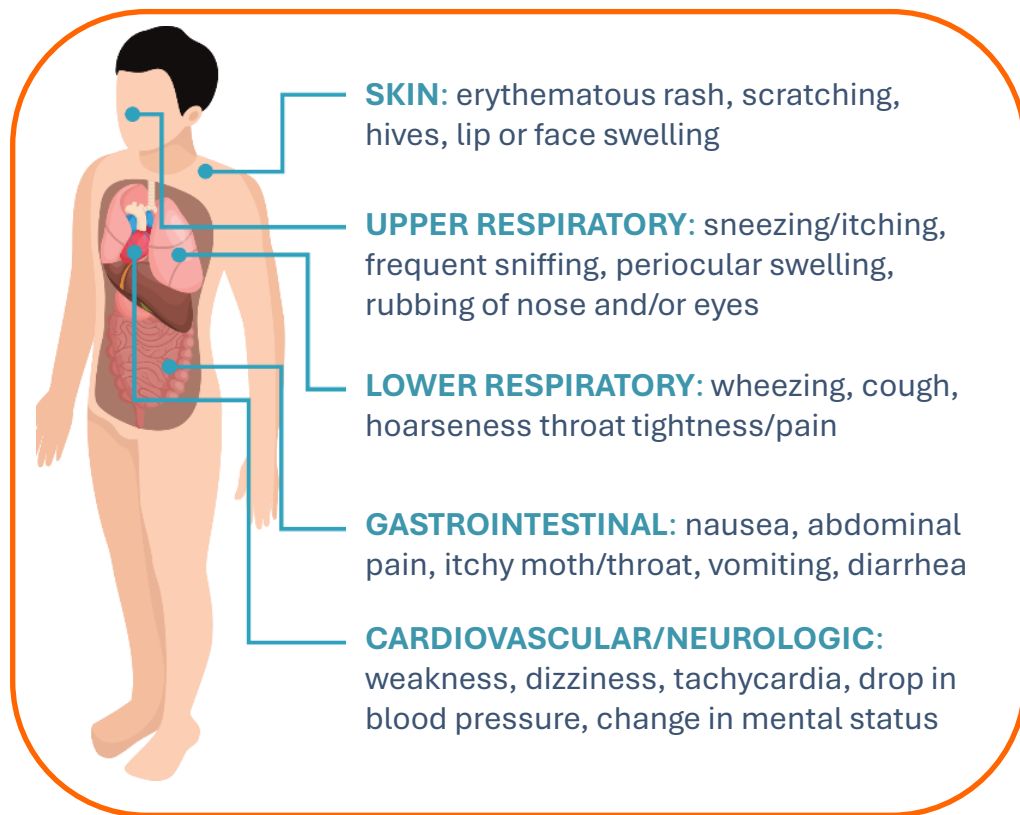
**Langerhans Cell**

(capturing allergen in the outer layer of the epidermis)

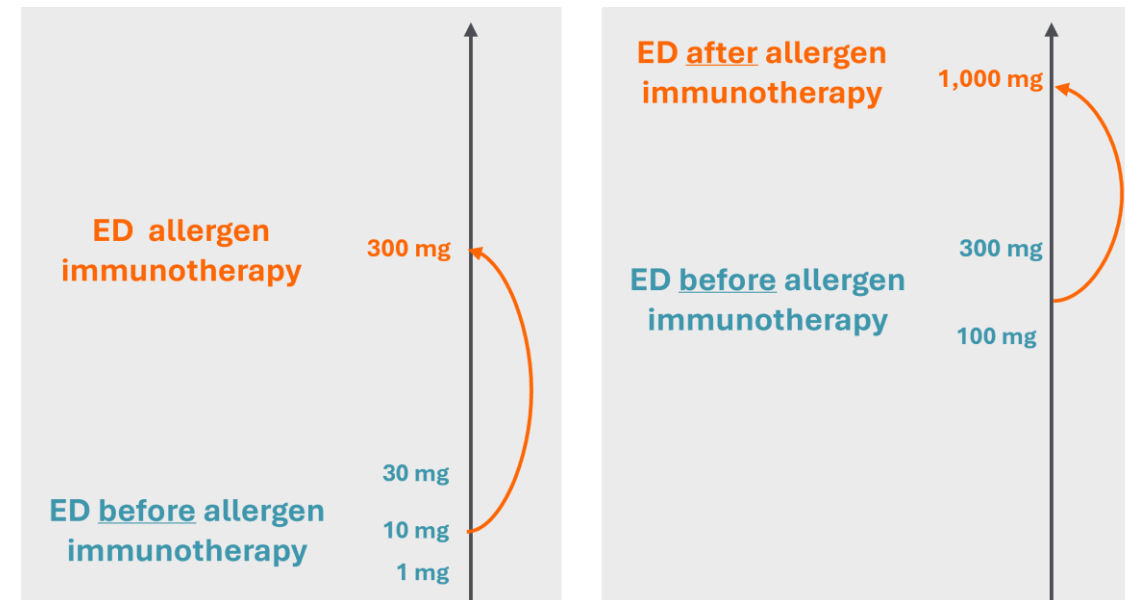


## Desensitization is Measured by Increases in Eliciting Dose (ED)

**ED = the amount of allergen that induces allergic symptoms<sup>1</sup>:**



## Decrease in Reaction Risk with Increased ED Following Allergen Immunotherapy



**Modeling\* data suggest increasing a patient's ED decreases the risk of an allergic reaction<sup>1</sup>**

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

- 654 subjects ages 4-7 YO (vs target enrollment of 600<sup>1</sup>)
- Largest immunotherapy clinical trial for this patient population<sup>2</sup>
- DBV's CIRCULAR VIASKIN® Peanut patch (containing 250 mg peanut protein extract)

## Global Phase 3 Trial

Randomized, double-blind, placebo-controlled

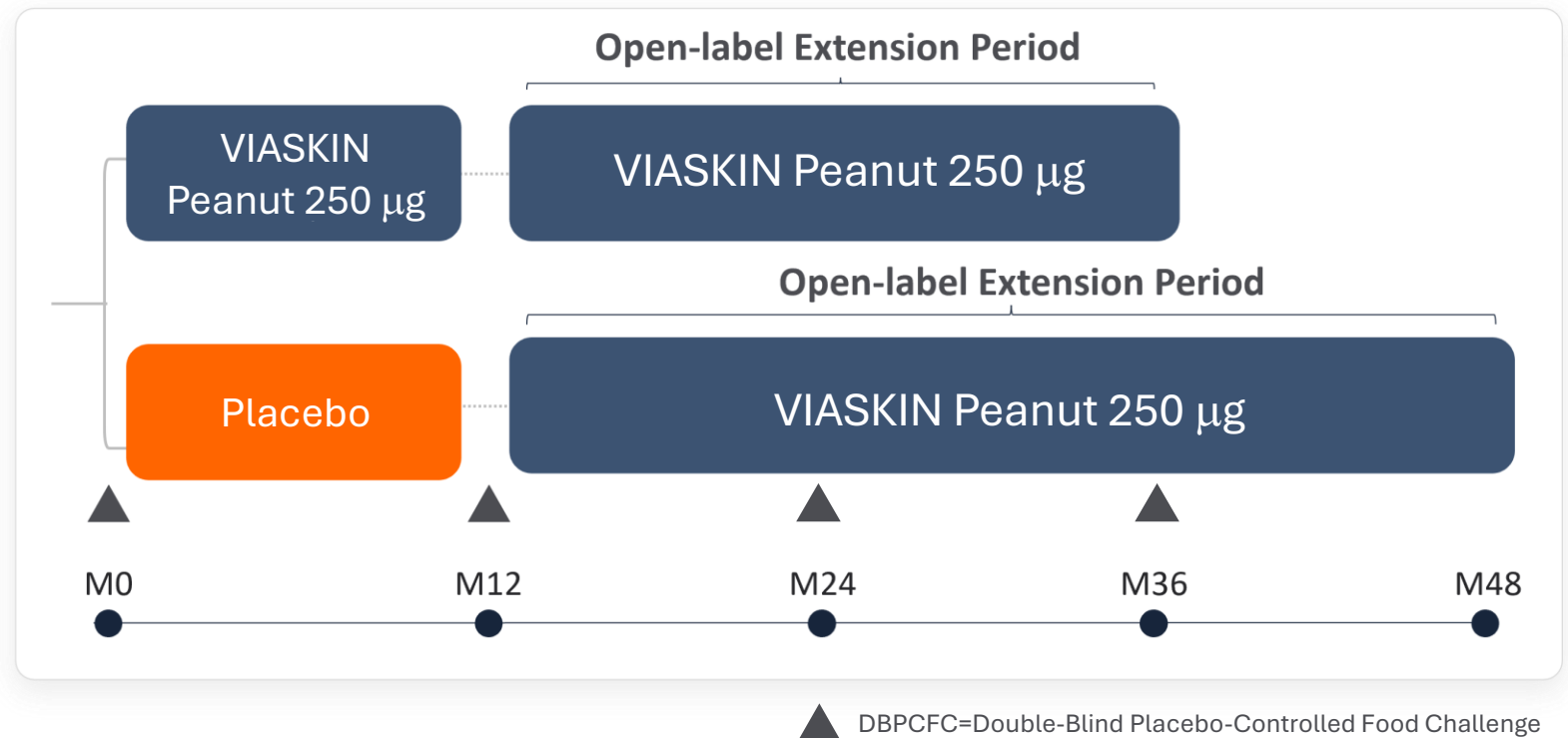
- 654 subjects Randomized 2:1
- Inclusion Criterion Baseline ED  $\leq 100$  mg
- 86 sites in US, Canada, UK, Europe, Australia

### Primary endpoint:

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

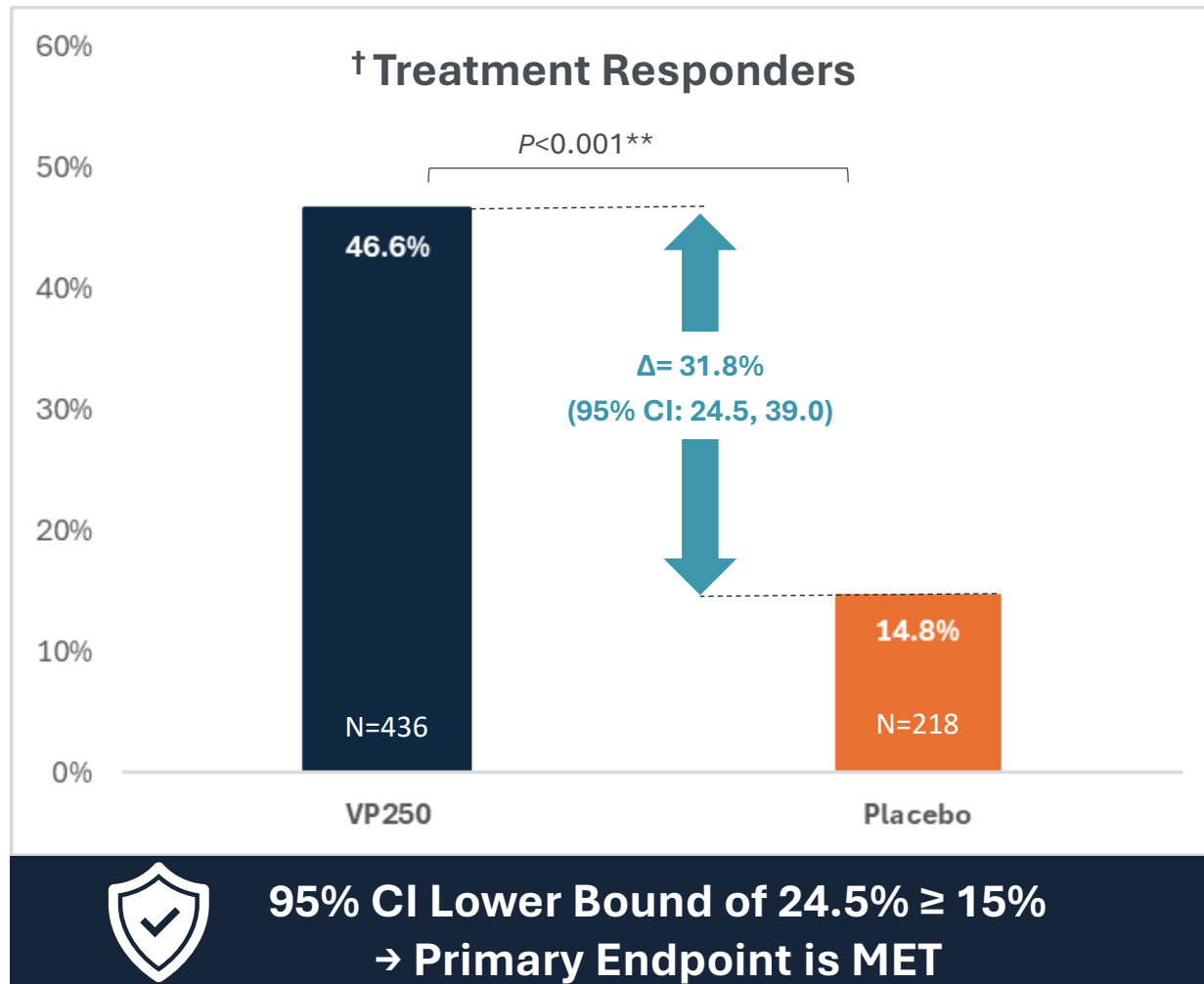
### Treatment responder (assessed by DBPCFC) defined as:

If ED  $\leq 30$  mg at baseline, responder if ED  $\geq 300$  mg at M12  
If ED = 100 mg at baseline, responder if ED  $\geq 600$  mg at M12





# The VITESSE Phase 3 Study Met the Primary Endpoint



The treatment effect observed in **VITESSE (31.8%)** is consistent with the treatment effect observed in the Phase 3 **EPITOPE (33.4%)** study in 1-3-year-olds





## VITESSE Safety Summary

- ✓ Safety results consistent with prior trials, which now encompass over 1,600 children and more than 1.1 million patch applications
- ✓ The most common Treatment Emergent Adverse Events (TEAEs) observed during VITESSE were mild-to-moderate local skin reactions at the patch application site
- ✓ Discontinuations due to TEAEs were low at 3.2% in the treatment arm compared to 0.5% of in the placebo arm
- ✓ No treatment-related serious TEAEs
- ✓ Treatment-related anaphylaxis was low at 0.5% (n=2)
- ✓ Treatment compliance was 96.2%; patch adhesion in-line with the company's expectations

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.

epitone

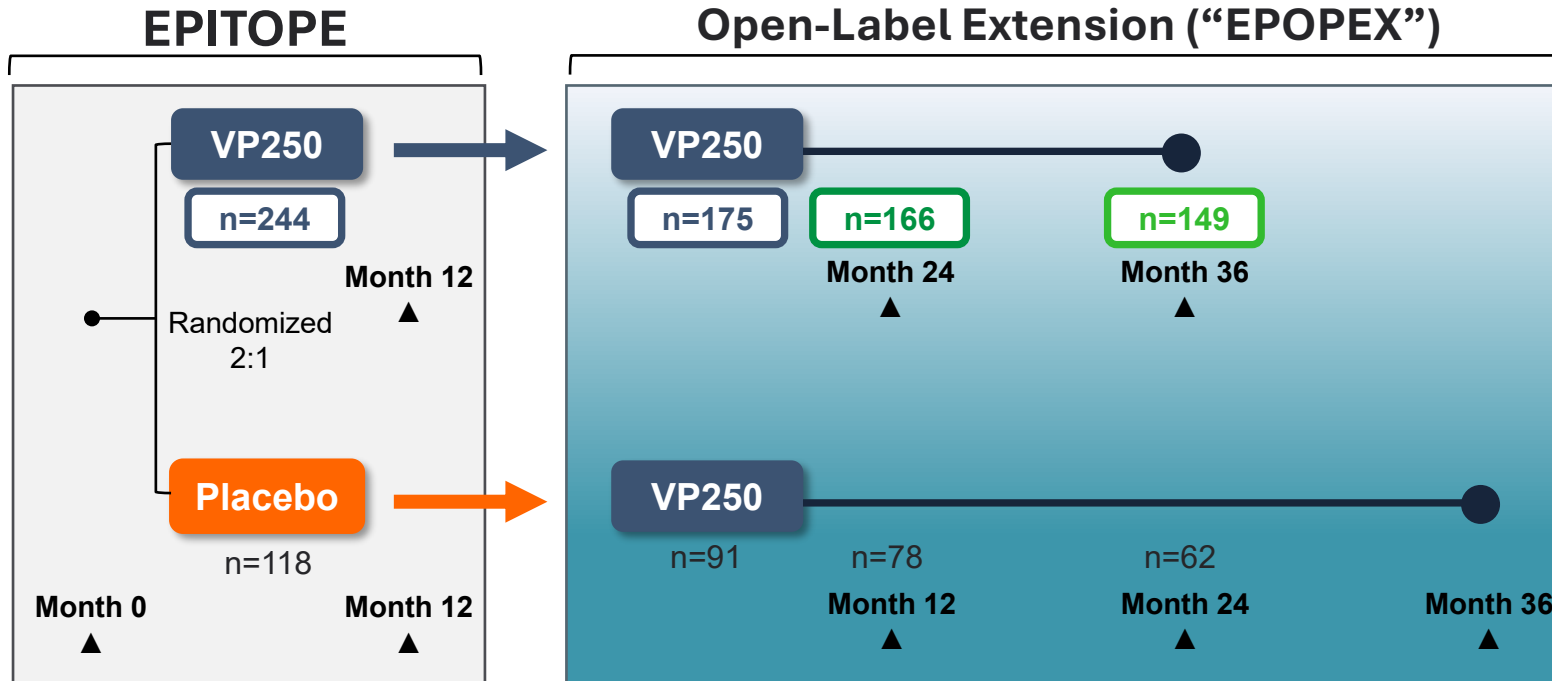
 **COMFORT**  
toddlers

**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 Study<sup>1</sup> & Open-Label Extension (OLE) to EPITOPE Study<sup>2</sup>



High % of subjects opted to stay on VP250 after Year 1 EPITOPE through 36 Months<sup>3,4</sup>

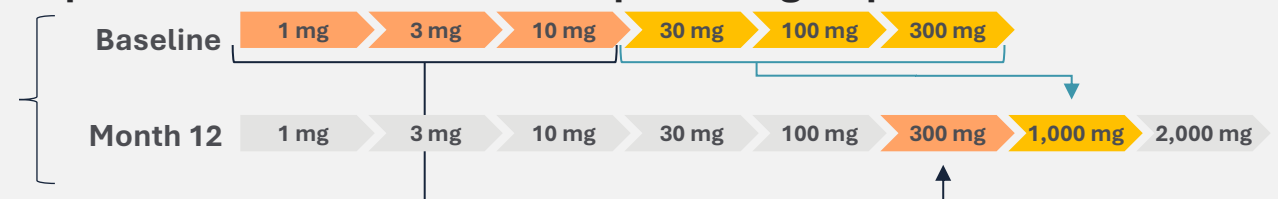
➤ 95% of VP250 subjects who entered OLE underwent DBPCFC at Month 24

➤ 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 <sup>1-3</sup>



**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 <sup>1-3</sup>

**64.2% of participants reached an ED of ≥1000 mg (equivalent of 3 peanuts; ≥8x more than the typical amount consumed upon accidental exposure<sup>3</sup> 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 <sup>1-3</sup>

**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**

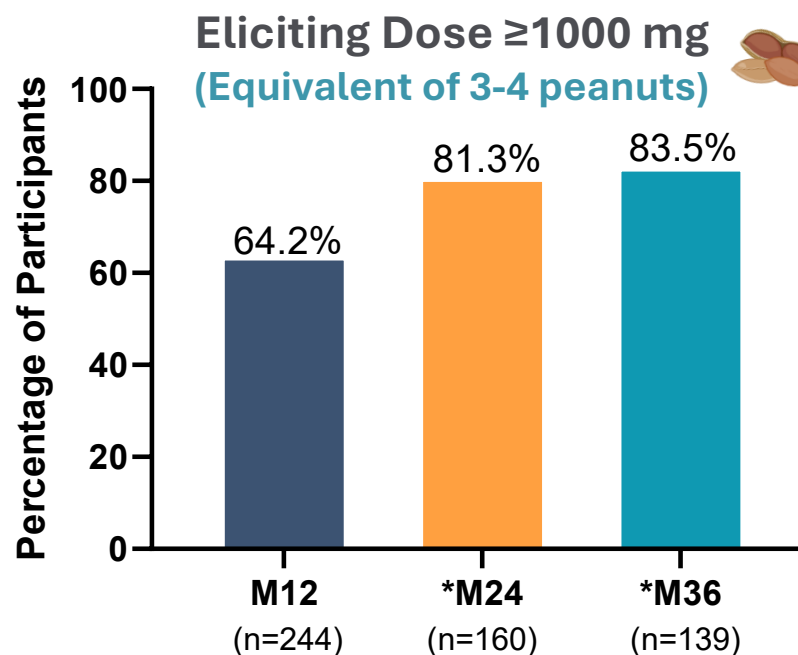
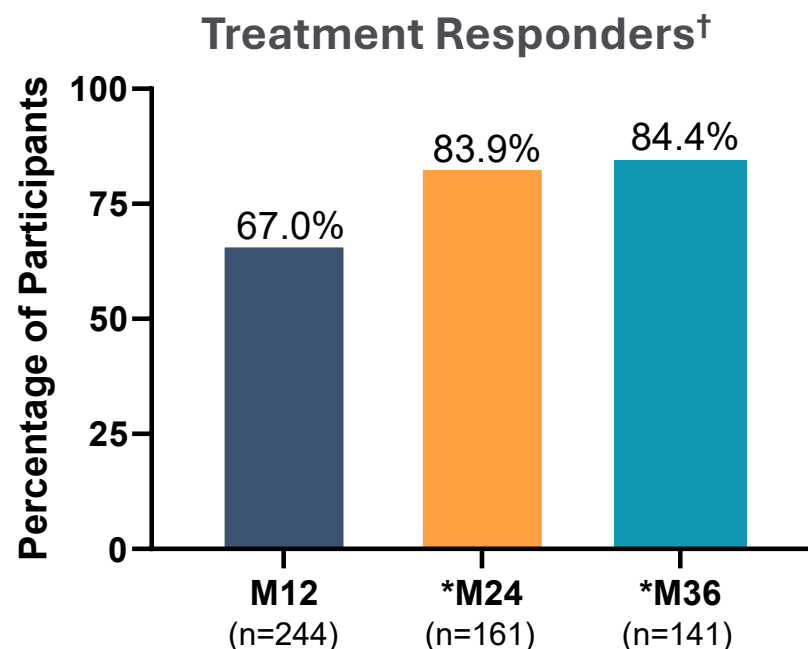
**Treatment-related anaphylaxis occurred in 1.6% in the VP250 group and none in the placebo group**

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 MO<sup>1-4</sup>

- 175 subjects entered OLE study (out of 244 randomized to receive VP250 in EPITOPE<sup>1</sup>)
- 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 (2-4 YO) who received VIASKIN<sup>®</sup> Peanut patch in the OLE study showed consistent improvement in efficacy over the course of 36 months<sup>2-4</sup>**

<sup>†</sup>In EPITOPE, a treatment responder (assessed by DBPCFC) was defined as: If ED  $\leq 10$  mg at baseline, responder if ED  $\geq 300$  mg at M12; If ED  $> 10$  mg at baseline, responder if ED  $\geq 1000$  mg at M12.

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

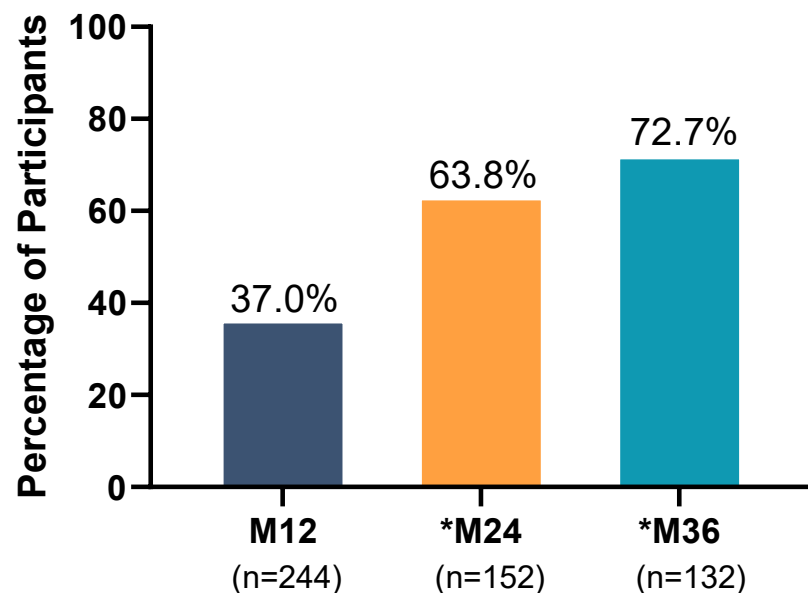
1. Greenhawt M, et al. Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy. *N Engl J Med.* 2023;388:1755-1766; 2. Greenhawt M, et al. Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Toddlers: Open-Label Extension to EPITOPE. *J Allergy Clin Immunol Pract.* 2025;13:1176-1187; 3. 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. 4. Greenhawt, M et al. Long-Term Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Toddlers: EPOPEX End-of-Study Results. Presentation at The American College of Allergy, Asthma & Immunology. November 6-10, 2025.





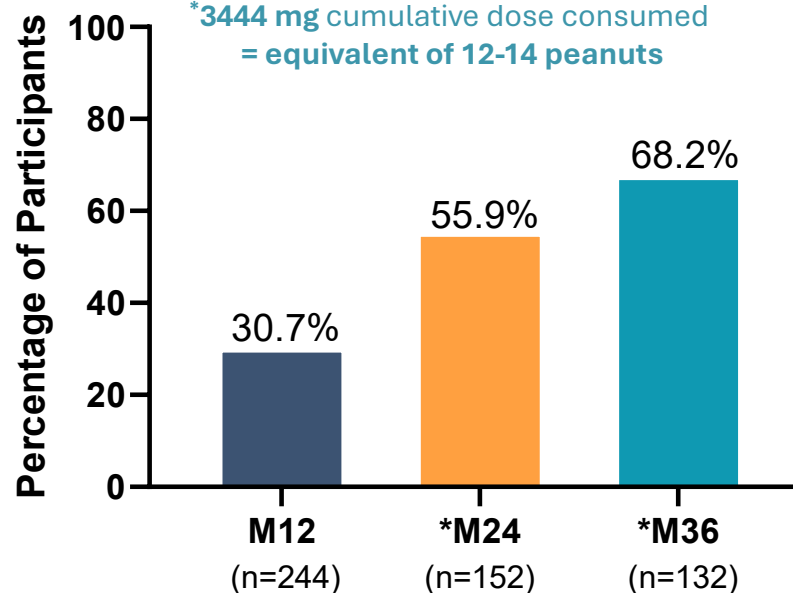
# Data from EPITOPE Open-Label Extension Show Continued Improvement in Treatment Response in Toddlers Through 36 MO<sup>1-4</sup>

Eliciting Dose  $\geq 2000$  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 (2-4 YO) who received VIASKIN® Peanut patch in the OLE study showed consistent improvement in efficacy over the course of 36 months<sup>2-4</sup>**

<sup>†</sup>In EPITOPE, a treatment responder (assessed by DBPCFC) was defined as: If ED  $\leq 10$  mg at baseline, responder if ED  $\geq 300$  mg at M12; If ED  $> 10$  mg at baseline, responder if ED  $\geq 1000$  mg at M12.

\*Number of subjects with non-missing food challenge endpoint. VP250=VIASKIN® Peanut patch 250  $\mu$ 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. 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. 4. Greenhawt, M et al. Long-Term Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Toddlers: EPOPEX End-of-Study Results. Presentation at The American College of Allergy, Asthma & Immunology. November 6-10, 2025.



# Study Results of VIASKIN® Peanut Patch Consistently Demonstrate a Favorable Safety & Tolerability Profile in Toddlers<sup>1-4</sup>

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

- Consistent with other studies<sup>5</sup>, 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 <sup>†</sup> (EPITOPE) (N=175)	Year 2 (OLE) (N=175)	Year 3 (OLE) (N=165)
<b>Adverse Event Category, n (%)</b>			
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.

<sup>†</sup>175 subjects entered OLE study (out of 244 randomized to receive VP250 in EPITOPE).



# Accelerated Approval Pathway for VIASKIN<sup>®</sup> 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 met<sup>2</sup>**

2

**Generally provides a meaningful advantage  
over available therapies<sup>†</sup>**



**FDA states it is met<sup>2</sup>**

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 Letter<sup>1</sup>**

- ✓ 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<sup>††</sup>



## 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**



**Actionable market: parents & allergists want 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
<b>VIASKIN® Milk Patch (DBV135)</b> – Cow's Milk Allergy; MILES: Ages 2-17 years <sup>1</sup>					
<b>VIASKIN® Milk Patch (DBV135)</b> – Eosinophilic Esophagitis; SMILEE: Ages 4-17 years <sup>2</sup>					
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:

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

# Patch Manufacturing Capabilities

## Integrated End-to-End Patch Manufacturing in Place



Source Material

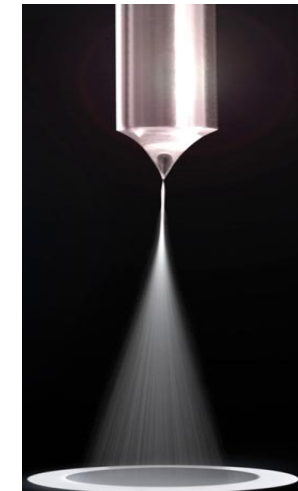


Active Pharmaceutical Ingredient (API)



Final Product Process

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



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