DBV TECHNOLOGIES

Corporate Presentation I September 2023

Euronext Paris: DBV I Nasdaq: DBVT

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As of the date of this presentation, EPIT™ and DBV's Viaskin™ technology platform 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.

Investment Highlights

Two Distinct Opportunities for Viaskin™ Peanut

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 (Phase 3 Study) Met Primary Endpoint
- Agreement with FDA for a 6-Month Supplemental Safety Study (COMFORT Toddlers)

4–7-year-olds

- Ongoing Phase 3 Pivotal Trial (VITESSE) Informed from Prior Phase 3 Trial (PEPITES) in 4–11-Year-Olds
- Agreement with FDA for a 6-Month Supplemental Safety Study (COMFORT Children)

Anticipated Clinical & Regulatory Milestones

1–3-year-olds

COMFORT Toddlers:

- FDA Alignment on Protocol
- First Patient Enrolled
- Topline Results

4–7-year-olds

VITESSE:

- Completion of Enrollment
- Topline Results

COMFORT Children:

- FDA Alignment on Protocol
- First Patient Enrolled

Financial Position

$174M

of Cash and Equivalents as of June 30, 2023

EPIT™ and DBV's Viaskin™ technology platform 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.

Generating Robust Viaskin™ Peanut Data in Toddlers (Ages 1-3 Years Old) & Children (Ages 4-7 Years Old)

Recently Completed, Currently Ongoing & Planned Phase 3 Clinical Trials*

Viaskin™ Peanut Phase 3 Study	Age Group (Program)	Patch Type	Phase 3 Status
EPITOPE (Safety & Efficacy)	1-3 years (Toddlers)	SQUARE (Original)	●
EPOPEX (Open-Label Extension)			◐
COMFORT Toddlers (Supplemental Safety)			○
VITESSE (Safety & Efficacy)	4-7 years (Children)	CIRCULAR (Modified)	◐
COMFORT Children (Supplemental Safety)			○

Viaskin™ programs in indications beyond peanut allergy are provided on page 29

● Completed ◐ Ongoing ○ Planned

*Phase 3 legacy studies in 4–11-year-old children are not included here (see Appendix: pages 37-44).
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.

Square (Original) and Circular (Modified) Patches Are Separate Product Candidates

Independent Clinical and Regulatory Paths for Viaskin™ Peanut in Toddlers 1–3 Years & in Children 4–7 Years

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

Key Takeaways:

- Square and circular Viaskin™ patches have the same condensation chamber (foam ring and 250 µg amount of peanut protein)
- Viaskin™ patches differ only in the size (circular patch is ~50% larger*) and shape of the overlay

*The surface area of the adhesive overlay that is in contact with the skin is ~50% larger in the modified circular patch than the original square patch. The condensation chamber is the same size in both patches.

In the US, More Children Are Living With Peanut Allergy Than Ever Before

Approximately ~75% will not outgrow their allergy[1]

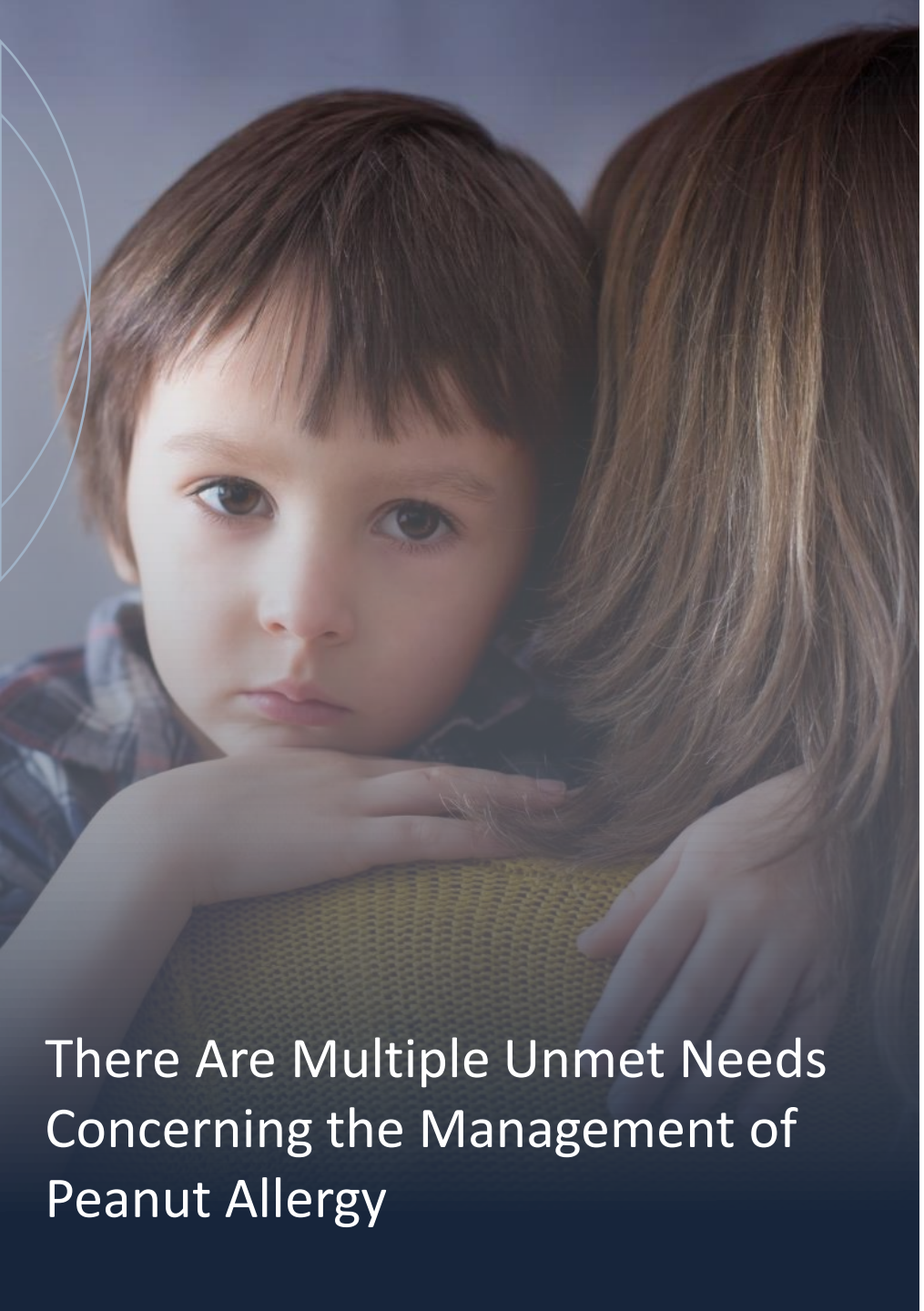
1-3 years old

280,000 Toddlers[2,3]

4-7 years old

390,000 Children[2,3]

1. Savage J, et al. *J Allergy Clin Immunol Pract*. 2016;4:196-203. **2**. Gupta RS, et al. *Pediatrics*. 2018;142:e20181235. **3**. DBV Data on File.



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[1]
- In a follow-up, prospective study, approximately 41% of peanut-allergic children reported an accidental exposure within 3 years of diagnosis[2]

Reactions Are Unpredictable

- Reactions to peanut are more likely to be severe than in other food allergies[3]
- Many factors — such as exercise, infection, asthma, hormones and stress — contribute to reaction severity, making it unpredictable[4]

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 life[7]
- Nearly 80% of peanut-allergic children report that fear of accidental exposure impacts their emotional well-being[7]

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.

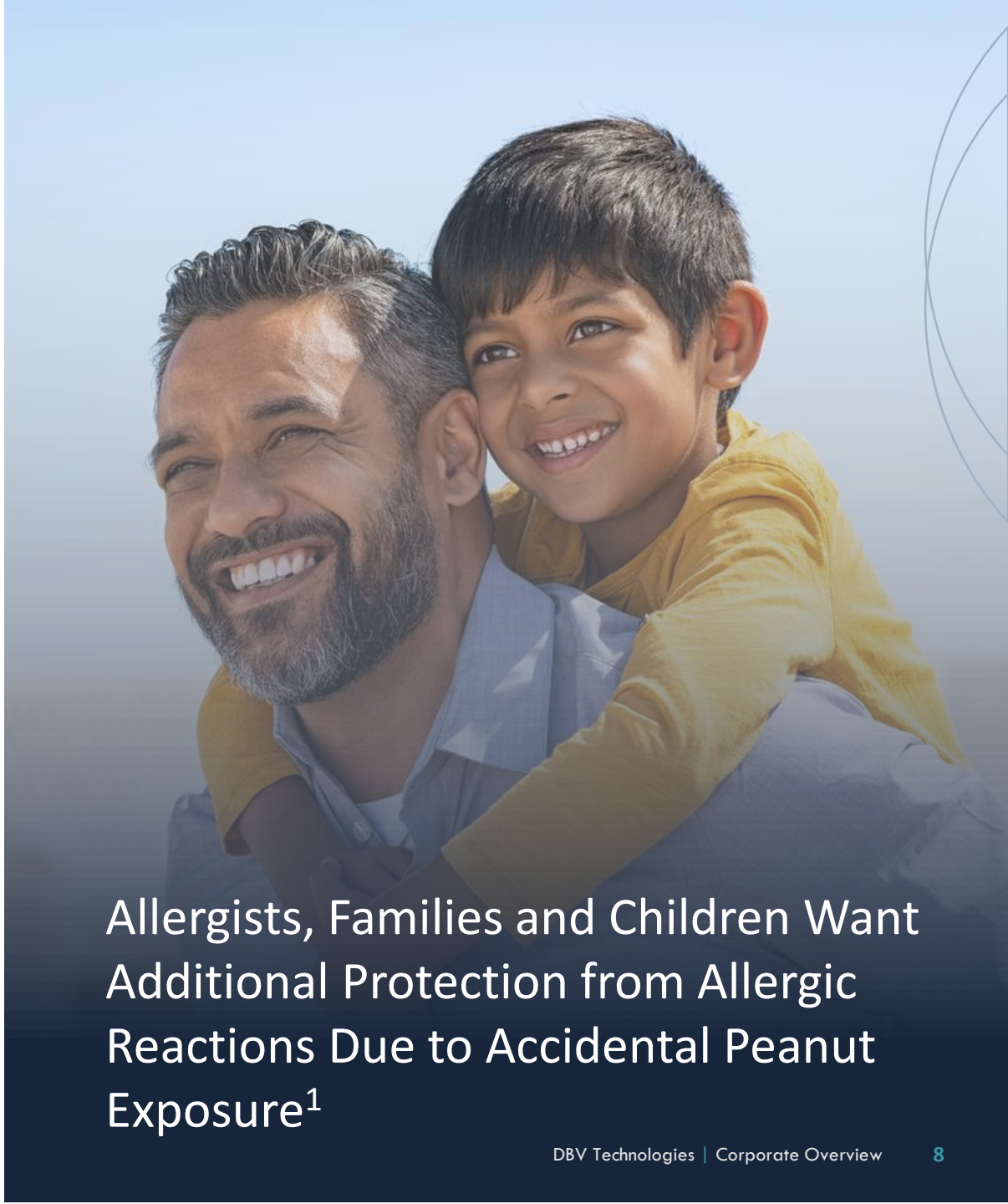
Caregivers and physicians are seeking a treatment that[1,2]:

- 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

The goals of peanut allergy treatment aim to maximize effectiveness by balancing efficacy, safety, and practicality[1,3]

Multiple treatment options are desired so families and allergists can together choose the best approach considering[3]:

- Patient preference
- Family lifestyle
- Medical evidence



Allergists, Families and Children Want Additional Protection from Allergic Reactions Due to Accidental Peanut Exposure[1]

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" and 7 means "very important to me."
3. Anagnostou A, et al. *J Allergy Clin Immunol Pract*. 2020;8:46-51.

Families and Allergists Want Additional Therapy Options for Peanut Allergy[1,3]

Oral immunotherapy is often not an ideal option for many patients and their families:[1,2]

- Complex dose escalation schedule, requiring multiple visits to an allergist's office that can each last more than 1 hour
- Avoidance of certain activities (sports, other strenuous physical activities and hot showers/baths) within 3 hours of dose
- Increased risk of an allergic reaction to OIT dose if patient is having an illness such as a 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

90% of allergists see the need for additional options in the treatment of pediatric peanut allergy[3]

1. Chu DK et al. *Lancet.* 2019 Jun 1;393(10187):2222-2232. **2.** Mack DP et al. *Clin Exp Allergy*. 2022;52:1391-1402. **3.** Based on primary market research conducted on behalf of DBV among 100 allergists in the United States conducted in May 2022. Survey question: Do you see the need for additional options in the treatment of pediatric peanut allergy?

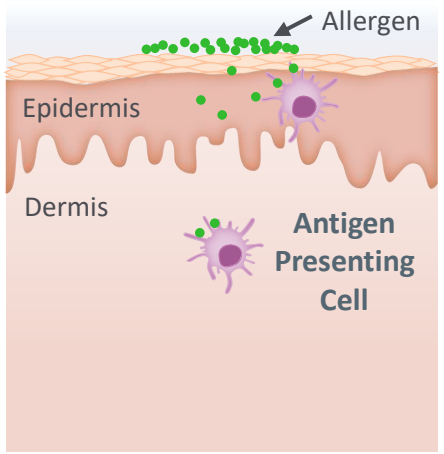
Target Product Profile: A Treatment for Peanut Allergy That Can Be Incorporated into the Busy Lives of Families

	Viaskin™ Peanut:
No treatment escalation requiring frequent doctor's appointments	✓
No increased risk of side effects due to illness, missed sleep, or stress	✓
No restriction on activities such as sports, exercise or hot bath/shower	✓
No oral peanut ingestion required	✓
Applied at home, once a day	✓

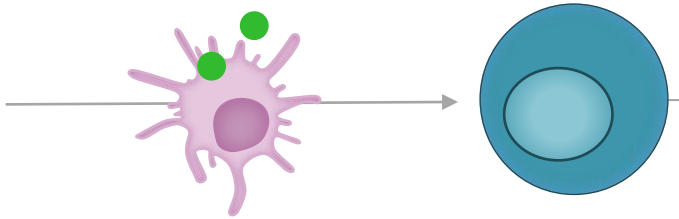
EPIT™ and DBV's Viaskin™ technology platform are investigational and have not yet been approved by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or any other regulatory agencies.

Epicutaneous Immunotherapy (EPIT™) Aims To Re-educate the Immune System by Suppressing the Allergic Response[1-6]

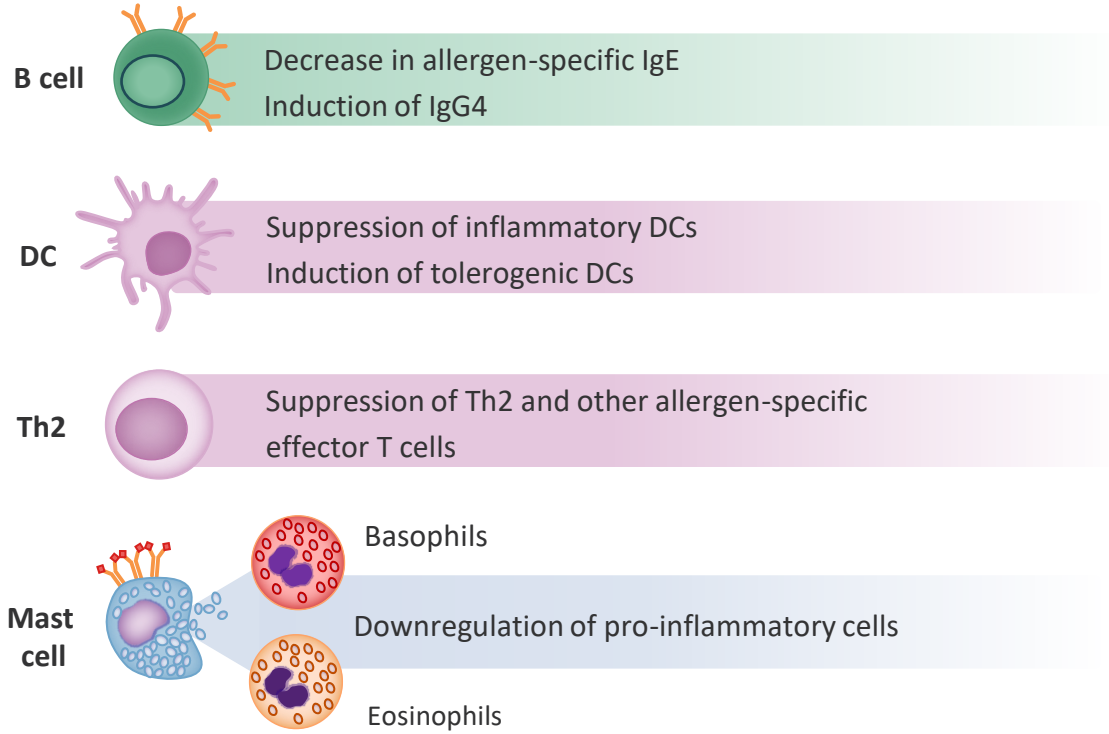
EPIT delivers allergen to the skin



Antigen Presenting Cells capture allergen and induce unique Regulatory T Cells



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

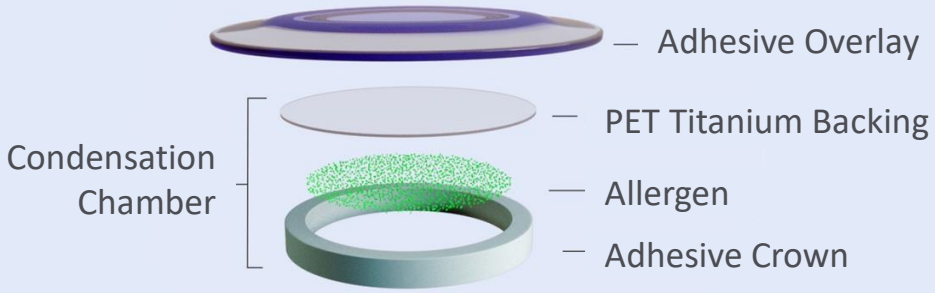


DC=dendritic cell; IgE=immunoglobulin E; IgG4=immunoglobulin G4; Th2=T-helper 2 cell.

1. Mondoulet L, et al. *J Allergy Clin Immunol*. 2015;135:1546-57. **2.** Mondoulet L, et al. *Allergy*. 2019;74:152-164. **3.** Moingeon P, Mascarell L. *Sem Immunol*. 2017;30:52-60.
4. Feuille E, Nowak-Wegrzyn A. *Allergy Asthma Immunol Res*. 2018;10:189-206. **5.** Tordesillas L, et al. *Immunity*. 2017;47(1):32-50. **6.** Dioszeghy V, et al. *Cell Mol Immunol*. 2017;14:770-782.

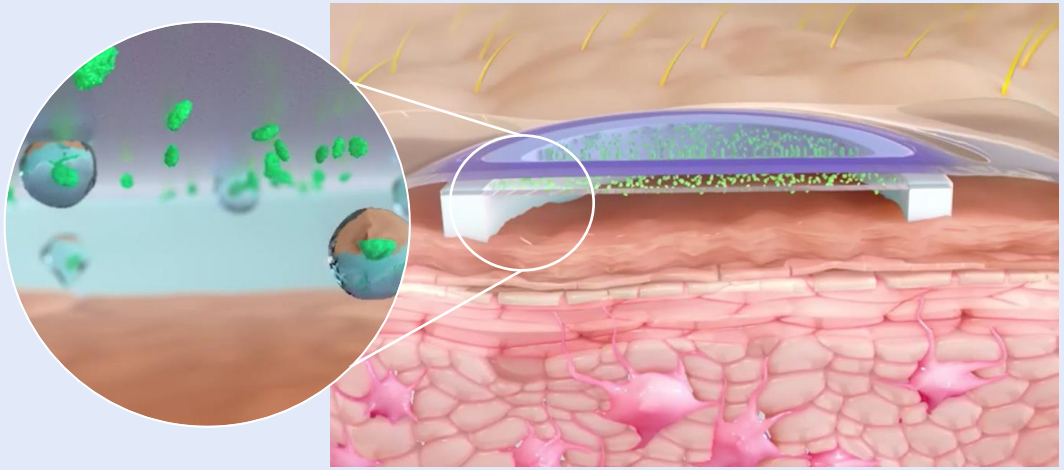
The Viaskin™ Patch: Our Innovative Approach to Epicutaneous Immunotherapy[1-3]

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

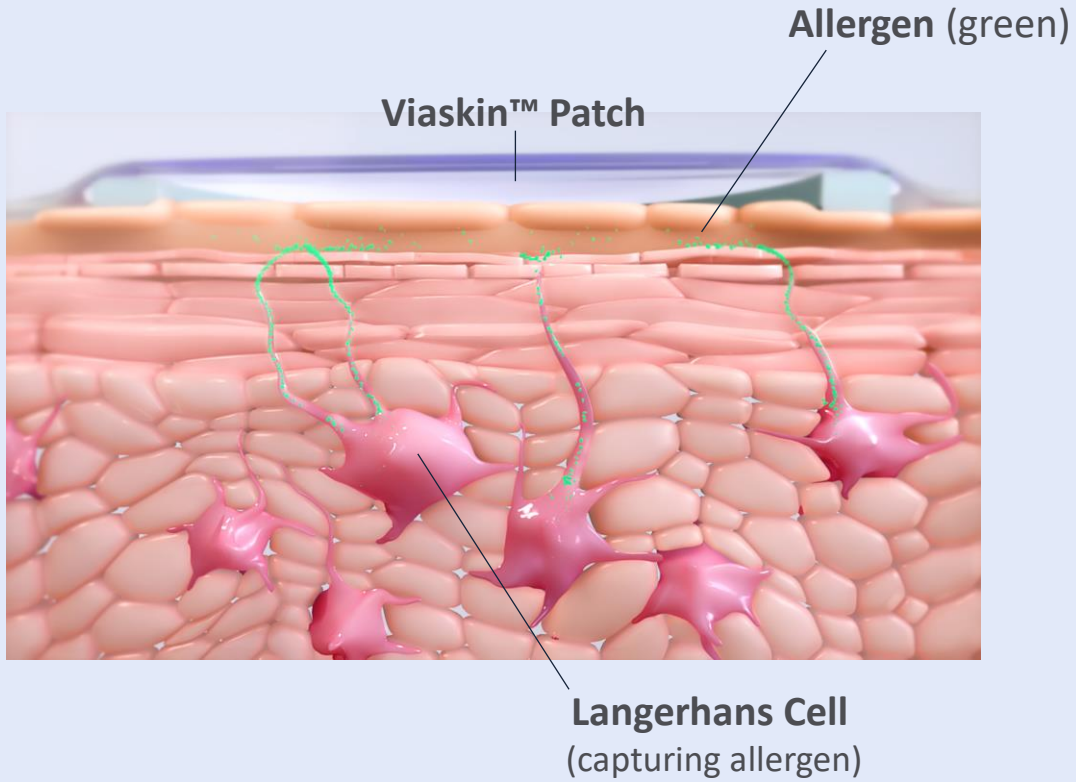
1. Dioszeghy V, et al. *J Immunol*. 2011;186:5629-5637. **2.** Mondoulet L, et al. *Immunotherapy*. 2015;7:1293-1305. **3.** Fleischer DM, et al. *Allergy Asthma Proc*. 2020; 41(5):326-335.

Viaskin™ Uses Minimal Amounts of Allergen to Induce an Immune Response[1-3]

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

Langerhans cells process the allergen, migrate to the 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

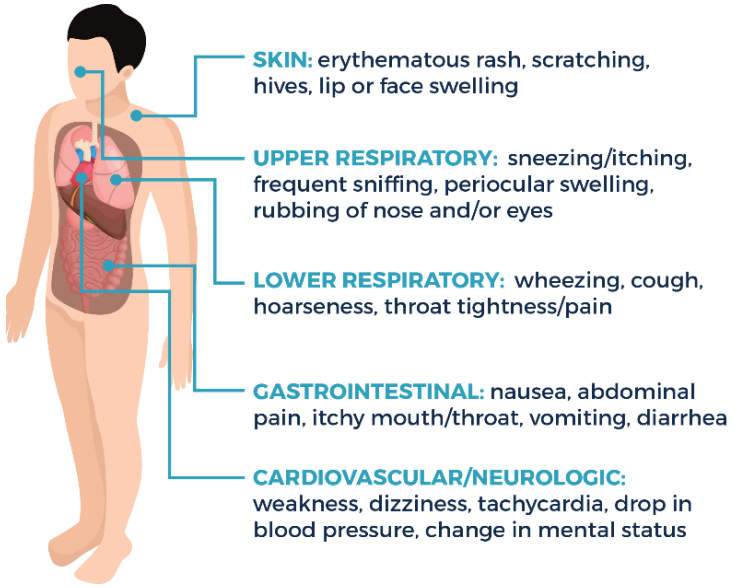


1. Dioszeghy V, et al. *J Immunol*. 2011;186:5629-5637. **2.** Mondoulet L, et al. *Immunotherapy*. 2015;7:1293-1305. **3.** Mondoulet L, et al. *Clin Transl Allergy*. 2012;2:22.

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[1]:

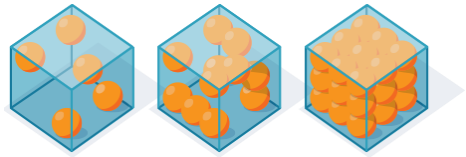


Exposure Dose

The amount of allergen accidentally ingested, determined by two factors[2]:

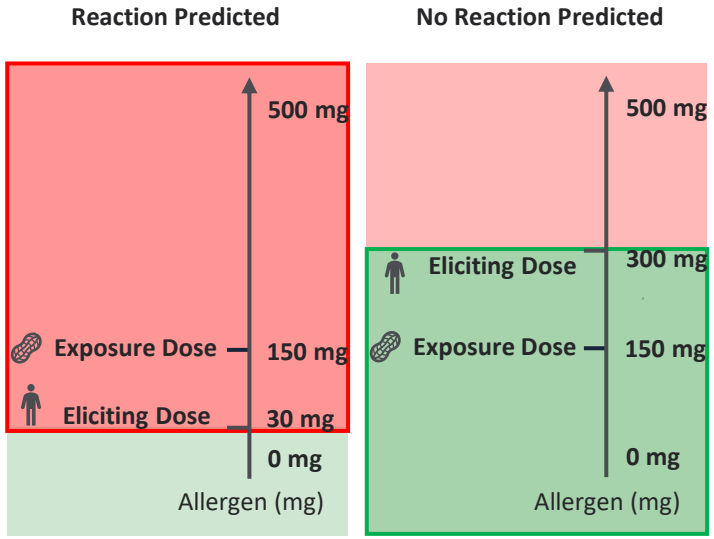
How much food was consumed?

How much allergen was present in the food?



Reaction Prediction

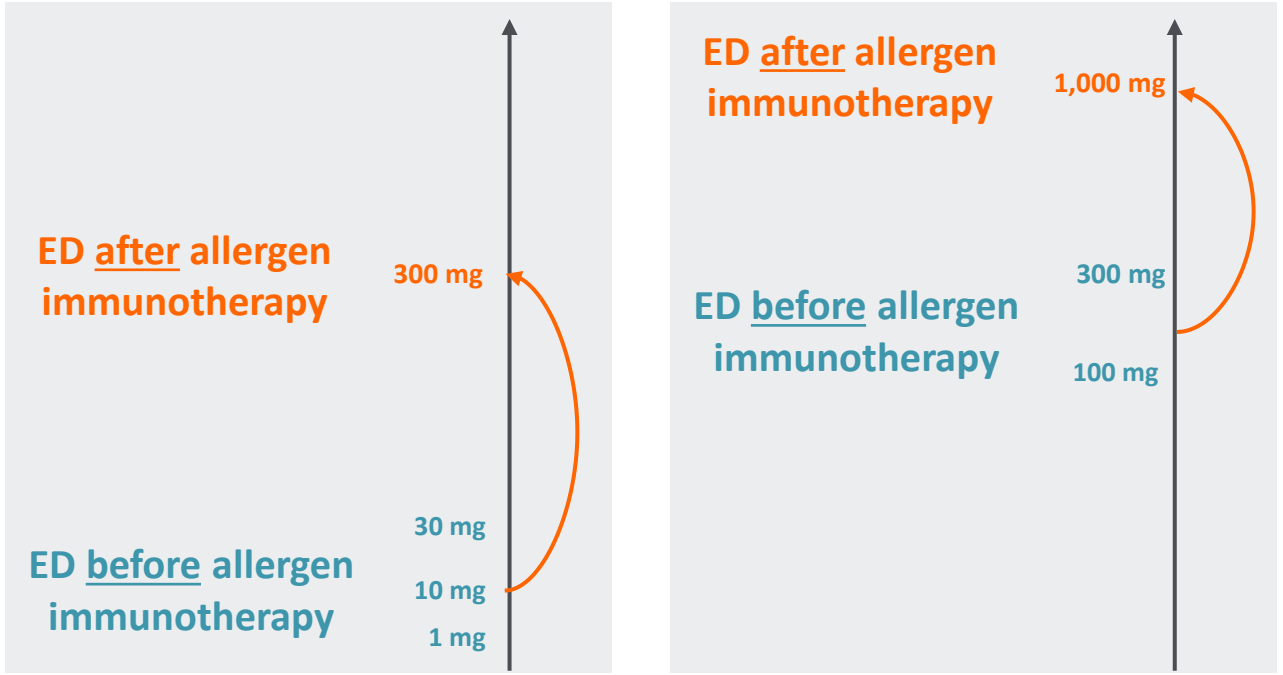
An allergic reaction is predicted to occur when a patient's eliciting dose is less than an exposure dose[3]



1. Sampson HA, et al. *J Allergy Clin Immunol*. 2012;130:1260-1274. **2.** Blom WM, et al. *Food Chem Toxicol*. 2019;125:413-421. **3.** Baumert JL, et al. *J Allergy Clin Immunol Pract*. 2018;6:457-465.e4.

Modeling* data suggest increasing a patient's eliciting dose decreases the risk of an allergic reaction[1]

Decrease in Reaction Risk Following Allergen Immunotherapy



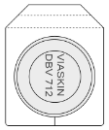
Increasing a patient's eliciting dose from **1**, **10**, or **30 mg** to **300 mg** or **100** or **300 mg** to **1,000 mg** via allergen immunotherapy is predicted to reduce their risk of an allergic reaction by **≥99%**

*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.

1. Baumert JL, et al. *J Allergy Clin Immunol Pract*. 2018;6:457-465.

Viaskin™ Peanut Clinical Development Program

Multiple Phase 3 Studies in Toddlers (Ages 1-3 Years) & in Children (Ages 4-7 Years)



TODDLERS (1-3 years)
Square (Original) Patch

EPITOPE
1-3 years of age
362* patients
12 months DBPC
Safety & Efficacy
COMPLETED

EPOPEX
Open-Label LT Follow-up
304 patients
36 months
Safety & Efficacy
ONGOING

COMFORT toddlers
1-3 years of age
~400 patients
6 months DBPC + 12 months OL
Supplemental Safety
PLANNED

CHILDREN (4-7 years)
Circular (Modified) Patch

VITESSE
4-7 years of age
~600 patients
12 months DBPC
Safety & Efficacy
ONGOING

COMFORT children
4-7 years of age
~270 patients
6 months DBPC + 12 months OL
Supplemental Safety
PLANNED

*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.
DBPC=double-blind, placebo-controlled; LT=long-term; OL=Open-Label.

Viaskin™ Peanut Program in Toddlers (1–3-Year-Olds)

Phase 3 EPITOPE: Viaskin™ Peanut 250 µg in Toddlers 1-3 Years of Age

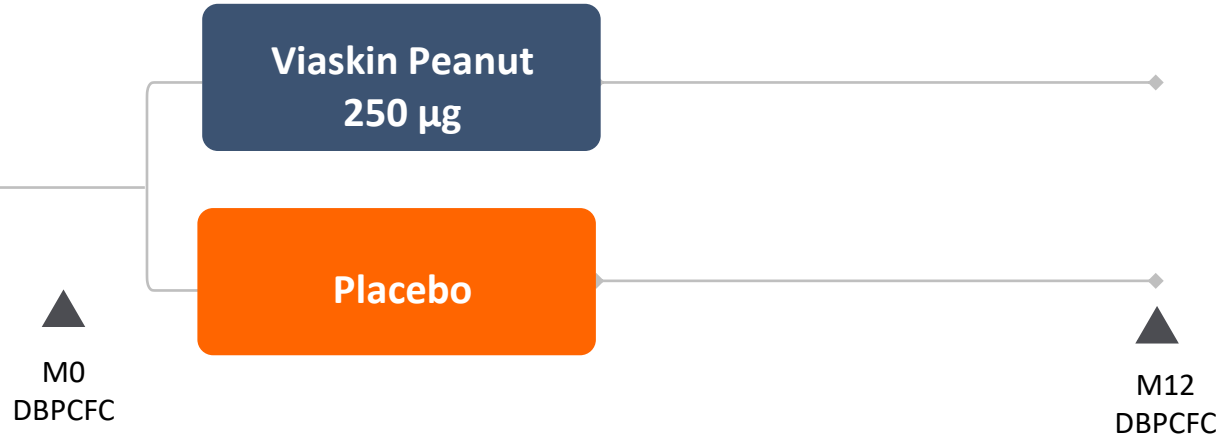
Results Published in NEJM in May 2023[1] & Presented at The American College of Allergy, Asthma and Immunology Meeting in November 2022[2]

Pivotal Global Phase 3 Trial
Randomized, double-blind, placebo-controlled

362 patients

Randomized 2:1

51 sites in US, Canada, Europe, Australia



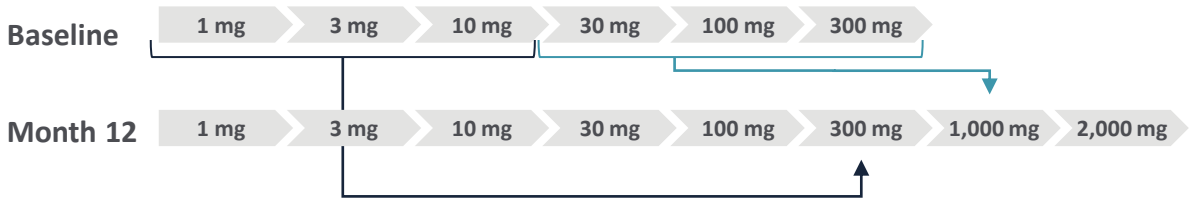
Primary endpoint:

Difference between the percentage of treatment responders in the active compared to the 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

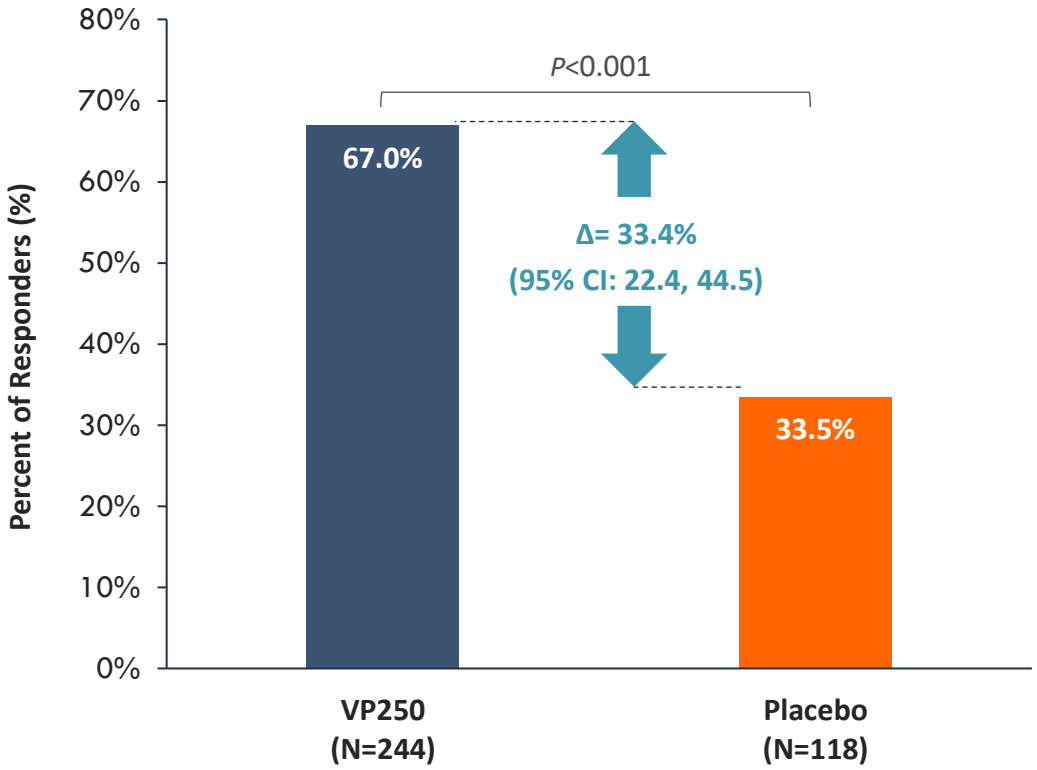
If ED >10 mg at baseline, responder if ED ≥1,000 mg at M12

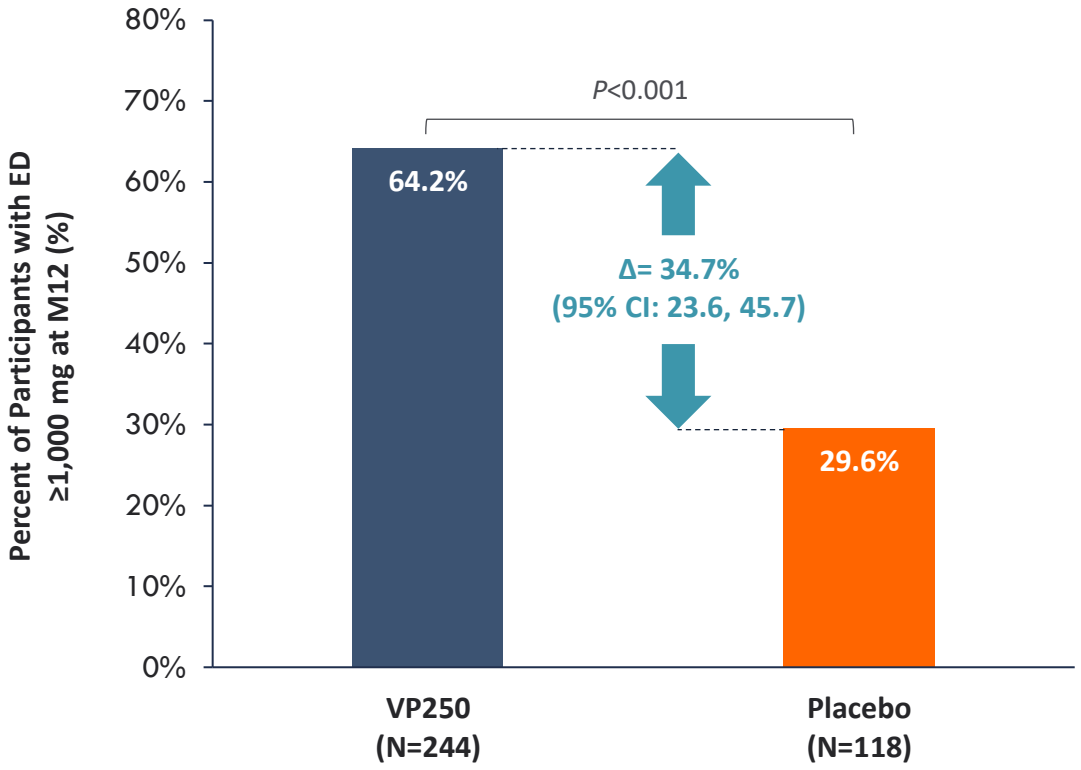


M=month; DBPCFC=double-blind, placebo-controlled food challenge; ED=eliciting dose.

1. Greenhawt M, et al. *N Engl J Med.* 2023; 388:1755-1766. **2.** EPITOPE Study Results: Phase 3, Randomized, Double-blind, Placebo-controlled Study of Epicutaneous Immunotherapy in Peanut-allergic Toddlers – Matthew Greenhawt, MD. Oral Presentation at ACAAI Annual Meeting November 2022.

Viaskin™ Peanut Demonstrated a Statistically Significant Treatment Effect[1,2]





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

Regardless of baseline ED, a statistically significantly larger percentage of participants on VP250 achieved an ED ≥1,000 mg

CI=confidence interval; ED=eliciting dose; VP250=Viaskin Peanut 250 µg.

1. Greenhawt M, et al. *N Engl J Med.* 2023; 388:1755-1766; **2.** EPITOPE Study Results: Phase 3, Randomized, Double-blind, Placebo-controlled Study of Epicutaneous Immunotherapy in Peanut-allergic Toddlers – Matthew Greenhawt, MD. Oral Presentation at ACAAI Annual Meeting November 2022.

Phase 3 EPITOPE: Viaskin™ Peanut 250 µg in Toddlers 1-3 Years Of Age

Results Published in NEJM May 11, 2023[1]


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy

LINK to NEJM ARTICLE

Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy


The NEW ENGLAND JOURNAL of MEDICINE

Good News for Toddlers with Peanut Allergy

Alkis Togias, M.D.

LINK to NEJM EDITORIAL:

Good News for Toddlers with Peanut Allergy

LINK to NEJM VIDEO highlighting key findings: NEJM QuickTake

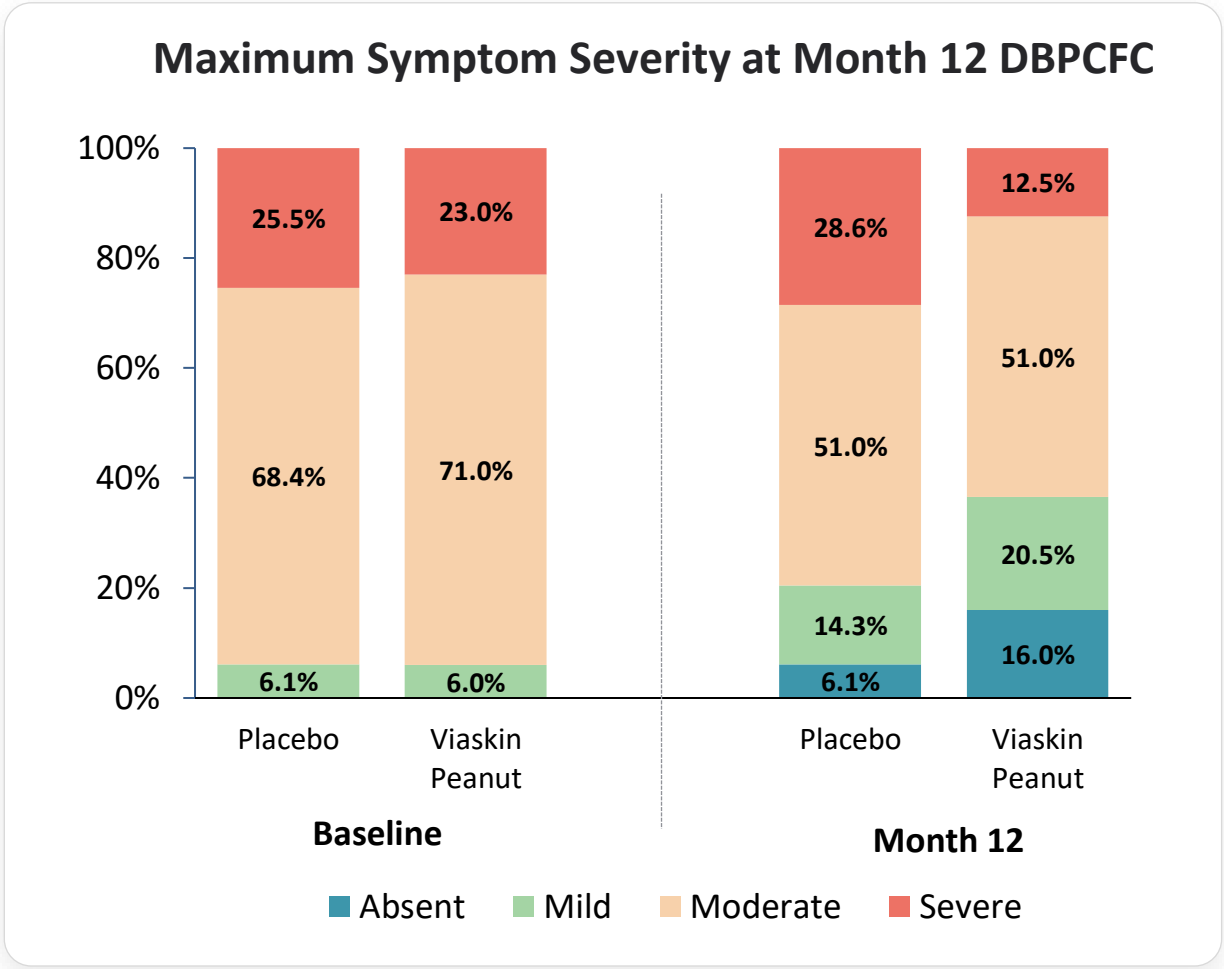
1. Greenhawt M, et al. *N Engl J Med.* 2023; 388:1755-1766.

Shift Toward Reduction in Symptom Severity Following 12 Months of Viaskin™ Peanut Treatment[1,2]

At baseline double-blind, placebo-controlled food challenge (DBPCFC), the proportions of maximum symptom severity were balanced between groups.

At Month 12, the distribution of maximum symptom severity was significantly shifted toward less severe symptoms in the original Viaskin™ Peanut 250 µg patch treated group relative to placebo (P<0.001).

This shift toward a reduction in symptom severity coincided with an increase in eliciting dose and a greater proportion of responders in the original Viaskin™ Peanut 250 µg patch treated group versus the placebo group.



CI=confidence interval; ED=eliciting dose; ITT=intent to treat population; M=month; VP250=Viaskin Peanut 250 µg.

1. Greenhawt M, et al. *N Engl J Med.* 2023; 388:1755-1766. **2.** Reduction in Reaction Severity Following 12 Months of Epicutaneous Immunotherapy with Peanut Patch in Toddlers – Terri Brown-Whitehorn, MD. Poster Presentation at ACAAI Annual Meeting November 2022.

EPITOPE Safety Summary[1,2]

Safety Profile Consistent with Prior Viaskin™ Peanut Studies

	VP250 vs Placebo
Local Application Site Reactions: *primarily mild to moderate that decreased in frequency with time*	**99.6% vs 94.1%**
Serious Adverse Events	**8.6% vs 2.5%**
Serious Adverse Events related to IMP: *1 case of mild periorbital edema*	**0.4% vs 0%**
Adverse Events leading to study discontinuation	**3.3% vs 0%**
Anaphylactic reaction related to IMP: *no severe events (3 moderate and 1 mild)*	**1.6% vs 0%**
Any Adverse Event leading to epinephrine intake considered related to IMP	**1.2% vs 0%**

IMP=investigational medicinal product; VP250=Viaskin Peanut 250 µg.

1. Greenhawt M, et al. *N Engl J Med.* 2023; 388:1755-1766. 2. EPITOPE Study Results: Phase 3, Randomized, Double-blind, Placebo-controlled Study of Epicutaneous Immunotherapy in Peanut-allergic Toddlers – Matthew Greenhawt, MD. Oral Presentation at ACAAI Annual Meeting November 2022.

Regulatory Pathway for Viaskin™ Peanut in Toddlers Outlined

No Requirement from FDA for Additional Efficacy Study – Supplemental Safety Trial To Be Initiated

April 2023: Pre-BLA Type B Meeting Written Responses from FDA[1]

- ✓ **FDA did not request an additional efficacy study in 1-3-year-olds –** primary endpoint was met in EPITOPE
- ✓ **Agreement on a SUPPLEMENTAL safety study (COMFORT Toddlers)** using the square Viaskin™ Peanut patch to augment safety data collected from EPITOPE and have ~600 patients on active treatment in safety database

July 2023: Type C Meeting Written Responses from FDA on COMFORT Toddler Study Design[2]

- ✓ **FDA feedback on key study design elements:**
  - Double-blind placebo-controlled, 6-month duration
  - No food challenge required
  - Study to include ~400 subjects (total) to bring total number of toddlers close to 600 on active treatment
  - 3:1 randomization (active:placebo)

BLA=Biologics License Application.

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

Next Steps To Advance Viaskin™ Peanut Toddlers Program

Seek Alignment with FDA on Final Protocol Before Initiation of COMFORT Toddlers

- Finalization of COMFORT Toddlers protocol
- DBV expects to submit the final COMFORT Toddlers protocol to the FDA to seek final alignment prior to commencing COMFORT Toddlers
- In parallel, DBV continues to actively progress appropriate start-up activities (e.g., site feasibility, contracting) for COMFORT Toddlers to enable efficient study initiation

Viaskin™ Peanut Program in Children (4-7-year-Olds)

Regulatory History for Viaskin™ Peanut in Children 4 Years and Older

Efficacy Study (VITESSE) in Progress – Supplemental Safety Trial (COMFORT Children) To Be Initiated

1 **August 2020**: FDA Issued a CRL Regarding the BLA for Viaskin™ Peanut in **4-11 Year Olds**[1]

Concerns raised on the impact of patch adhesion on efficacy and the need for patch modifications

2 Based on adhesion data collected from a Phase 1 trial of five modified patches conducted in healthy adult volunteers[2], DBV selected the CIRCULAR Viaskin™ Peanut patch

3 **DBV determined the most efficient approach to demonstrate efficacy, safety, & improved adhesion of the modified CIRCULAR Viaskin™ Peanut patch is a new, Phase 3 placebo-controlled efficacy trial in 4–7-year-olds, VITESSE**[3]

4 **May 2022**: Type C Written Response from FDA on VITESSE Study Protocol in **4-7 Year Olds**

- Modeled on the Phase 3 PEPITES pivotal study conducted in 4–11-year-olds
- **A supplemental Safety Study (COMFORT Children) is required to augment safety data in VITESSE** (increase total number of subjects to ~600 on active treatment, across both studies)

5 **July 2023**: Type C Meeting Written Responses from FDA on COMFORT Children Protocol[4]

✓ **FDA feedback on key study design elements:**

- Double-blind placebo-controlled, 6-month duration, no food challenges required, N=~400, 3:1 randomization, as previously agreed to (Type C Written Response; May 20, 2022)
- Confirmed other protocol elements related to inclusion/exclusion criteria and collecting adhesion data

VITESSE

COMFORT children

CRL=Complete Response Letter; BLA=Biologics License Application;

1. DBV Technologies Press Release August 4, 2020. **2.** DBV Technologies Press Release August 2, 2021. **3.** DBV Technologies Press Release December 20, 2021. **4.** DBV Technologies Press Release July 31, 2023.

VITESSE Is Designed for Younger, More Allergen-Sensitive Patients, Ages 4-7 years

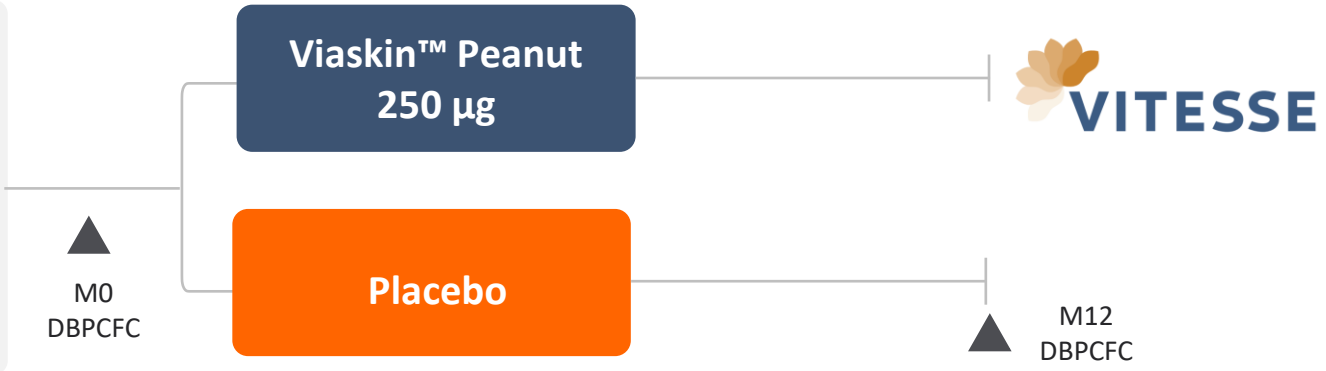
VITESSE Study Designed to Support the Agency's Review of a Potential BLA for Viaskin™ Peanut as a Peanut Allergy Treatment*

Global Phase 3 Trial
Randomized, double-blind, placebo-controlled

~600 patients aged 4-7 years; Randomized 2:1

Inclusion Criterion Baseline ED ≤100 mg

~80 sites in US, Canada, Europe, Australia

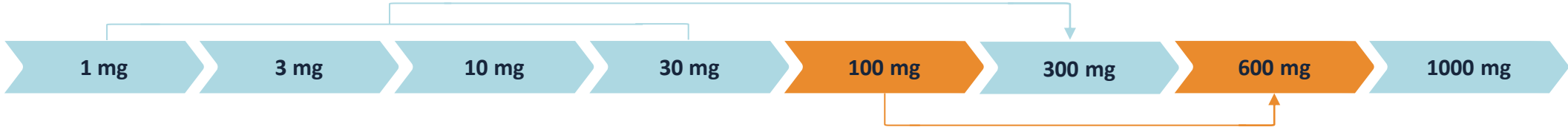


Primary endpoint:

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



*Following discussion with FDA due to Partial Clinical Hold (lifted in December 2022; DBV Technologies Press Release December 23, 2022). Note that inclusion criteria, primary efficacy endpoint, responder criteria, efficacy assessment methodology and safety endpoints were not impacted by the Partial Clinical Hold letter and remain unchanged from the initial VITESSE protocol.
DBPCFC=double-blind, placebo-controlled food challenge; M=month; ED=eliciting dose.

Regulatory Path for Viaskin™ Peanut in Children (4-7 Years) Outlined

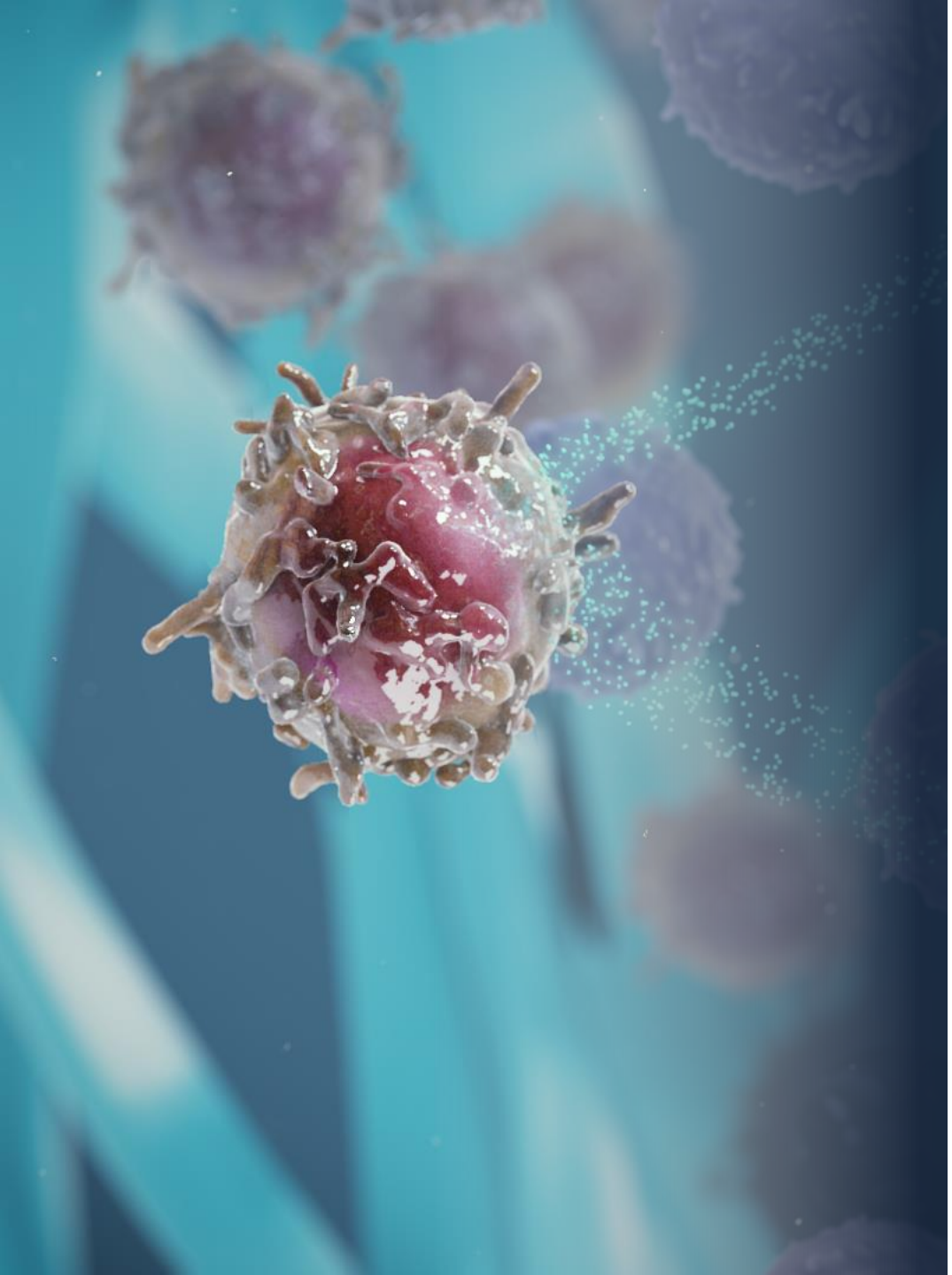
Seek Alignment with FDA on Final Protocol Before Initiation of COMFORT Children

- Phase 3 Efficacy Study VITESSE in 4–7-year-olds is currently enrolling
- Finalization of protocol for COMFORT Children
- DBV expects to submit the final COMFORT Children protocol to the FDA to seek final alignment prior to commencing the study (as with COMFORT Toddlers)
- Start-up activities will be aligned to VITESSE recruitment to ensure timely enrollment for both studies

Our Long-Term Vision Is to Realize the Full Potential of the Viaskin™ Platform

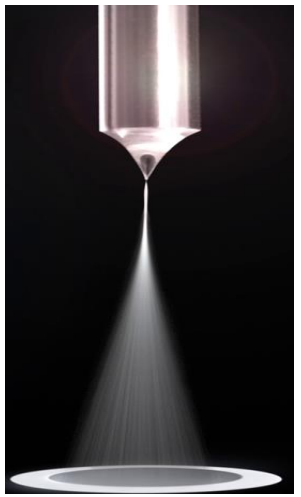
Program	Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3
Viaskin Milk *(DBV135) – Cow's Milk Allergy* *MILES: Ages 2-17 years*					
Viaskin Milk *(DBV135) – Eosinophilic Esophagitis (EoE)* *SMILEE: Ages 4-17 years*					
Non-IgE Mediated Cow's Milk Allergy Diagnostics Tool (DBV1605) with Nestlé Health Science (APTITUDE: 6 months to 5 years)					
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; APTITUDE=Diagnostic Accuracy and Safety of DBV1605 for the Diagnosis of Non-IgE Mediated Cow's Milk Allergy in Children.



We Aim to Unlock the Powerful Immune Properties of the Skin with our Viaskin™ Platform

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



Patented Patch Manufacturing Capabilities

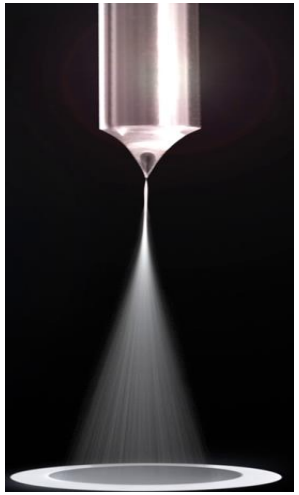
Integrated End-to-End Patch Manufacturing in Place

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



Robust Intellectual Property Portfolio

IP Covers:	
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
Specific indications	EPIT peanut, EoE, vaccines, etc.
Regulatory exclusivity	Up to 12 years of biologic exclusivity, if approved
Broad Geographic Coverage	Including US, Europe, Australia and Canada
Key patent expiries	Through 2035
Patent	Innovation-driven patent lifecycle management

$174M

in cash and cash equivalents as of June 30th, 2023

Anticipated Near-Term Milestones

Seek Alignment from FDA on Final COMFORT protocols

2023 Q3 Financial Results

Publication of EPITOPE Data Analyses (Including Adhesion Data)

Continue to Advance VITESSE Enrollment

Investment Highlights

Two Distinct Opportunities for Viaskin™ Peanut

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 (Phase 3 Study) Met Primary Endpoint
- Agreement with FDA for a 6-Month Supplemental Safety Study (COMFORT Toddlers)

4–7-year-olds

- Ongoing Phase 3 Pivotal Trial (VITESSE) Informed from Prior Phase 3 Trial (PEPITES) in 4–11-Year-Olds
- Agreement with FDA for a 6-Month Supplemental Safety Study (COMFORT Children)

Anticipated Clinical & Regulatory Milestones

1–3-year-olds

COMFORT Toddlers:

- FDA Alignment on Protocol
- First Patient Enrolled
- Topline Results

4–7-year-olds

VITESSE:

- Completion of Enrollment
- Topline Results

COMFORT Children:

- FDA Alignment on Protocol
- First Patient Enrolled

Financial Position

$174M

of Cash and Equivalents as of June 30, 2023

EPIT™ and DBV's Viaskin™ technology platform 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.

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

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

CHILDREN (4-11 years)
Square (Original) Patch

Pepites
356 patients
12 months DBPC
Safety & Efficacy
COMPLETED

PEOPLE
Open-Label LT Follow-up
298 patients
60 months DBPC
Safety & Efficacy
COMPLETED

REALISE
393 patients
6 months DBPC + 36 months OL
Real Life Use & Suppl Safety
COMPLETED

EPIT=epicutaneous immunotherapy; LT=long-term; OL=Open-Label; PEOPLE=PEPITES Open Label Extension Study; PEPITES=Peanut EPIT Efficacy and Safety Study; REALISE=Real Life Use and Safety of EPIT.

Phase 3 PEPITES/PEOPLE: Viaskin™ Peanut 250 µg in Children 4–11 Years Of Age

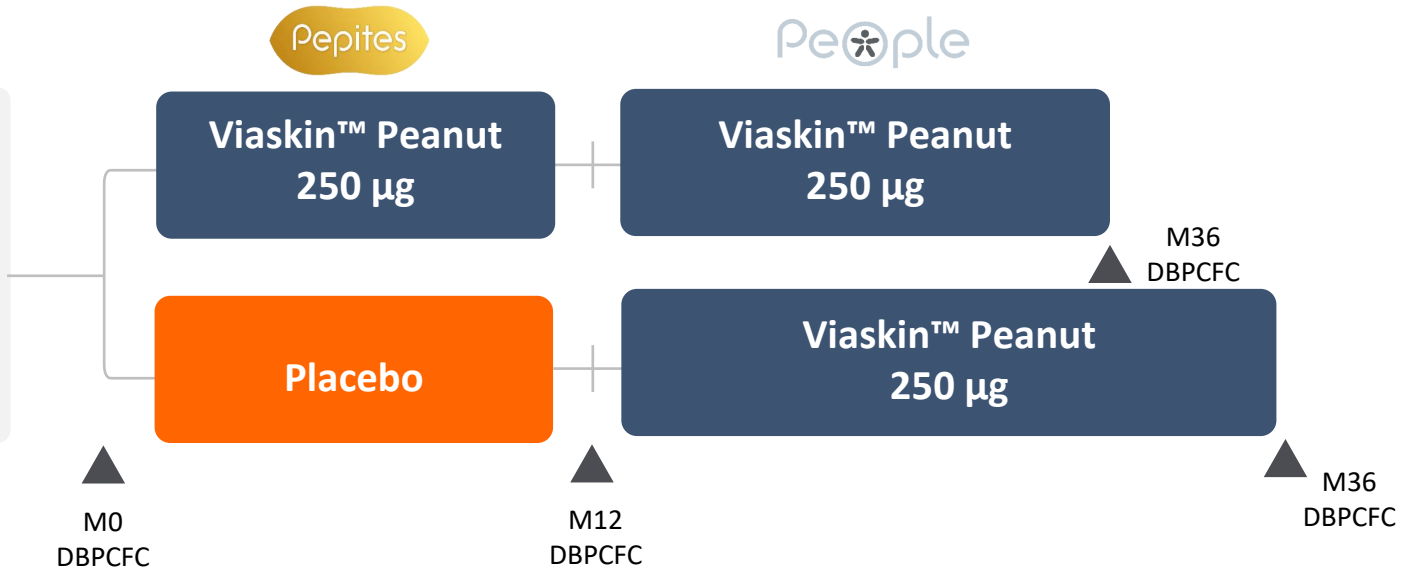
Results published in peer-reviewed publications JAMA (PEPITES)[1], Journal of Allergy & Clinical Immunology (PEOPLE)[2]

Global Phase 3 Trial
Randomized, double-blind, placebo-controlled

356 patients* aged 4-11 years; Randomized 2:1

298 rolled over into PEOPLE

~31 sites in US, Canada, UK, Europe, Australia



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 ≥1,000 mg after 24 months of additional treatment in PEOPLE

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

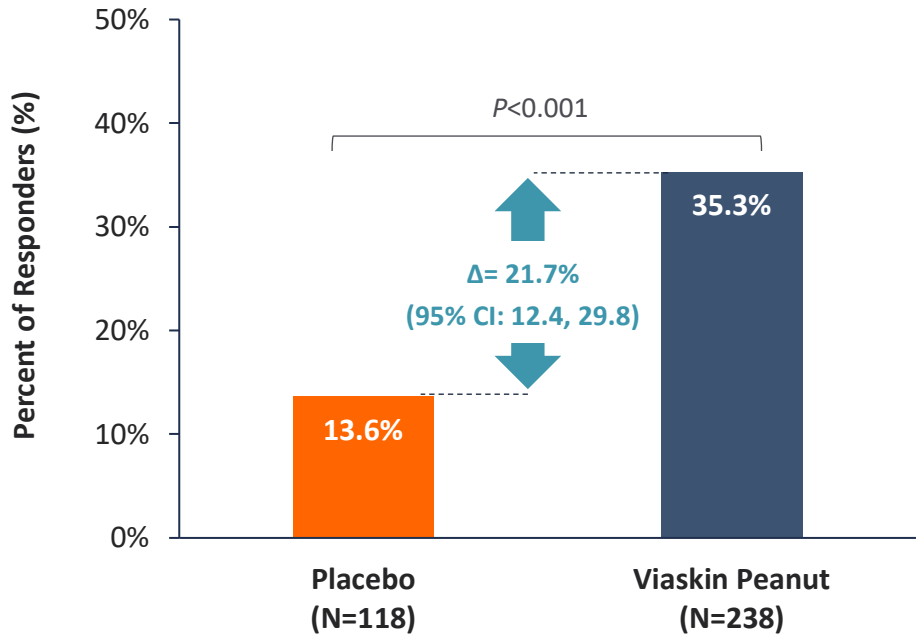
*Confirmed peanut allergy by SPT ≥6 mm for 4- to 5-year-olds or ≥8 mm for 6- to-11-year-olds and sIgE levels (>0.7 kUA/L).
DBPCFC=double-blind, placebo-controlled food challenge; ED=eliciting dose.

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

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

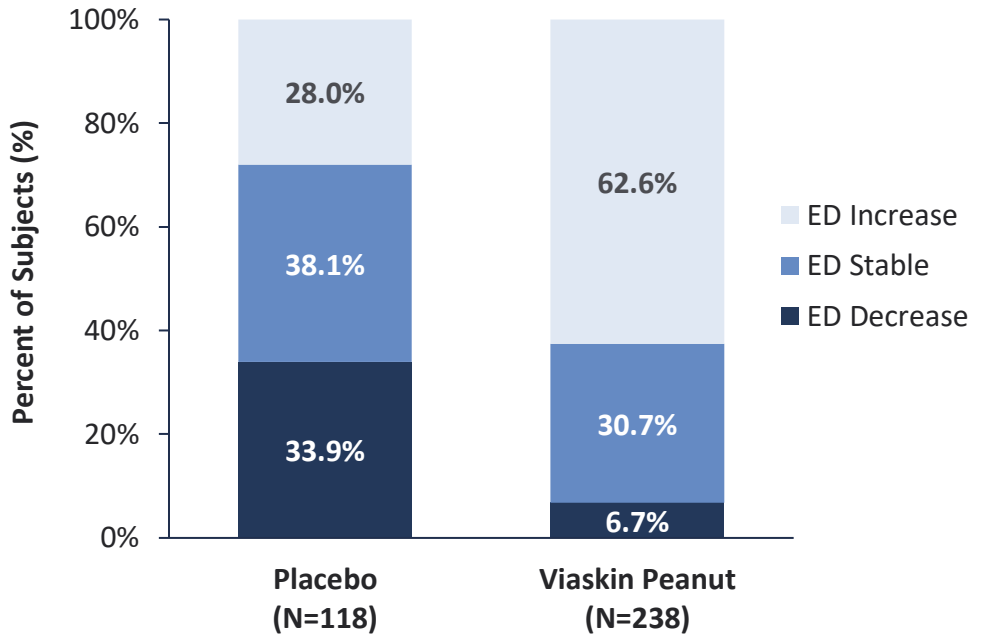
Primary efficacy outcome showed statistically significant treatment benefit

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*

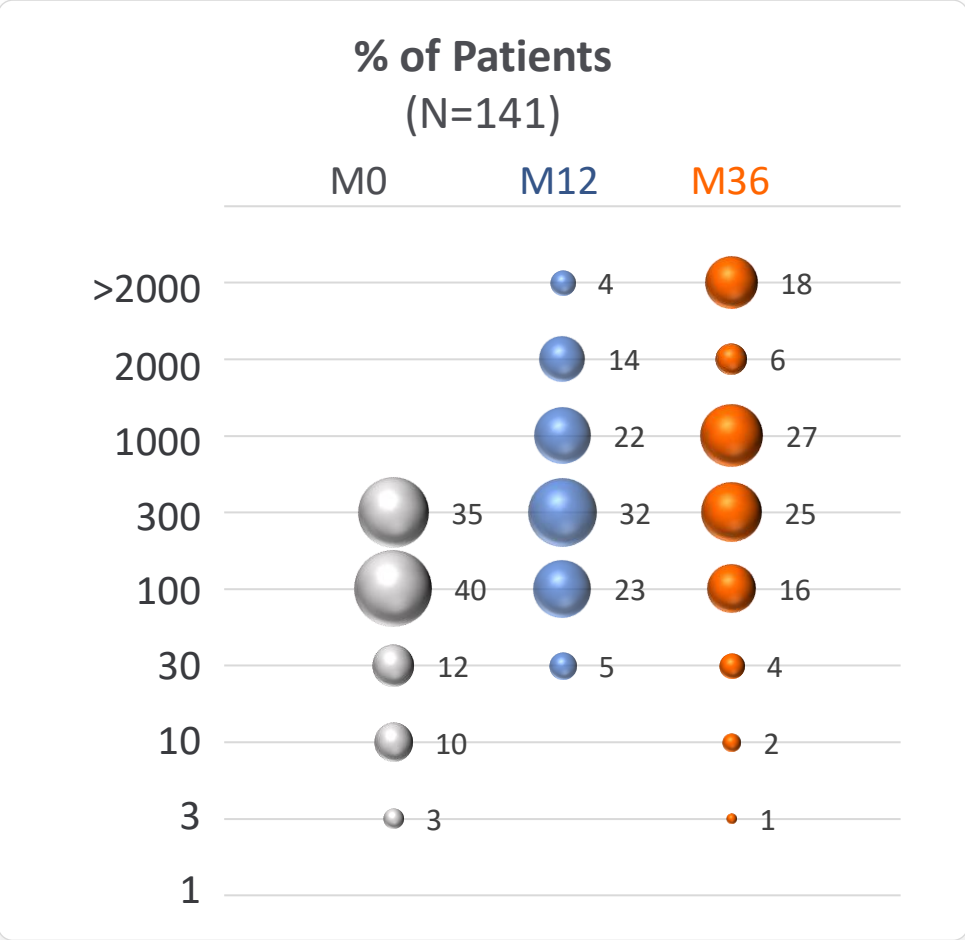


An increase in ED was >4 times more likely to occur in the Viaskin™ Peanut group compared with placebo

*Based on ITT population; missing data calculated using mBOCF. DBPCFC=double-blind, placebo-controlled food challenge; ED=eliciting dose.

1. Fleischer DM, et al. *JAMA.* 2019;321:946-955.

Changes in ED Maintained or Improved Over 3 Years in the Majority of Subjects in the Open-Label Extension Study[1]



51.8% of subjects reached an ED of ≥1,000 mg at Month 36, compared to 40.4% at Month 12

75.9% of subjects demonstrated an increase in ED from baseline to Month 36

13.5% of subjects were able to tolerate the full DBPCFC of 5,444 mg (~18 peanuts) at Month 36

77.8% (14/18) of subjects who completed the oral food challenge at Month 38 maintained desensitization with an ED ≥1,000 mg*

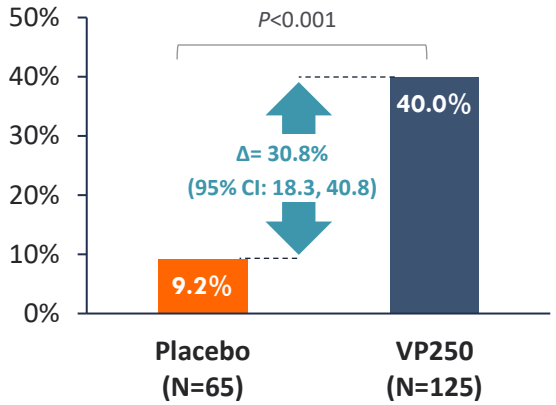
Food Allergy Quality of Life (QoL) Assessment in PEPITES, PEOPLE[2]

Based on validated food allergy QoL questionnaires, children experienced statistically significant QoL improvements after 2 years of Viaskin™ Peanut treatment

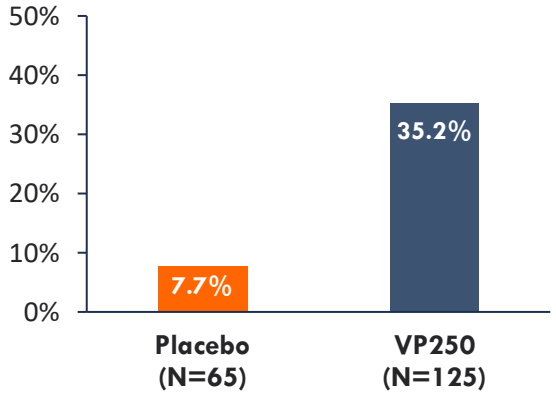
ED=eliciting dose; DBPCFC=double-blind, placebo-controlled food challenge.
*All participants who reached an ED ≥1,000 mg at Month 36 were eligible to continue the study for two additional months without treatment while maintaining a peanut-free diet. A further DBPCFC to determine ED was administered at the end of this period (Month 38). Similar sustained unresponsiveness results were reported in Phase 2b program (Sampson HA, et al. *JAMA*. 2017;318:1798-1809).
1. Fleischer DM, et al. *J Allergy Clin Immunol.* 2020;146:863-874. **2.** DunnGalvin A et al. *J Allergy Clin Immunol Pract*. 2021;9:216-224.e1.

Post-Hoc Analysis of PEPITES Data Supports Concept That Greater Gains in Desensitization May be Achieved in Younger vs Older Children[1]

Treatment Responders
Children Ages 4-7 Years



ED ≥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 250 µg (VP250) versus placebo was demonstrated

- **40.0% of subjects in the Viaskin™ 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™ 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™ Peanut 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

1. Efficacy of Epicutaneous Immunotherapy with Viaskin™ Peanut for 4–7-Year-Old Peanut-Allergic Children in a Phase 3 Clinical Trial (PEPITES). David Fleischer, MD Presented at Canadian Society for Allergy and Clinical Immunology Annual Meeting, September 2022.

Pooled Safety Data from Phase 3 Studies of Viaskin™ Peanut[1]

749 subjects included in the overall pooled safety analyses, including 630 subjects treated with Viaskin 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™ 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"[1]

*Identified through the algorithm of the Anaphylactic Reaction SMQ (Standardized MedDRA [Medical Dictionary for Regulatory Activities] Queries).
TEAE=treatment-emergent adverse event.

1. Pooled Safety Data from Phase 3 Studies of Epicutaneous Immunotherapy for Peanut Allergy in Children Aged 4-11 Years – Rachel Robison, MD. Presented at presented at AAAAI Annual Meeting, February 2022.

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

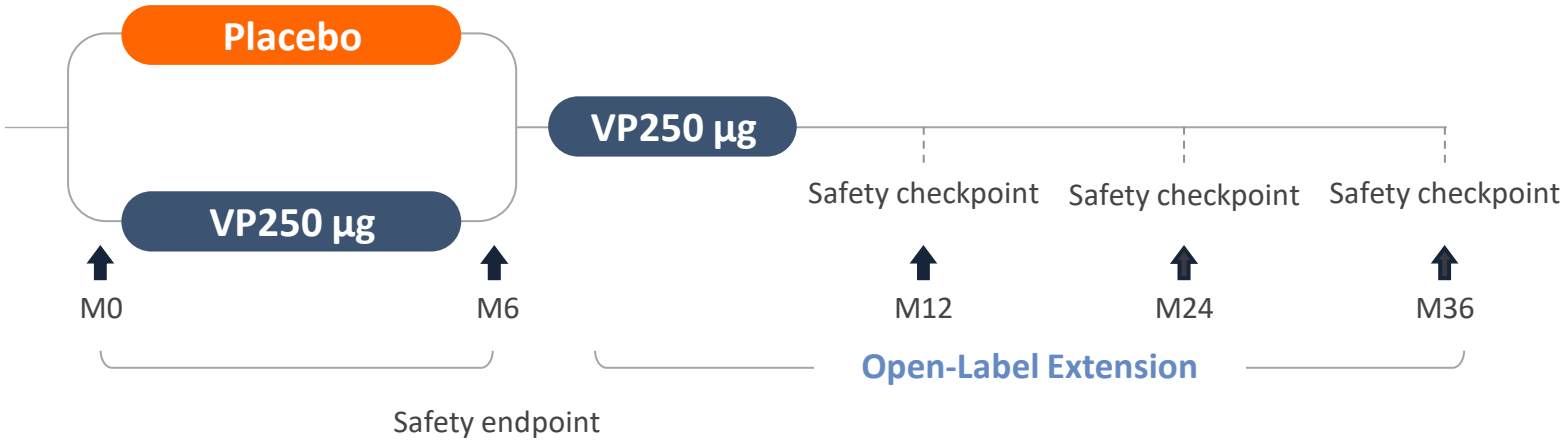
Children 4–11 years

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 was tolerated with no new or unexpected AEs[1]
- 36-month data show similar long-term safety profile in peanut-allergic children consistent with previous clinical trials[2]

AE=adverse event; IgE=immunoglobulin; sIgE=specific immunoglobulin E; SPT=skin prick test; VP250=Viaskin Peanut 250 µg; M=month.

1. Pongracic JA, et al. *J Allergy Clin Immunol Pract*. 2022 Jul;10(7):1864-1873.e10. **2.** Pongracic JA, et al. Presented at the American Academy of Allergy Asthma and Immunology, 2020.