



# DBV TECHNOLOGIES

Corporate Presentation | November 2024

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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 and EPIT is a trademark of DBV Technologies.

# DBV Technologies: Developing Novel Treatments for Pediatric Food Allergy



**Deep roots in food allergy**



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



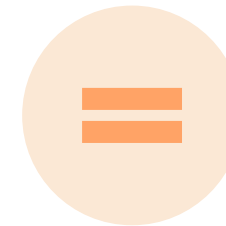
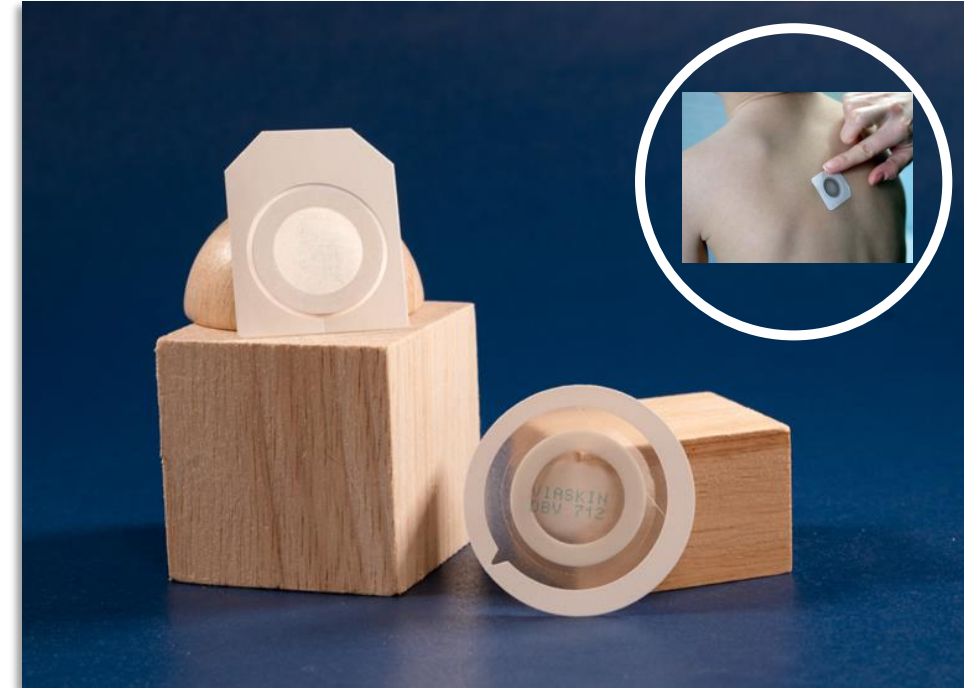
**Pioneered VIASKIN® patch technology**  
DBV's novel approach to epicutaneous immunotherapy



**VIASKIN® peanut patch as lead product candidate**  
for children ages 1-7 YO with ~1 million patches administered to 1300 children



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



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



# Company is Led By An Experienced Management Team & Renowned International Board of Directors



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**Pharis Mohideen**  
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**Virginie Boucinha**  
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**Kevin P. Malobisky**  
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& Chief of Staff



**Michele F. Robertson**  
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& Supply Chain Manager



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# ~670K Children Ages 1 to 7 Years-Old Have Peanut Allergy in The US<sup>1-3</sup>

Approximately 75% will not outgrow their allergy<sup>4,5</sup>



1-3 years old

280,000 Toddlers<sup>2,3</sup>



4-7 years old

390,000 Children<sup>2,3</sup>

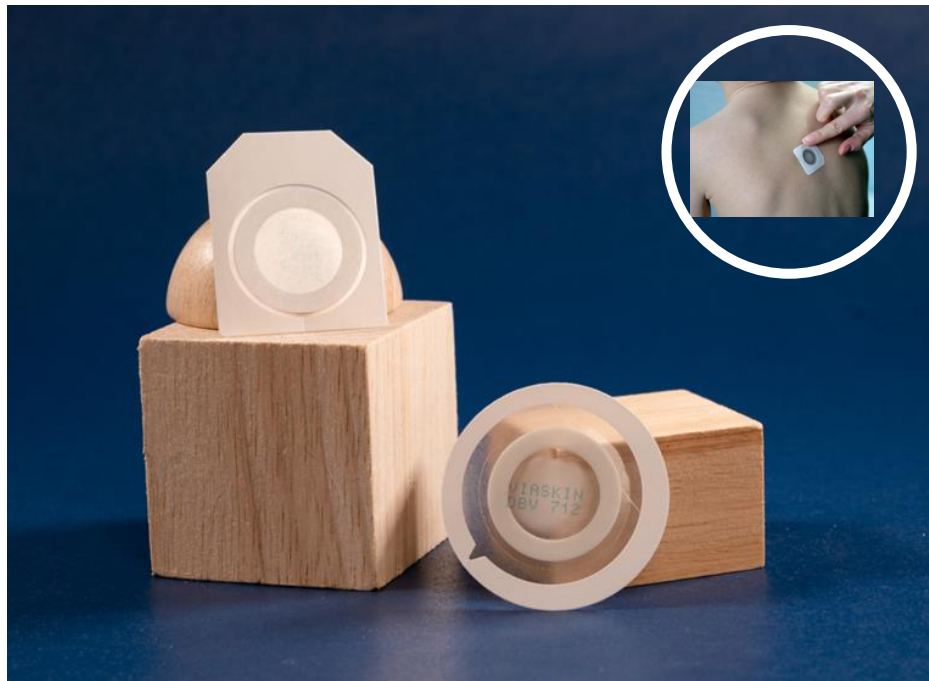


1. CDC National Population Projections 2014-2060 <https://wonder.cdc.gov/population-projections-2014-2060.html>
2. Gupta RS, et al. *Pediatrics*. 2018;142:e20181235.
3. DBV Data on File.
4. Savage J, et al. *J Allergy Clin Immunol Pract*. 2016;4:196-203.
5. Peters RL, et al. *J Allergy Clin Immunol* . 2022; 150: 657-665.



# Square (Original) and Circular (Modified) VIASKIN® Peanut Patches Are Separate Product Candidates

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


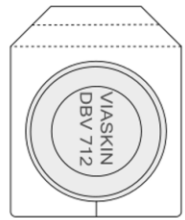








	Square Patch (Original)	Circular Patch (Modified)
<b>Target Age</b>	<b>1-3 years old</b>	<b>4-7 years old</b>
<b>Overlay Size</b>	34 mm/side	44 mm diameter
<b>Dose</b> (Peanut Allergen Extract)	250 µg	250 µg

- Square and Circular VIASKIN® peanut patches have the SAME condensation chamber (foam ring & 250 µg dose)
- VIASKIN® peanut patches differ only in the SIZE (circular patch is ~50% larger\*) and SHAPE of the overlay



# Two Distinct Opportunities for VIASKIN Peanut in Toddlers & Children with Independent Regulatory Pathways

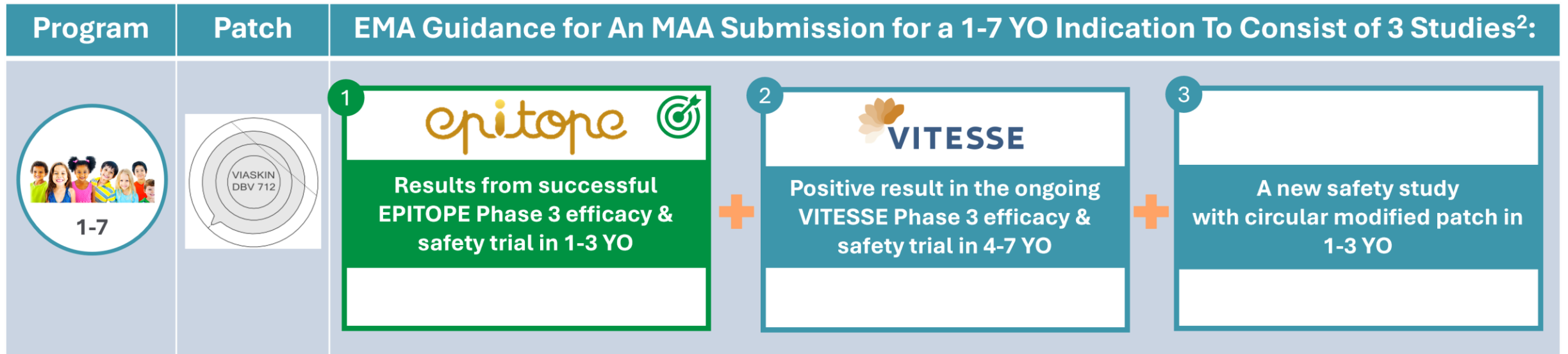
Program	Patch	Core Phase 3 Studies for Each Program/BLA		Key Program Highlights <sup>1</sup>
 <p>1-3</p>		<p><b>1</b></p>  <p><b>COMPLETED</b> Efficacy &amp; Safety</p> <ul style="list-style-type: none"> <li>✓ Primary endpoint met</li> <li>✓ Satisfactory to FDA<sup>2</sup></li> <li>✓ Published in NEJM<sup>3,4</sup></li> </ul>	<p><b>2</b></p>  <p>6-Month Supplemental Safety<sup>†</sup></p> <p>Alignment with FDA on study design</p>	<ul style="list-style-type: none"> <li>▪ FDA provided guidance for Accelerated Approval Pathway for Toddlers program</li> <li>▪ Aligned on wear time collection methodology for COMFORT Toddlers</li> <li>▪ COMFORT Toddlers anticipated to start in Q2 2025</li> </ul>
 <p>4-7</p>		<p><b>1</b></p>  <p><b>ONGOING</b> Efficacy &amp; Safety</p> <ul style="list-style-type: none"> <li>✓ Enrollment complete<sup>5</sup> (654 participants)</li> </ul>	<p><b>2</b></p>  <p>6-Month Supplemental Safety<sup>†</sup></p> <p>Alignment with FDA on study design</p>	<ul style="list-style-type: none"> <li>▪ VITESSE topline data anticipated in Q4 2025</li> <li>▪ COMFORT Children anticipated to start in Q2 2025</li> </ul>

<sup>†</sup> To bring the total number of participants on active treatment close to 600, per ICH guidelines.



# EMA Provided Guidance for Marketing Authorization Application for VIASKIN Peanut in 1-7 Year Olds With Circular (Modified) Patch

- **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>



3 DBV is currently assessing the optimal timing of the new safety study in 1-3-year-olds with the circular (modified) patch





## 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 efforts<sup>1</sup>
- In a follow-up, prospective study, approximately 41% of peanut-allergic children reported an accidental exposure within 3 years of diagnosis<sup>2</sup>

### Reactions Are Unpredictable

- Reactions to peanut are more likely to be severe than in other food allergies<sup>3</sup>
- Many factors — such as exercise, infection, asthma, NSAID usage, and stress — contribute to reaction severity, making it unpredictable<sup>4</sup>

### 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<sup>5,6</sup>
- Approximately 35% of caregivers and 42% of children report that their peanut allergy interferes with their daily life<sup>7</sup>
- Nearly 80% of peanut-allergic children report that fear of accidental exposure impacts their emotional well-being<sup>7</sup>

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-Wegrzyn A, et al. *World Allergy Organ J.* 2021 Feb 15;14(2):100512.

# Current Treatment Options are Often Not Ideal For Many 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 hours 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 ages 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



### 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 (vs 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.



# Treatment Goals of Physicians, Patients & Their Caregivers



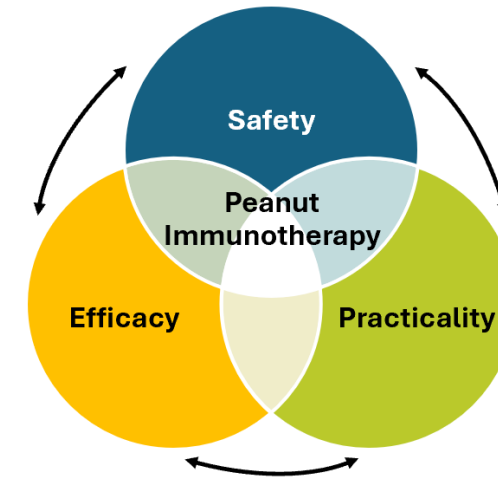
## Needs of Physicians, Patients & Their Caregivers/Families

- **90% of allergists see the need for additional options in the treatment of pediatric peanut allergy<sup>1</sup>**
- **Caregivers & physicians are seeking a treatment that<sup>2,3</sup>:**
  - ✓ Reduces the likelihood of an allergic reaction in case of accidental exposure
  - ✓ Has a low risk of a serious reaction caused by the treatment and low risk of side effects
  - ✓ Is accepted by the caregiver and child



## Goals for New Peanut Allergy Treatments

The goals of peanut allergy treatment aim to maximize effectiveness by balancing 3 key elements:  
**EFFICACY, SAFETY & PRACTICALITY<sup>2,4,5</sup>**



**Multiple treatment options are desired so families and allergists can together choose the best approach considering patient preference, family lifestyle & medical evidence<sup>4</sup>**



# VIASKIN® Peanut Patch – A Potential Treatment for Peanut Allergy That Can Be Incorporated Into The Busy Lives of Families



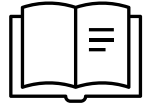
## Potential Benefits of Epicutaneous Immunotherapy with VIASKIN® peanut patch

- ✓ Applied at home, once a day onto child's back
- ✓ No treatment escalation requiring frequent doctor's appointments
- ✓ No restriction on activities (sports, exercise or hot bath/shower)
- ✓ No increased risk of side effects due to illness, missed sleep, or stress
- ✓ No oral peanut ingestion required
- ✓ Potentially disease modifying therapy<sup>1-3</sup>

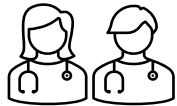
## VIASKIN peanut is designed to meet treatment goals of patients, caregivers & clinicians



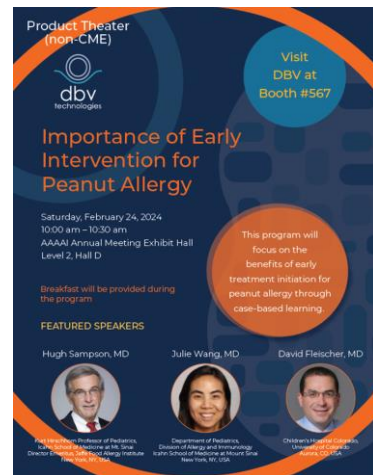
# Increasing Interest in VIASKIN® Peanut Patch In a Growing Competitive Landscape



3 invited review articles published in top allergy journals in 2024 alone<sup>1-3</sup>



Record-breaking attendance at 2024 AAAAI product theatre on early intervention with VIASKIN® peanut patch

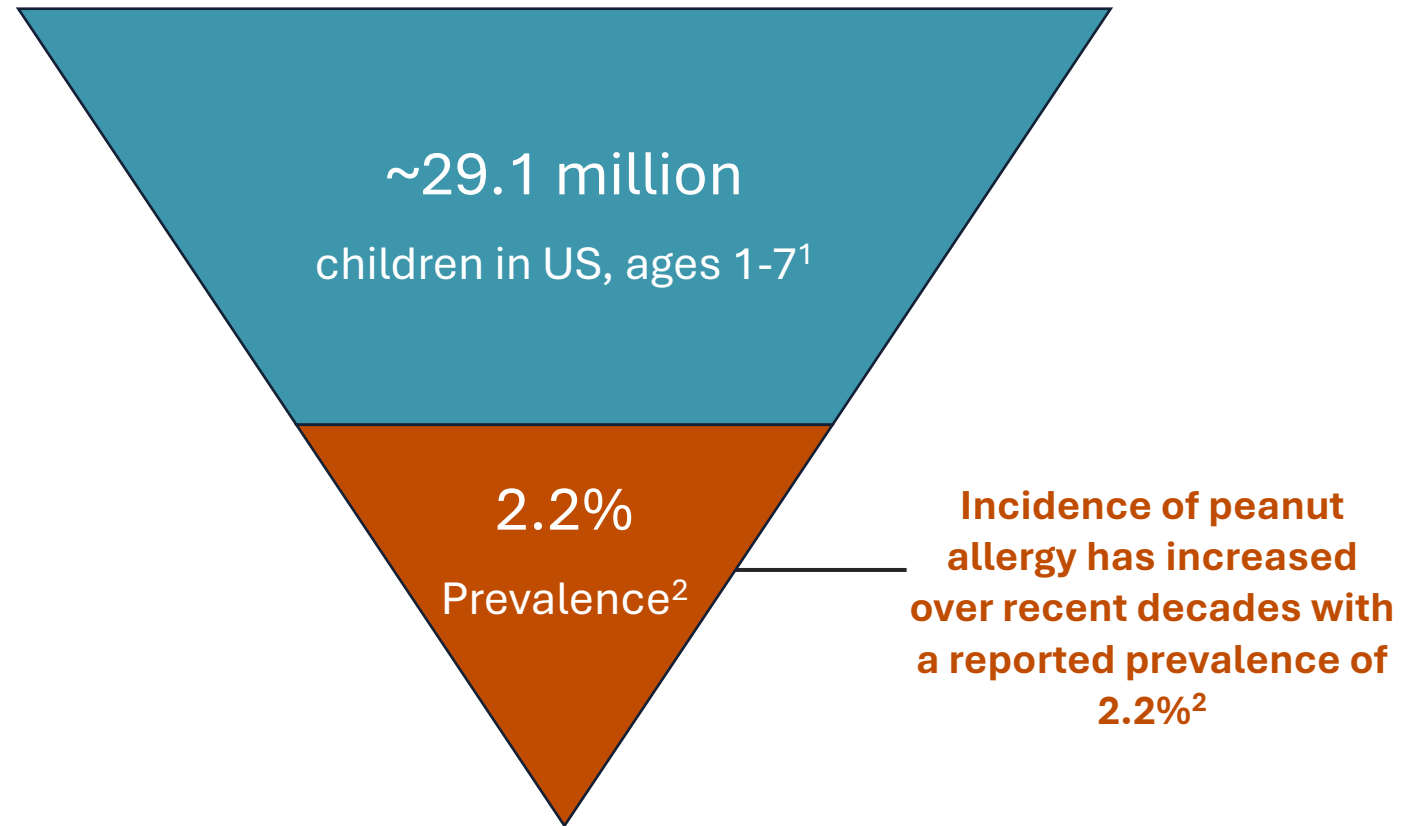


**DBV hosted Product Theater “The Importance of Early Intervention for Peanut Allergy” at AAAAI in Washington D.C. on February 24, 2024**

Chaired by Professor Hugh A. Sampson (Mount Sinai School of Medicine, NYC) with >330 allergists in attendance

# VIASKIN<sup>®</sup> Peanut Patch May Provide a Tailored Solution to a Large Number of Peanut Allergic Children Ages 1-7 YO, if Approved

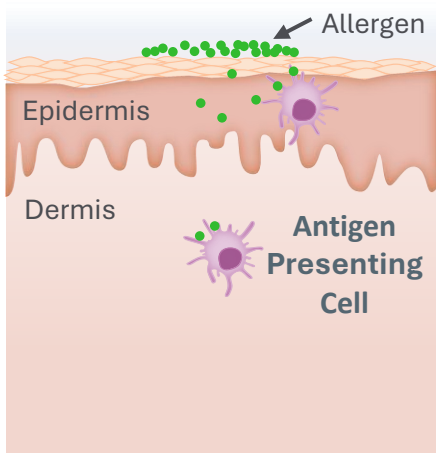
Potential multi-billion-dollar U.S. market opportunity



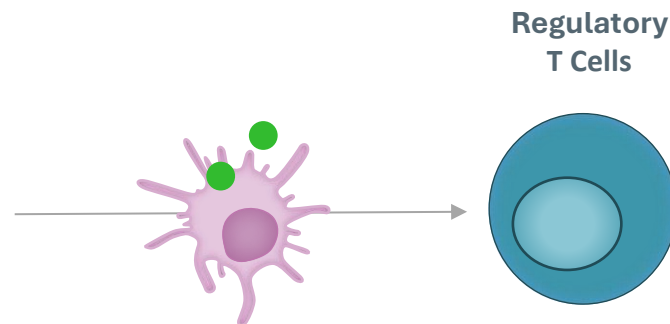
Significant market opportunity for VIASKIN peanut with ~670K eligible children ages 1-7 YO

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

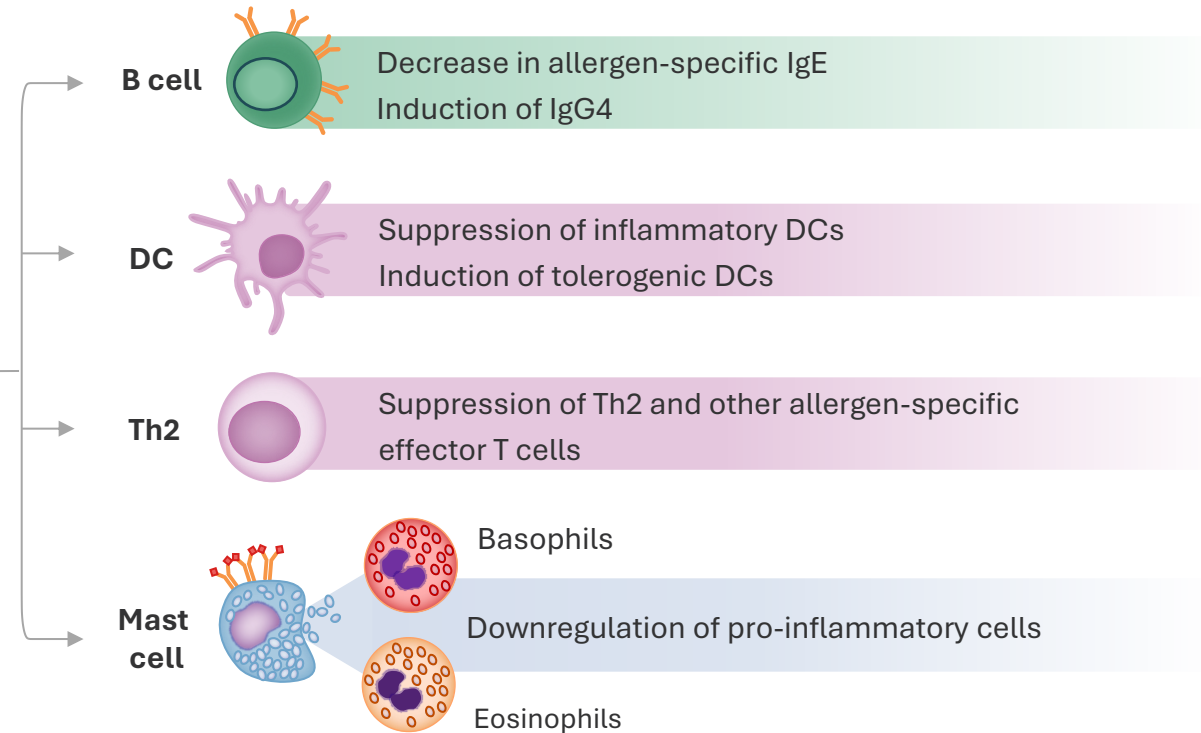
EPIT delivers allergen to the skin



Antigen Presenting Cells capture allergen and induce unique Regulatory T Cells



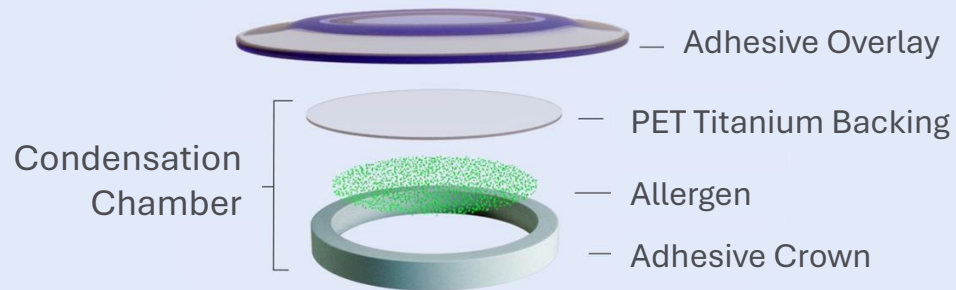
Regulatory T Cells act on the immune system to suppress the allergic response



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

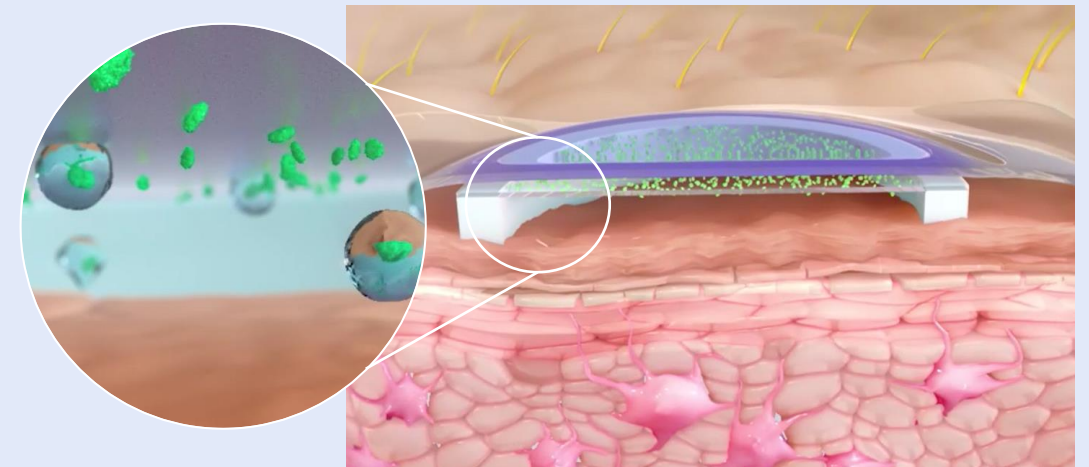
# VIASKIN Patch: Our Innovative Approach to Epicutaneous Immunotherapy<sup>1-3</sup>

## 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 Uses Minimal Amounts of Allergen to Induce an Immune Response<sup>1-3</sup>

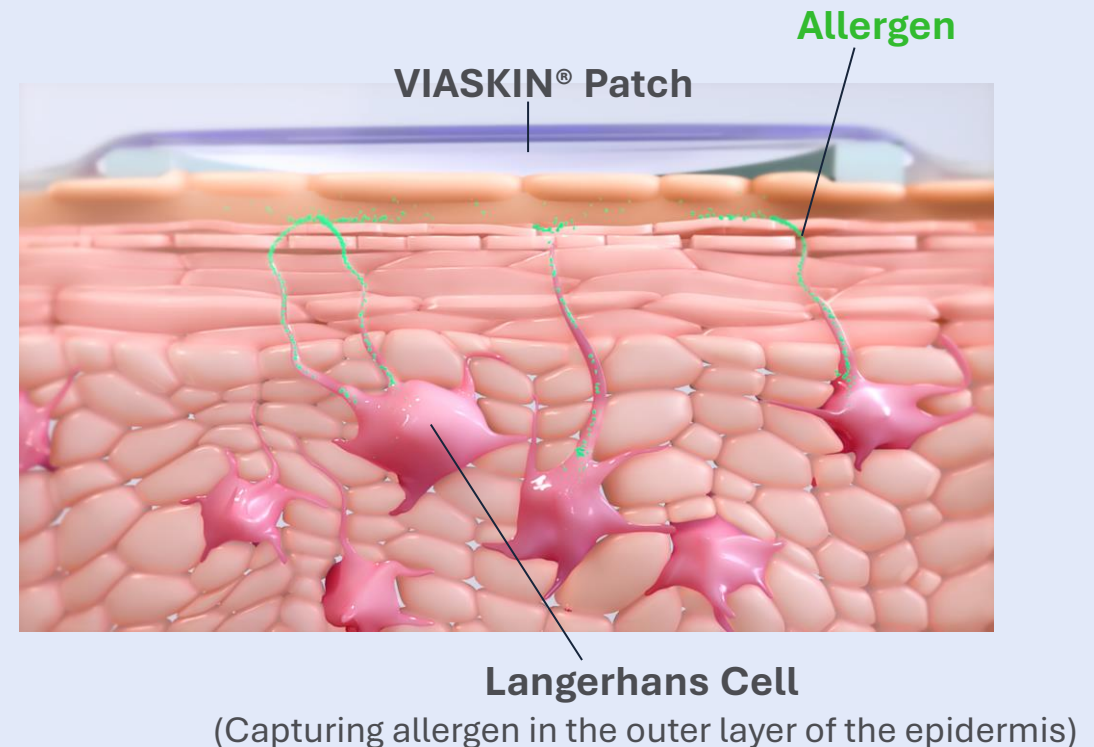
**1/1000<sup>th</sup> of a peanut is applied daily to the skin**

3 years of treatment with VIASKIN<sup>®</sup> 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 (epitopes) to T-cells, leading to a specific immune response that suppresses the allergic reaction

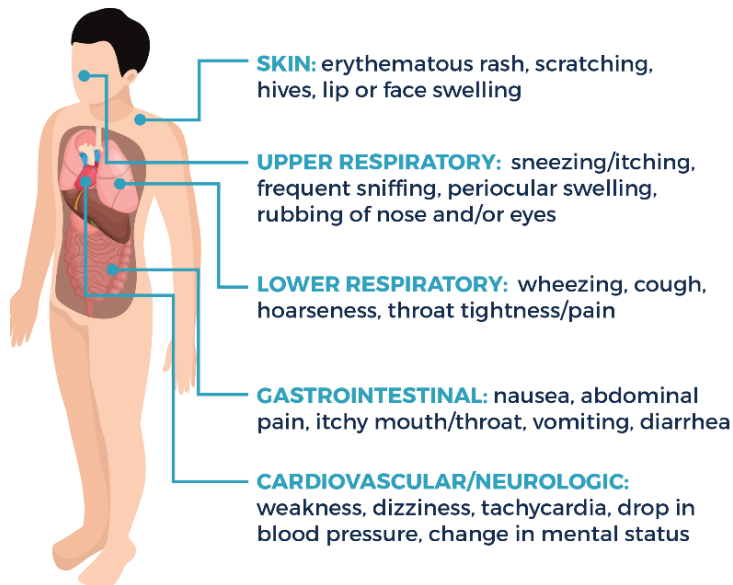
Allergen delivered via VIASKIN is **not detected in the bloodstream** in animal models



# Occurrence of Allergic Reactions is Determined by the Relationship Between Eliciting Dose and Exposure Dose

## Eliciting Dose

The amount of allergen that induces unmistakable allergic symptoms<sup>1</sup>:



## Exposure Dose

The amount of allergen accidentally ingested, determined by two factors<sup>2</sup>:

How much food was consumed?

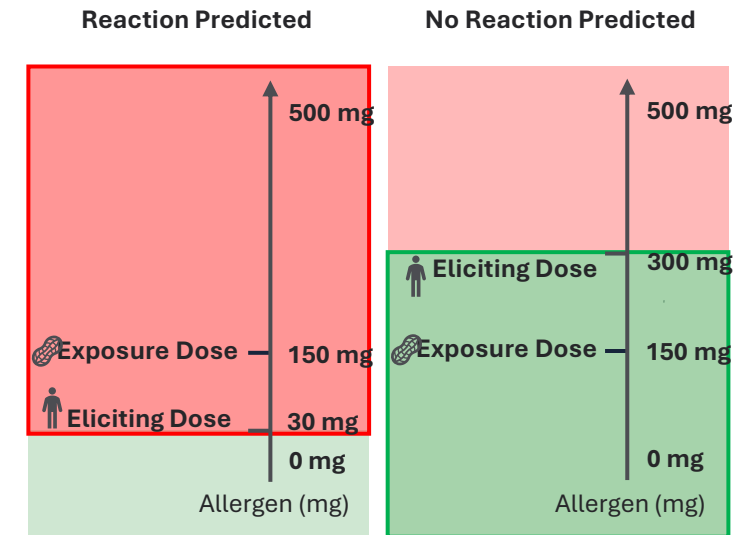


How much allergen was present in the food?



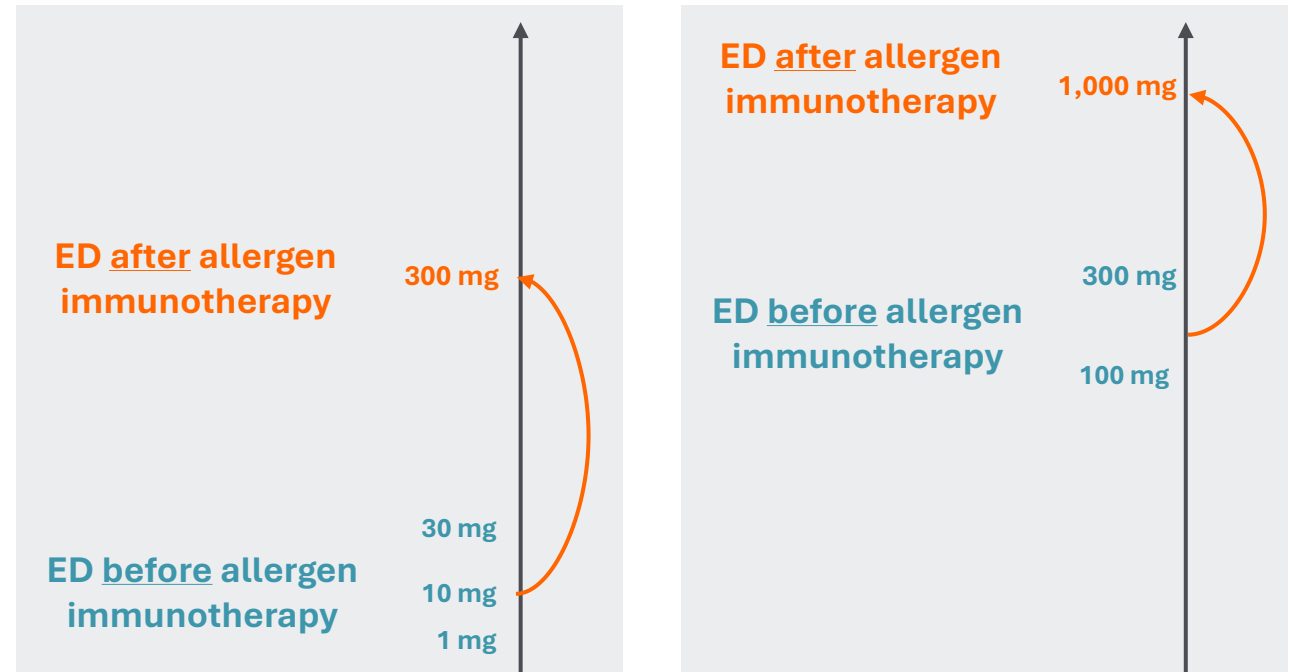
## Reaction Prediction

An allergic reaction is predicted to occur when a patient's eliciting dose is less than an exposure dose<sup>3</sup>



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

## Decrease in Reaction Risk Following Allergen Immunotherapy

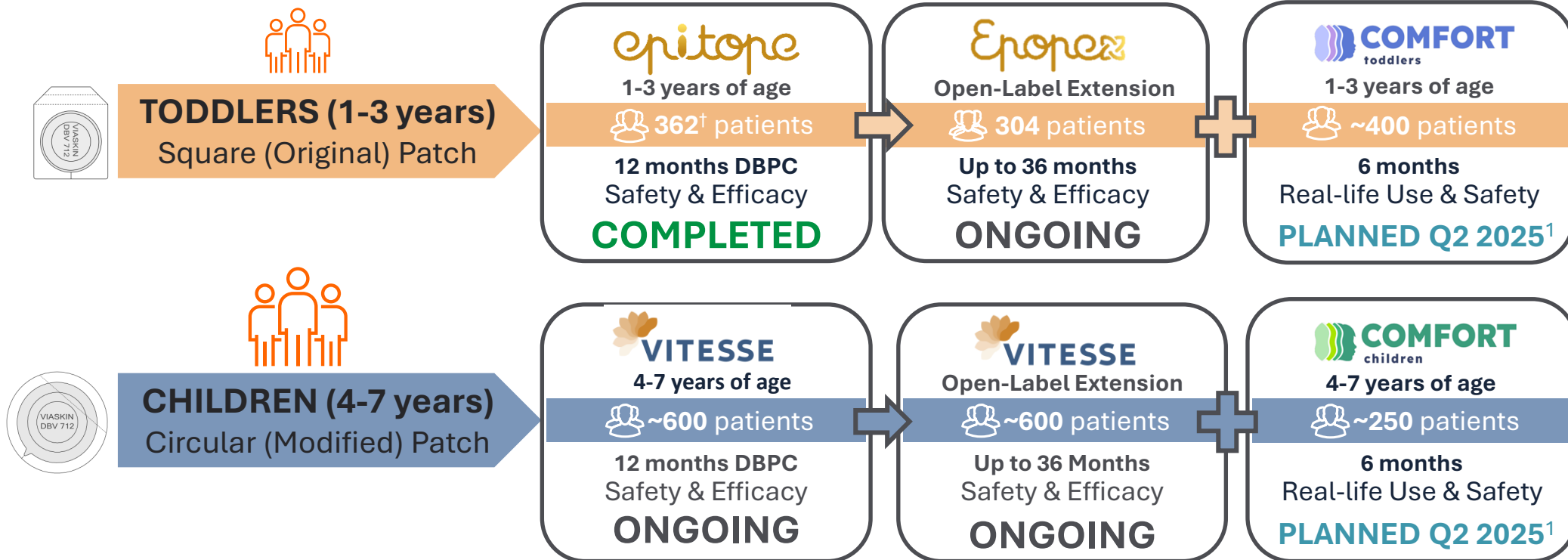


Increasing a patient's eliciting dose from **1, 10, or 30 mg** to **300 mg** or **100 or 300 mg** to **1,000 mg** via allergen immunotherapy is predicted to reduce their risk of an allergic reaction by **≥99%**

\*The Quantitative Risk Analysis model inputs variables including the clinical threshold for peanut-allergic individuals and the exposure dose of peanut residue to predict the allergenic risk associated with the exposure to residual peanut protein. ED=eliciting dose.

# Generating Robust Data in Peanut-Allergic Toddlers (Ages 1-3 YO) & Children (Ages 4-7 YO)

Recently Completed, Currently Ongoing & Planned Phase 3 Clinical Trials with VIASKIN® Peanut Patch\*



\*Phase 3 legacy studies in 4–11-year-old children are not included here: Appendix – pages 40-46.

<sup>†</sup>Total number of patients in EPITOPE=413 when both Parts A (N=51) and B (N=362) of the study are included. Part A was a sub-study involving 51 children with peanut allergy randomized to receive 12 months of placebo or peanut-protein containing patches at a dose of 100 µg or 250 µg, with the 250 µg dose selected for Part B.

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

DBPC=double-blind, placebo-controlled; EPIT=epicutaneous immunotherapy; EPITOPE=EPIT in Toddlers with Peanut Allergy; EPOPEX=EPITOPE Open Label Extension Study.

COMFORT=Characterization of the Optimal Management of Food Allergy Relief and Treatment; VITESSE=Viaskin Peanut Immunotherapy Trial to Evaluate Safety, Simplicity and Efficacy.

# VIASKIN Peanut Program in Toddlers (1–3-Year-Olds)



epitope



# Positive Results from Phase 3 EPITOPE Study With Primary Endpoint Met & With Favorable Safety & Tolerability Profile



## PRIMARY ENDPOINT MET <sup>1-3</sup>



**67% 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**

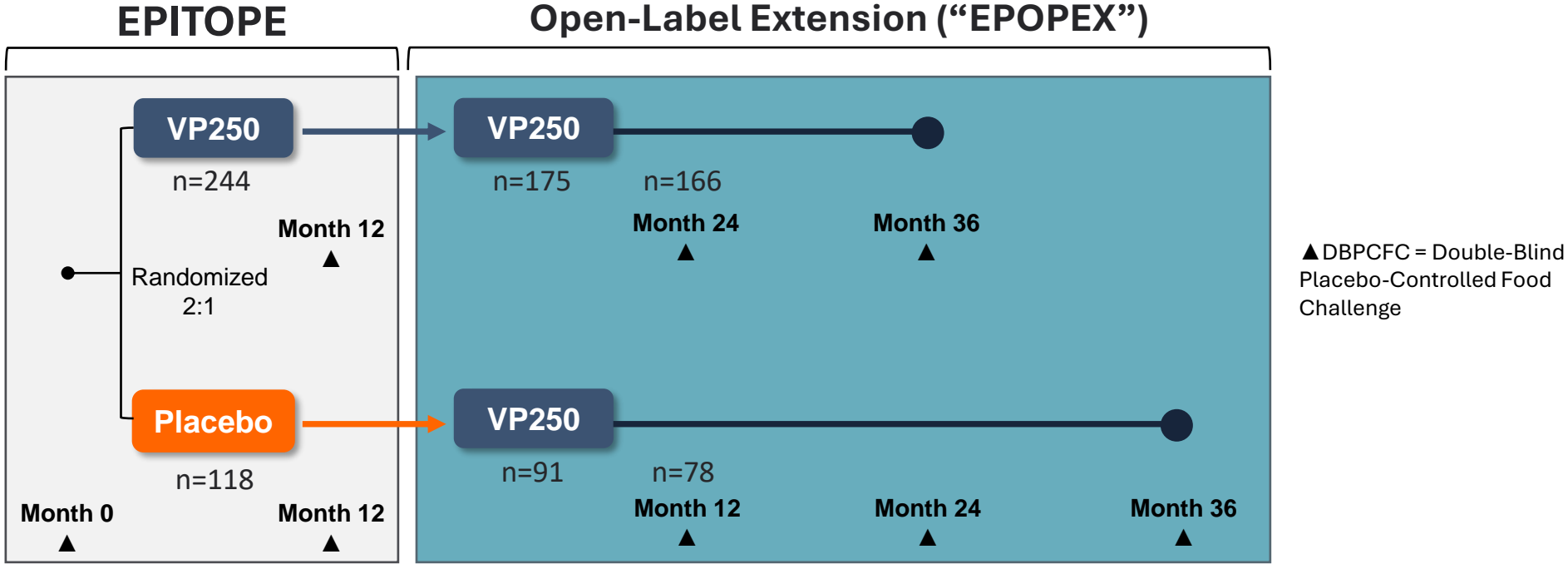
**Serious treatment-related AEs occurred in 0.4% of subjects treated with VP250 vs 0% in the placebo group**

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

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

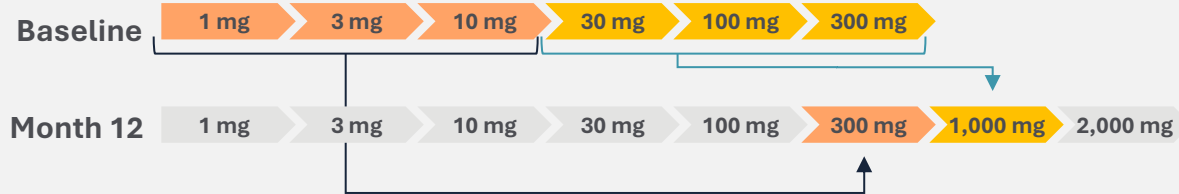
# Phase 3 EPITOPE: VIASKIN Peanut 250 µg in Toddlers 1-3 Years of Age

## Study Design for EPITOPE Pivotal Global Study<sup>1</sup> & Open-Label Extension to EPITOPE Study<sup>2</sup>



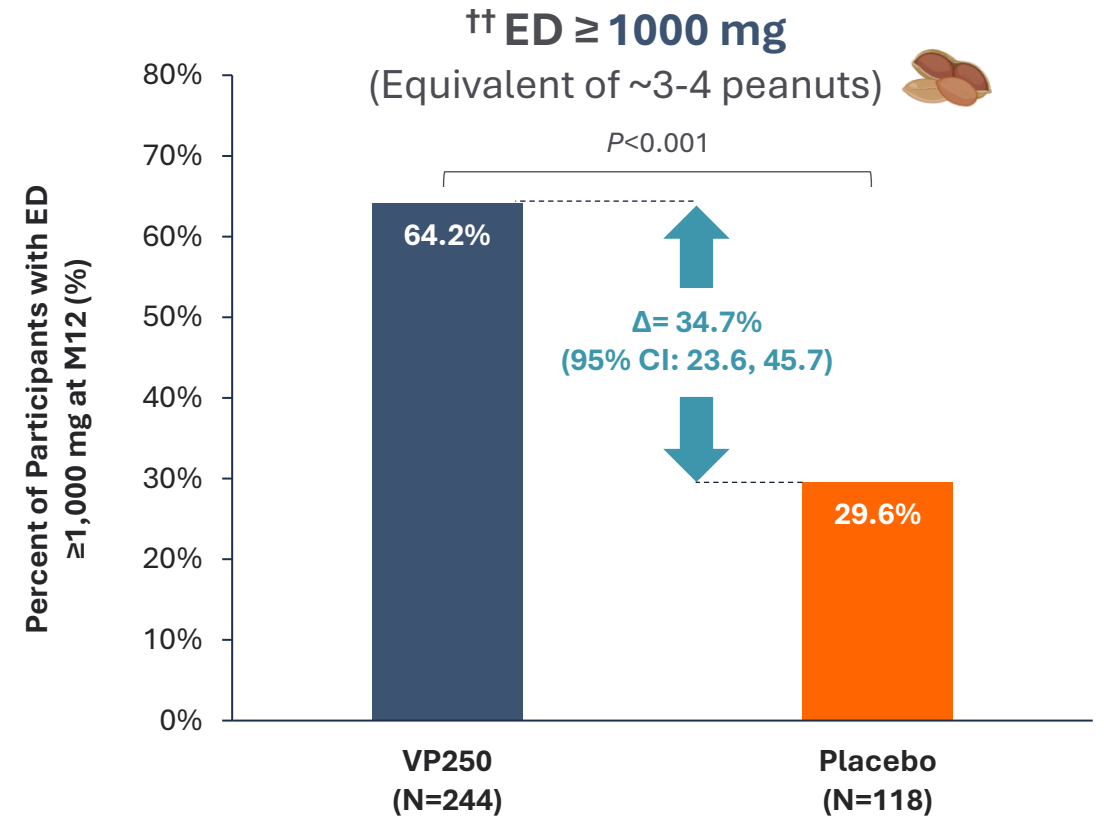
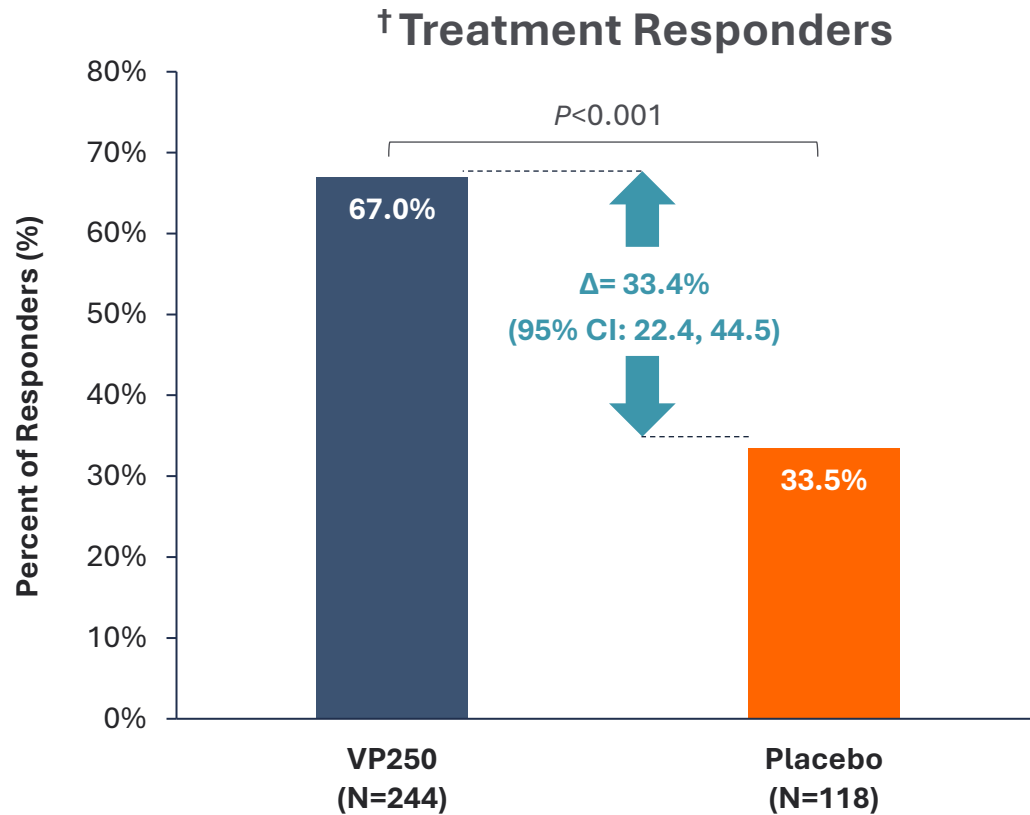
**Primary endpoint = difference between % of treatment responders in the active versus placebo group after 12 months:**

**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





# VIASKIN<sup>®</sup> Peanut Patch Demonstrated a Statistically Significant Treatment Effect in Toddlers After 12 MO<sup>1,2</sup>



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 consumption<sup>3</sup>

<sup>†</sup>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.

VP250=VIASKIN<sup>®</sup> peanut 250  $\mu$ g; CI=Confidence Interval; 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.

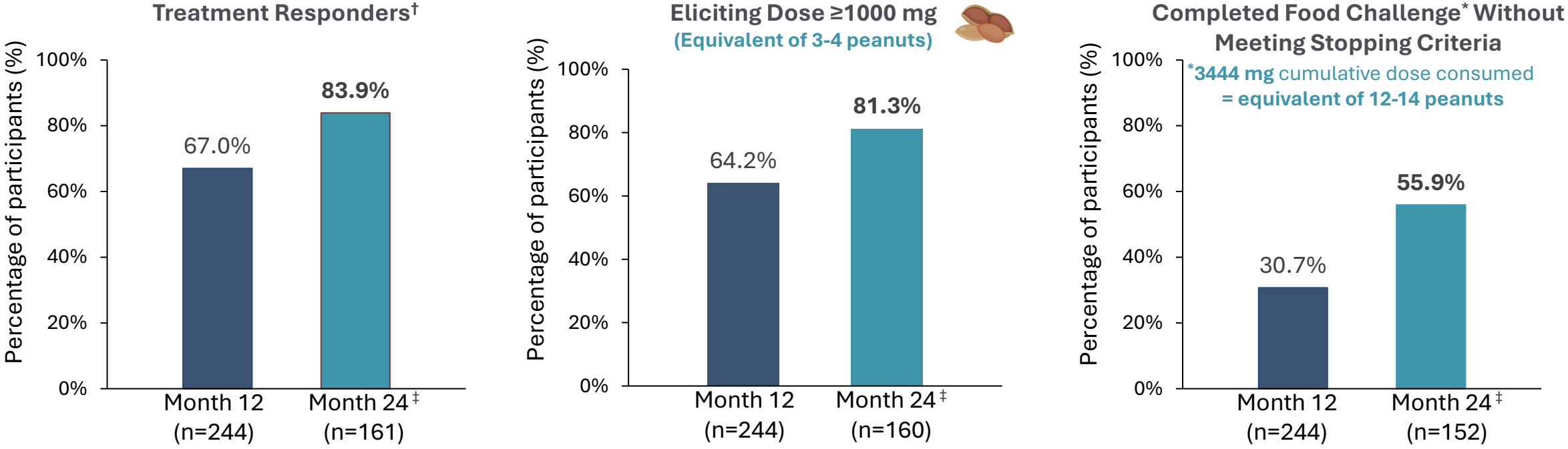
2. Togias A. Good News for Toddlers with Peanut Allergy. *N Engl J Med.* 2023; 388:1814-1855.

3. Deschildre A, et al. Peanut-allergic Patients in the MIRABEL Survey: Characteristics, Allergists' Dietary Advice and Lessons from Real Life. *Clin Exp Allergy.* 2015;46:610-620.





# Interim Data from EPITOPE Open-Label Extension Show Continued Improvement in Treatment Response in Toddlers After 24 MO<sup>1</sup>



**In EPITOPE placebo participants who received 12 months of treatment with VP250 in the OLE study (2-4 YO), efficacy was consistent with results seen after 12 months of VP250 treatment in EPITOPE<sup>1,2</sup>**

<sup>†</sup>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.

<sup>\*</sup>Number of subjects with non-missing food challenge endpoint.

VP250=VIASKIN® peanut 250 µg; OLE=Open Label Extension.

1. Greenhawt et al. EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: 1-year Open-Label Extension to EPITOPE. Oral Presentation at ACAAI Nov 2023.

2. DBV Technologies Press Release, November 9, 2023.

# Study Results of VIASKIN® Peanut Patch Consistently Demonstrate A Favorable Safety & Tolerability Profile in Toddlers<sup>1,2</sup>



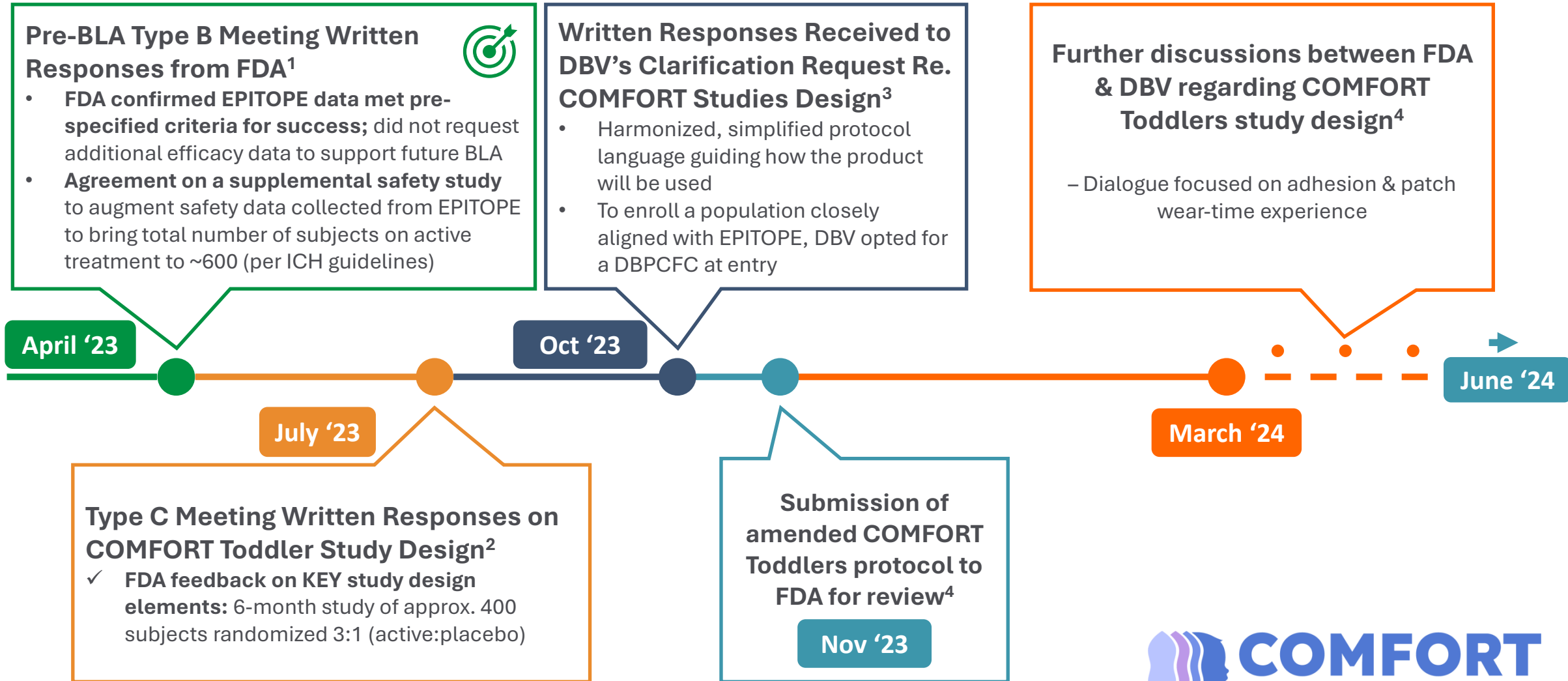
- Consistent with other studies<sup>3</sup>, local application site reactions were the most reported adverse event; however, the **frequency of reactions decreased in the 2nd year of treatment**
- **Frequency of treatment-related TEAEs was reduced in the 2<sup>nd</sup> year of treatment with VP250 vs the first year**
- **No subjects had treatment-related serious TEAEs during second year of treatment (vs 1% in Year One), and no treatment-related permanent study discontinuations occurred**
- **No treatment-related anaphylaxis was observed during the second year of treatment with VP250 (vs 1.7% in Year One)**

	First Year of Active Treatment	Second Year of Active Treatment	First Year of Active Treatment
Adverse Event Category [n (%)]	VP250 (N=175)	VP250+VP250 (N=175)	PLB+VP250 (N=91)
TEAEs	175 (100%)	171 (97.7%)	90 (98.9%)
<b>Treatment-related TEAEs</b>	<b>175 (100%)</b>	<b>160 (91.4%)</b>	87 (95.6%)
Serious TEAEs	17 (9.7%)	7 (4.0%)	2 (2.2%)
<b>Treatment-related serious TEAEs</b>	<b>1 (0.6%)</b>	<b>0</b>	1 (1.1%)
<b>TEAEs leading to permanent study treatment discontinuation</b>	<b>0</b>	<b>0</b>	0
Treatment-emergent local AESI	40 (22.9%)	25 (14.3%)	2 (2.2%)
Anaphylactic reaction	11 (6.3%)	11 (6.3%)	6 (6.6%)
<b>Treatment-related anaphylactic reaction</b>	<b>3 (1.7%)</b>	<b>0</b>	1 (1.1%)

VP250=VIASKIN® peanut patch 250 µg; TEAEs=treatment-emergent adverse events.



# Regulatory History for VIASKIN® Peanut Patch in Toddlers [I/II]



BLA=Biologics License Application.

1. DBV Technologies Press Release April 19, 2023; 2. DBV Technologies Press Release July 31, 2023; 3. DBV Technologies Press Release October 31, 2023.

4. Q3 2024 Form 10-Q filing statement.





# Regulatory History for VIASKIN® Peanut Patch in Toddlers [II/II]

## DBV proposed to FDA a “label-in/label-out” approach<sup>1</sup>:

- Crafted on *post-hoc* analysis of EPITOPE efficacy & wear time data to bring efficacy as an essential element of understanding adhesion & wear time with VP250
- Identifies patients most likely to benefit from VP250 based on wear time experience in the first 90 days of treatment

## FDA offered guidance on the intermediate clinical endpoint (ICE) to satisfy the 3rd criterion<sup>2</sup>:

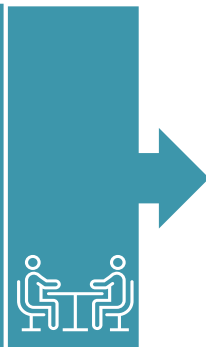
DBV agreed in informal discussions to FDA guidance and suggestion on Accelerated Approval pathway contingent upon:

- Successful completion of **6-month safety study** where patch adhesion is NOT a co-primary objective
- Successful completion of a **post-marketing confirmatory study** to confirm clinical benefit



## This approach REDEFINED the conversation with FDA & externally

- Solution exists in EPITOPE
- Discussing labeling
- Sense of urgency



## FDA provided guidance for DBV to pursue an Accelerated Approval pathway for VP250<sup>2</sup>

VIASKIN peanut met 1<sup>st</sup> & 2<sup>nd</sup> criteria for AA:

- ✓ Product treats a serious condition
- ✓ Product generally provides meaningful advantage over available therapies



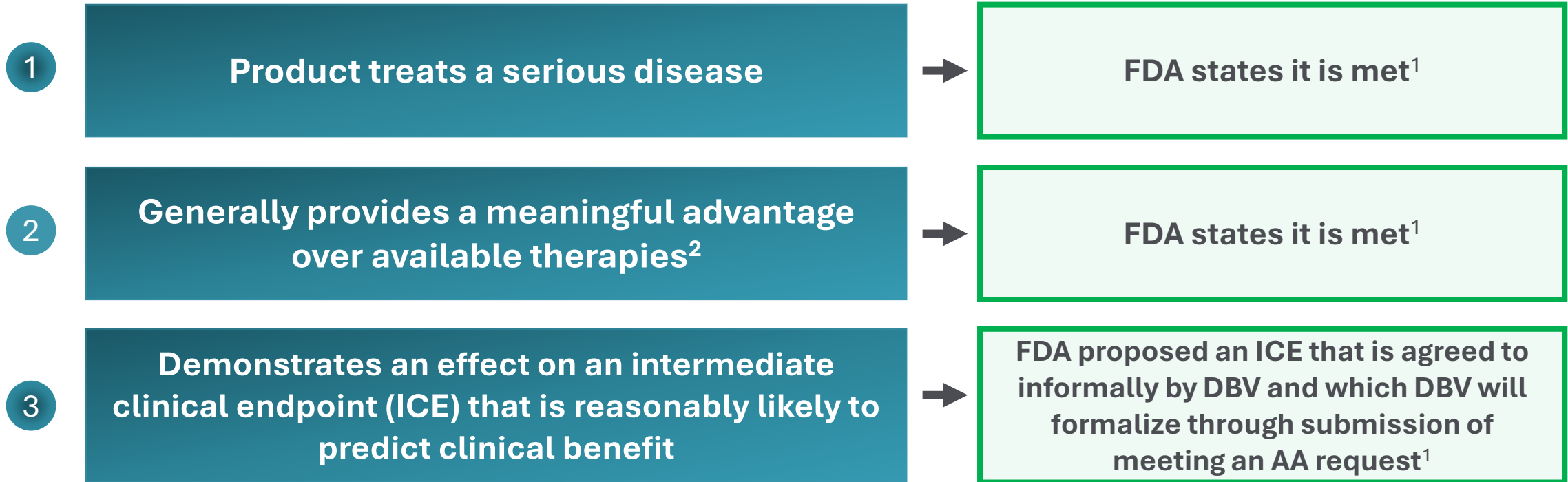
VP250=VIASKIN® peanut patch 250 µg; AA=Accelerated Approval.  
 1. DBV Technologies Press Release July 30, 2024; 2. DBV Technologies Press Release October 22, 2024.



# FDA Provided Guidance to Pursue An Accelerated Approval Pathway for VIASKIN peanut in Toddlers

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

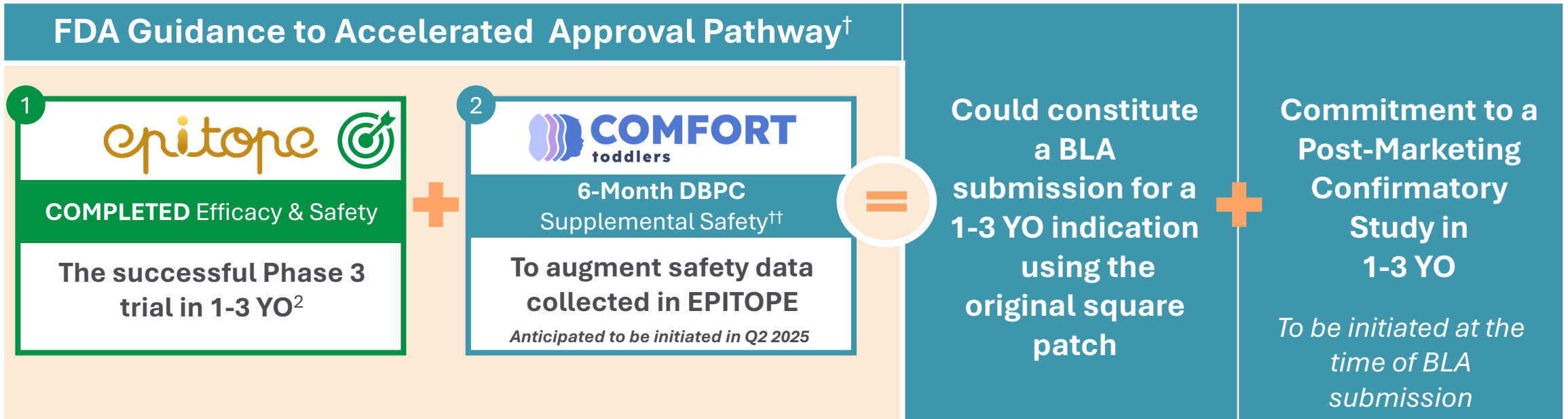
Three criteria must be satisfied to qualify for Accelerated Approval (AA)<sup>1</sup>:





# US Regulatory Pathway for Toddlers Ages 1-3 YO

## FDA provided guidance to Accelerated Approval Pathway for Toddlers Program<sup>1</sup>



DBPC=Double-blind, placebo-controlled

<sup>†</sup> Subject to DBV formalizing the AA guidance via submission of a meeting request to confirm the general elements of the COMFORT Toddlers study and confirmatory study<sup>1</sup>

<sup>††</sup> The company anticipates enrolling approximately 300 – 350 subjects on active treatment into the safety study, which would bring the total VIASKIN<sup>®</sup> peanut patch safety database in toddlers to approximately 600 subjects, consistent with prior FDA guidance<sup>1</sup>

**VIASKIN Peanut Program  
in Children  
Ages 4-7 Years Old**



**VITESSE**



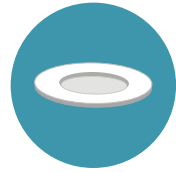
**COMFORT**  
children





# VIASKIN Peanut Program in Children 4 Years and Older

Phase 3 Efficacy & Safety Study (VITESSE) Based on Prior Phase 3 Study Conducted in 4-11 YO



## VITESSE IS ASSESSING EFFICACY & SAFETY OF THE MODIFIED PATCH

- ✓ VIASKIN® peanut patch (VP250) was modified for children ages  $\geq 4$  YO, as requested by FDA<sup>1</sup>
- ✓ The modified CIRCULAR VIASKIN® patch was selected based on adhesion data collected from a Phase 1 study conducted in healthy adults<sup>2</sup>

**DBV determined the most efficient approach to demonstrate the effectiveness, safety, & improved adhesion of the modified VIASKIN® peanut patch was to conduct a new Phase 3 efficacy study<sup>3</sup>**



## VITESSE MODELED ON PRIOR PHASE 3 PIVOTAL TRIAL IN 4-11 YO<sup>4</sup>

Post-hoc analysis of Phase 3 trial PEPITES with original square patch showed greater efficacy in younger children (4-7 YO) where 40.0% of participants on VP250 were responders vs 9.2% on placebo ( $p < 0.001$ )<sup>5</sup>

**4-7 YO subset selected by DBV as the age-range for children most likely to significantly benefit from immunotherapy with VP250 in VITESSE**





# VITESSE Study Design Schematic with Open-Label Extension Targeting a Younger, More Sensitive Patient Population<sup>1</sup>

- VITESSE Phase 3 is the largest immunotherapy clinical trial for this patient population<sup>2</sup>
- Fully enrolled since end of Q3 2024<sup>2</sup> (654 participants versus target enrollment of 600<sup>3</sup>)

## Global Phase 3 Trial

Randomized, double-blind, placebo-controlled

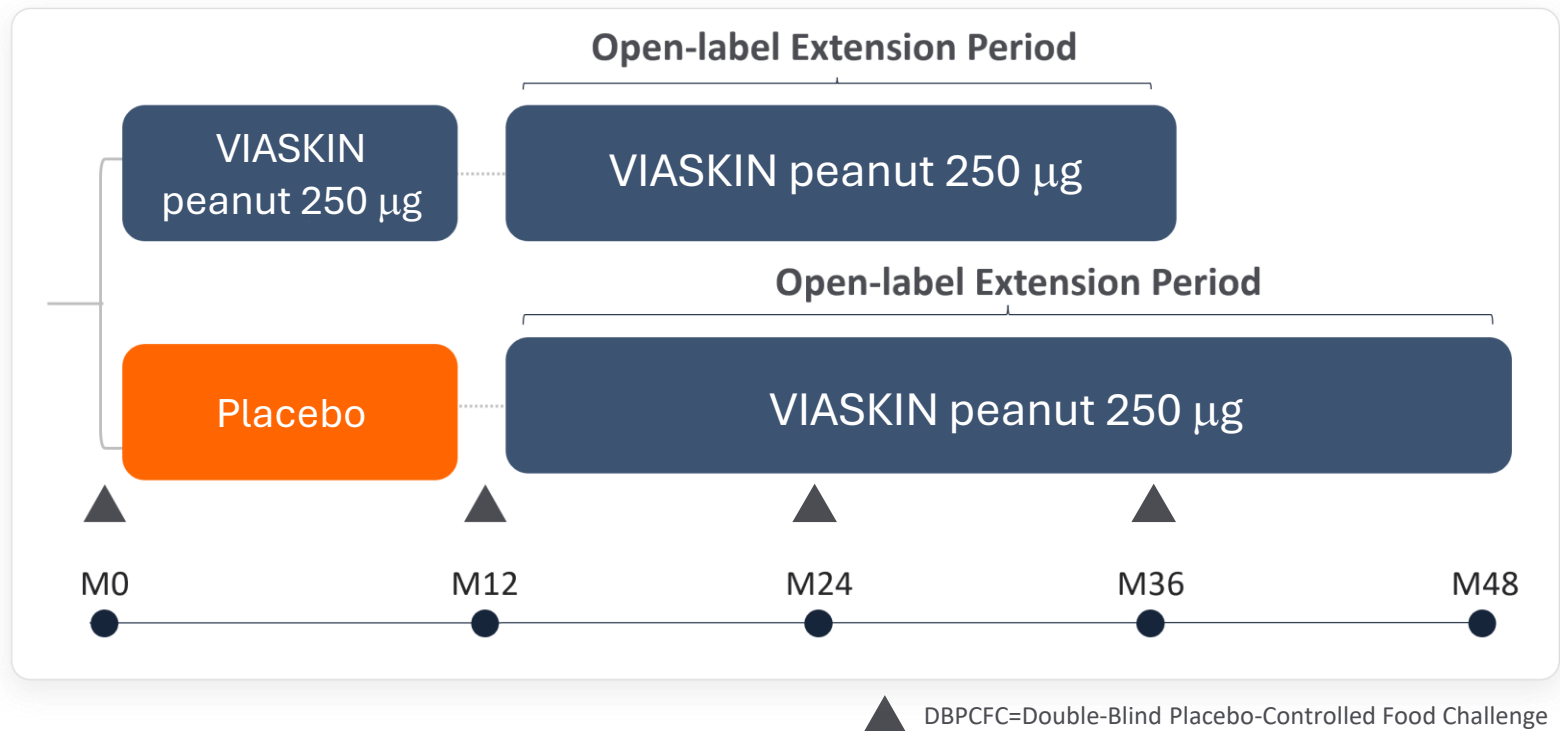
- 600+ patients Randomized 2:1
- Inclusion Criterion Baseline ED  $\leq$  100 mg
- 86 sites in US, Canada, Europe, Australia

### 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  $\leq$  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





# US Regulatory Pathway for Children Ages 4-7 Years Old

## FDA Guidance for VIASKIN Peanut in Children 4-7 YO

1



**VITESSE**

**ONGOING** Efficacy & Safety

**A positive result in the ongoing, fully enrolled VITESSE Phase 3 efficacy & safety Phase 3 trial**

**– Topline data expected in Q4 2025<sup>1,2</sup>**

2



**6-Month DBPC Supplemental Safety<sup>†</sup>**

- Anticipate ~250 subjects in total
- 2:1 randomization
- No Food Challenge required
- **Start-up activities have begun**

**– Study expected to be initiated in Q2 2025<sup>2</sup>**

=

**Could constitute a BLA submission for a 4-7 YO indication using the circular modified patch**



<sup>†</sup> To achieve FDA Guideline of ~600 subjects on active treatment for at least 6 months

# 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 (DBV135) – Cow’s Milk Allergy</b> <i>MILES: Ages 2-17 years<sup>1</sup></i>	▶				
<b>VIASKIN milk (DBV135) – Eosinophilic Esophagitis</b> <i>SMILEE: Ages 4-17 years<sup>2</sup></i>	▶				
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



1. Spergel JM et al. Efficacy of Epicutaneous Immunotherapy in Children With Milk-Induced Eosinophilic Esophagitis *Clin Gastroenterol Hepatol.* 2020 Feb;18(2):328-336.  
 2. Petroni D et al. Varying Doses of Epicutaneous Immunotherapy With Viaskin Milk vs Placebo in Children With Cow’s Milk Allergy: A Randomized Clinical Trial. *JAMA Pediatr.* 2024 Apr 1;178(4):345-353.

# 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

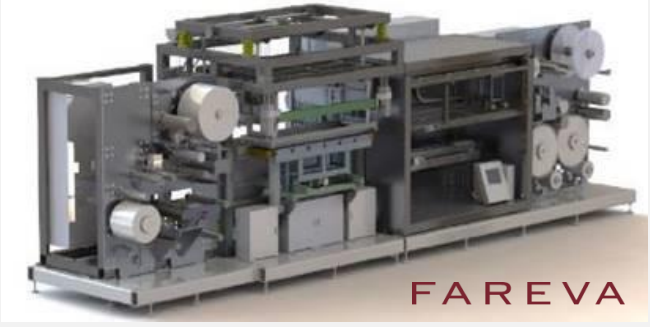
## Integrated End-to-End Patch Manufacturing in Place



Source Material

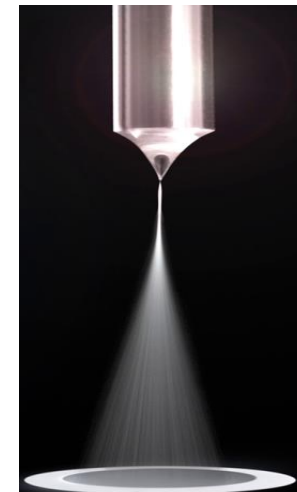


Active Pharmaceutical Ingredient (API)



Final Product Process

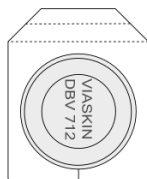
**Proprietary electrospray technology**  
deposits a precise antigen dose without  
any adjuvant on a PET titanium backing film





# Anticipated Near-Term Milestones

## Upcoming Milestones & Catalysts Anticipated Over Next 12 Months



### TODDLERS (1-3 years)



**Formalize Accelerated Approval Pathway per FDA guidance**



**Initiation of COMFORT Toddlers safety trial anticipated in Q2 2025**



**End-of-Study results from the Open-label Extension to EPITOPE**



### CHILDREN (4-7 years)



**Continue to advance VITESSE with topline data anticipated in Q4 2025**



**Initiation of COMFORT Children anticipated in Q2 2025**





# Investment Highlights (US)

## Two Distinct Opportunities for VIASKIN® peanut patch

One BLA in 1–3-year-olds with **SQUARE** (Original) VIASKIN® peanut patch



One BLA in 4–7-year-olds with **CIRCULAR** (Modified) VIASKIN® peanut Patch



## Clear Clinical Pathway for Both Programs

**1–3-year-olds**  
EPITOPE (DBV’s Phase 3 pivotal safety & efficacy study in toddlers) met the primary endpoint & meets criteria for FDA accelerated approval



**4–7-year-olds**  
Ongoing, fully-enrolled 12-month Phase 3 pivotal trial (VITESSE) informed from prior Phase 3 trial in 4–11-YO (PEPITES)



## Anticipated Clinical & Regulatory Milestones

**1–3-year-olds**

- Formalize Accelerated Approval pathway
- Initiation of COMFORT Toddlers (anticipated Q2 ‘25)



**4–7-year-olds**

- Topline data for VITESSE anticipated in Q4 ‘25
- Initiation of COMFORT Children in Q2 ‘25



## Financial Position

**\$46.4 M**

of Cash and Cash Equivalents as of September 30, 2024



**APPENDIX:**  
**Legacy Phase 3 Studies in**  
**Children Ages 4-11 Years Old**

Pepites

PeoPle

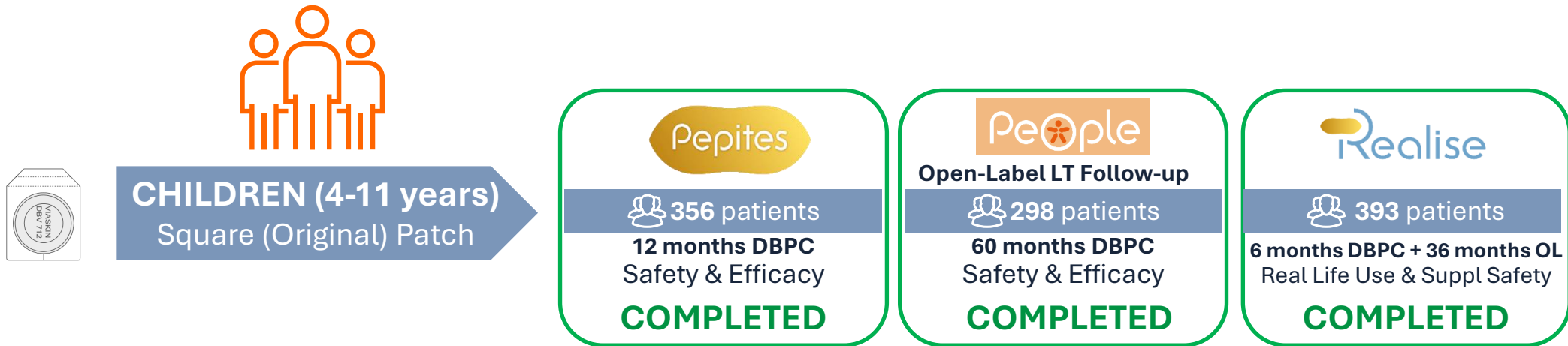
Realise





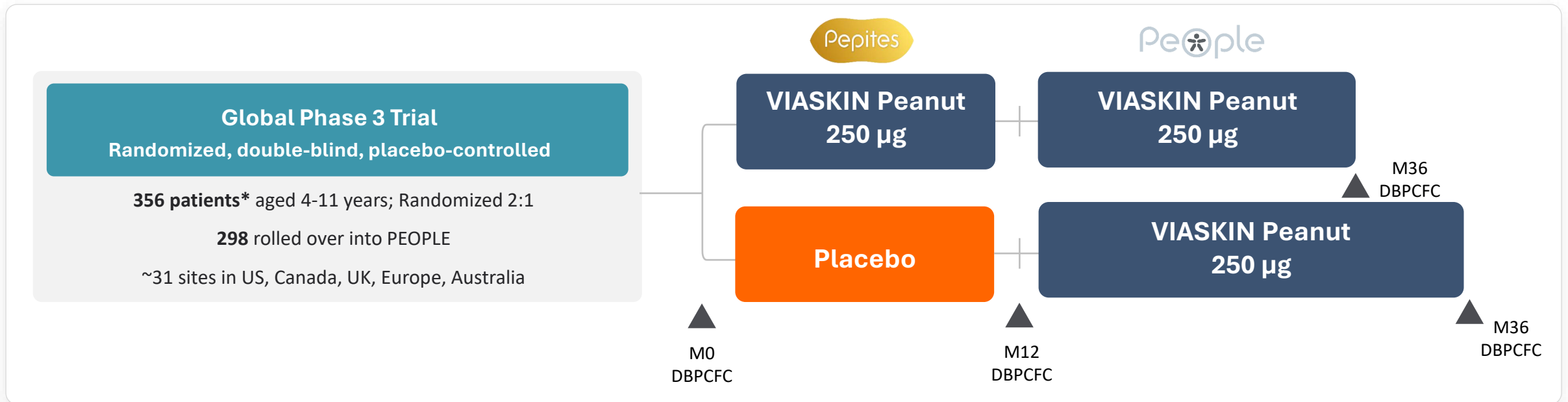
# VIASKIN Peanut Clinical Development Program in 4–11-Year-Olds

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 250 µg in Children 4–11 YO

Results published in JAMA (PEPITES)<sup>1</sup> & Journal of Allergy & Clinical Immunology (PEOPLE)<sup>2</sup>



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

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

**Treatment responder** (assessed by DBPCFC) 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  $\geq$ 1,000 mg at M12

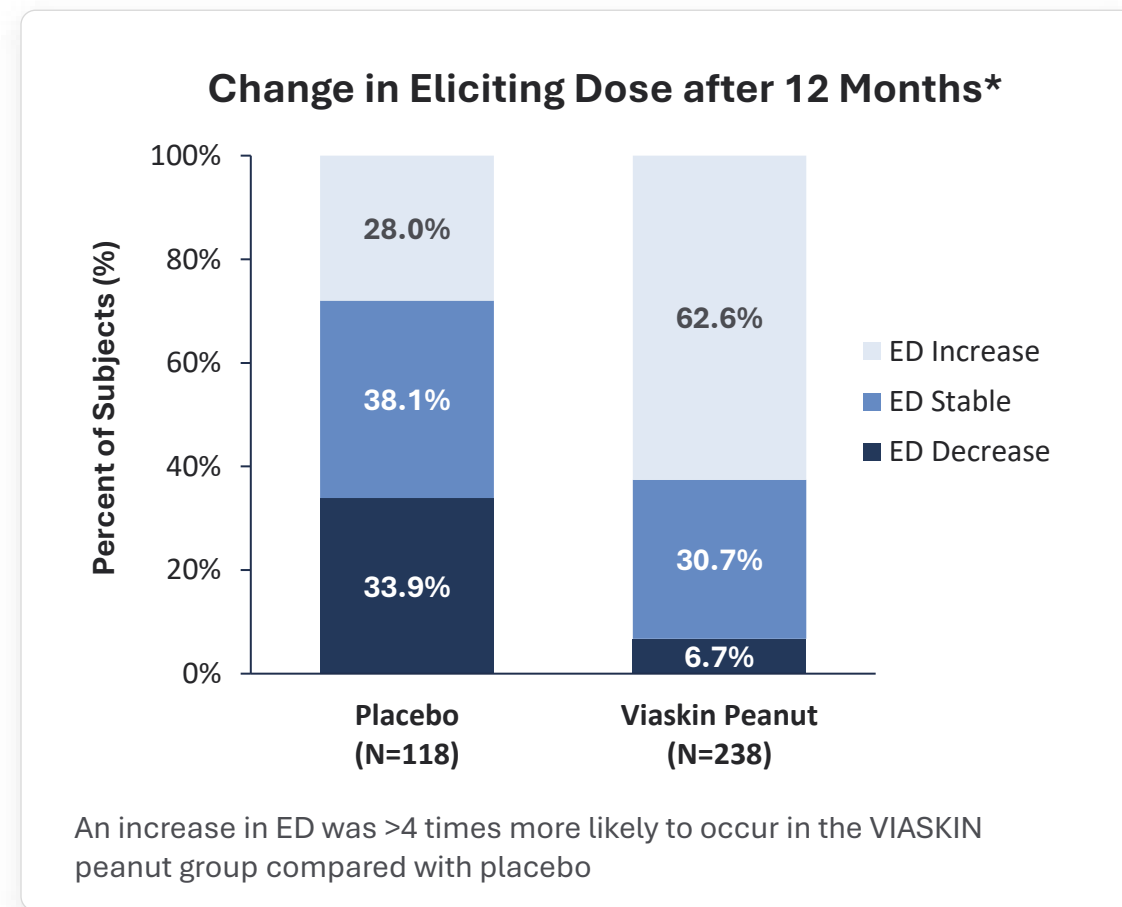
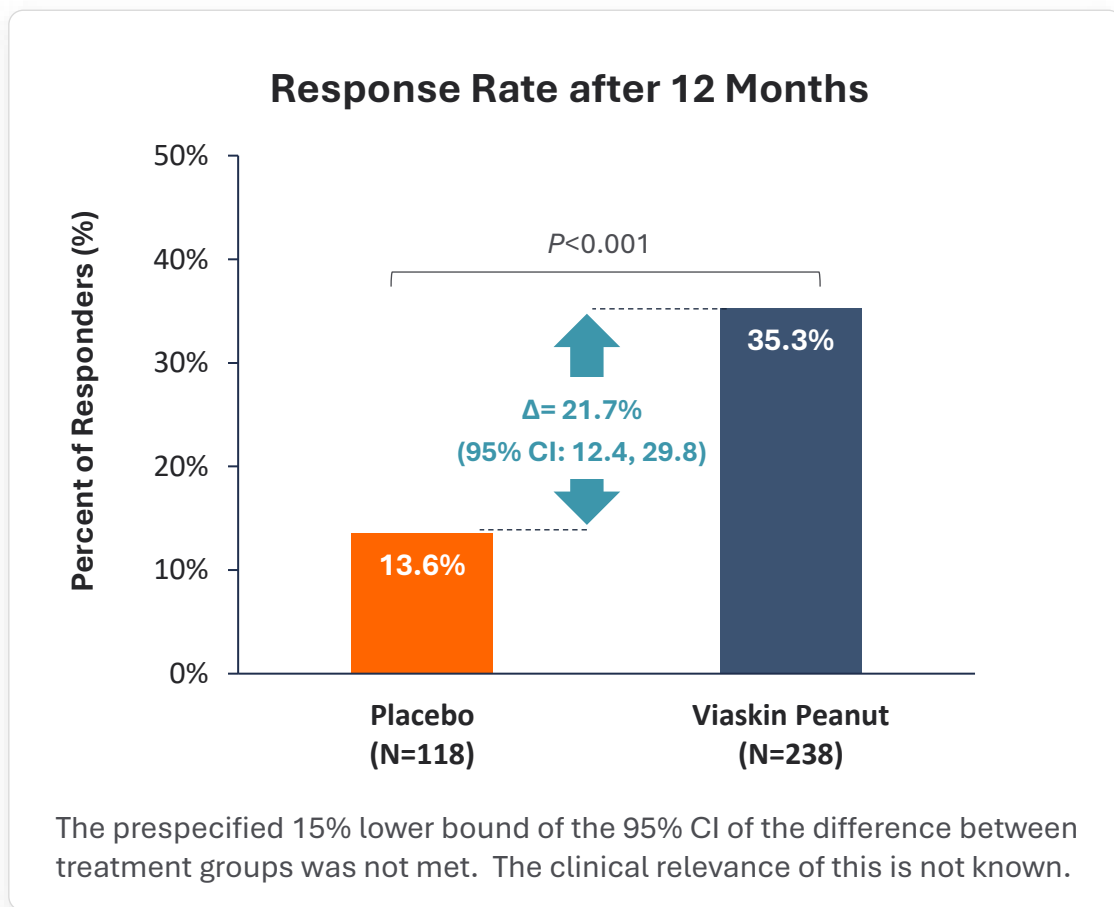
\*Confirmed peanut allergy by SPT  $\geq$ 6 mm for 4- to 5-year-olds or  $\geq$ 8 mm for 6- to 11-year-olds and sIgE levels (>0.7 kUA/L).

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 Treatment Achieved Clinically Meaningful Changes in Eliciting Dose (ED) After 1 Year

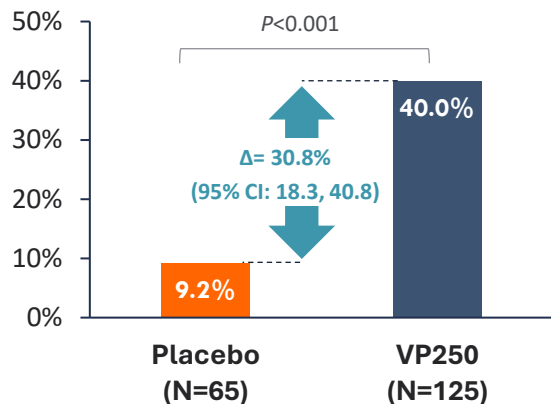
Primary efficacy outcome showed statistically significant treatment benefit



# Post-Hoc Analysis of PEPITES Data Supports Concept That Greater Gains in Desensitization May be Achieved in Younger vs Older Children<sup>1</sup>

## Treatment Responders

Children Ages 4-7 Years

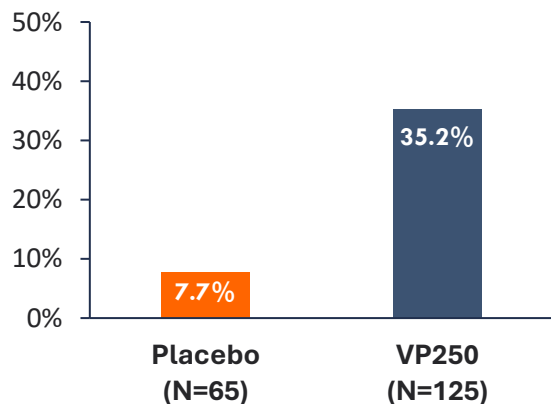


By *post hoc* analysis, a larger treatment effect in subjects aged 4–7 years who received VIASKIN<sup>®</sup> peanut 250 μg (VP250) versus placebo was demonstrated

- **40.0% of subjects in the VIASKIN<sup>®</sup> Peanut 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<sup>®</sup> Peanut 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<sup>®</sup> Peanut 250 μg arm versus 7.7% in the placebo arm reached an ED of ≥1000 mg at Month 12**

## ED ≥1,000 mg at Month 12

Children Ages 4-7 Years



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<sup>1</sup>

749 subjects included in the overall pooled safety analyses, including 630 subjects treated with VIASKIN<sup>®</sup> Peanut 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 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 vs 0% with placebo

## 630 Subjects Treated with VIASKIN peanut for Up to 36 Months

- Treatment with VIASKIN<sup>®</sup> peanut 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 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”<sup>1</sup>

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

## Children 4–11 years

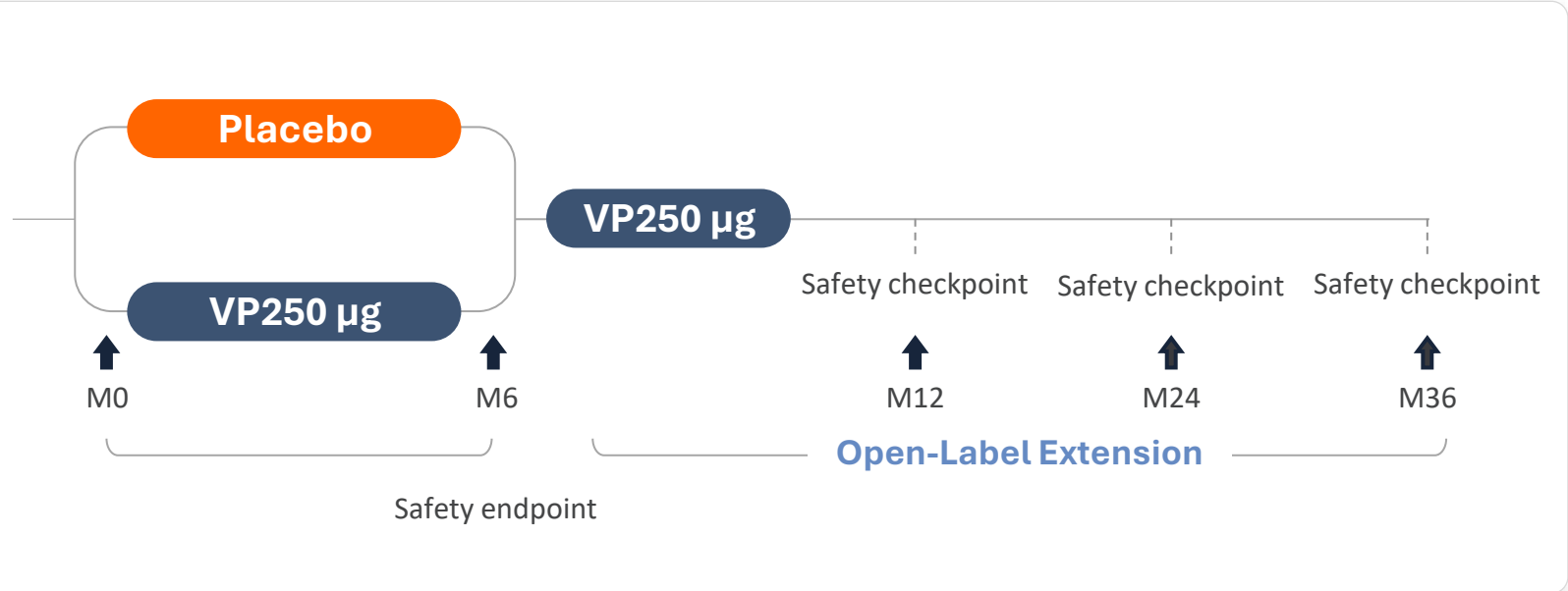
**REALISE Phase 3**  
**Randomized, double-blind, placebo-controlled**

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**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 ( $\geq 8$  mm), and sIgE levels ( $\geq 14$  kU/L)



- REALISE met its primary endpoint in the 6-month blinded portion of the study, demonstrating that VIASKIN peanut was tolerated with no new or unexpected AEs<sup>1</sup>
- 36-month data show similar long-term safety profile in peanut-allergic children consistent with previous clinical trials<sup>2</sup>



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