



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



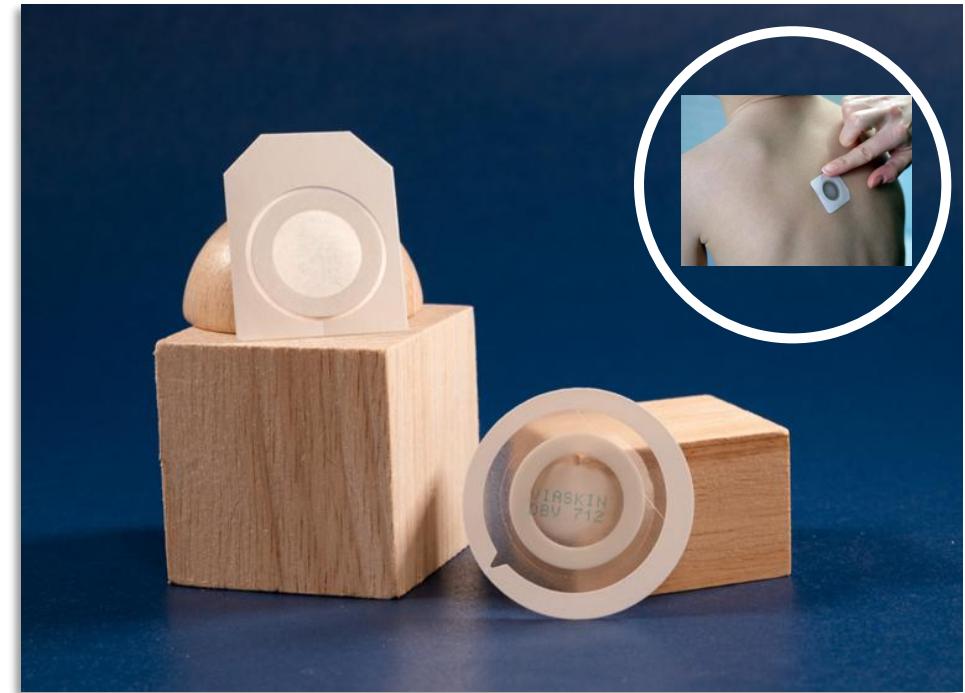
Pioneered VIASKIN® patch technology
DBV's novel approach to epicutaneous immunotherapy



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)



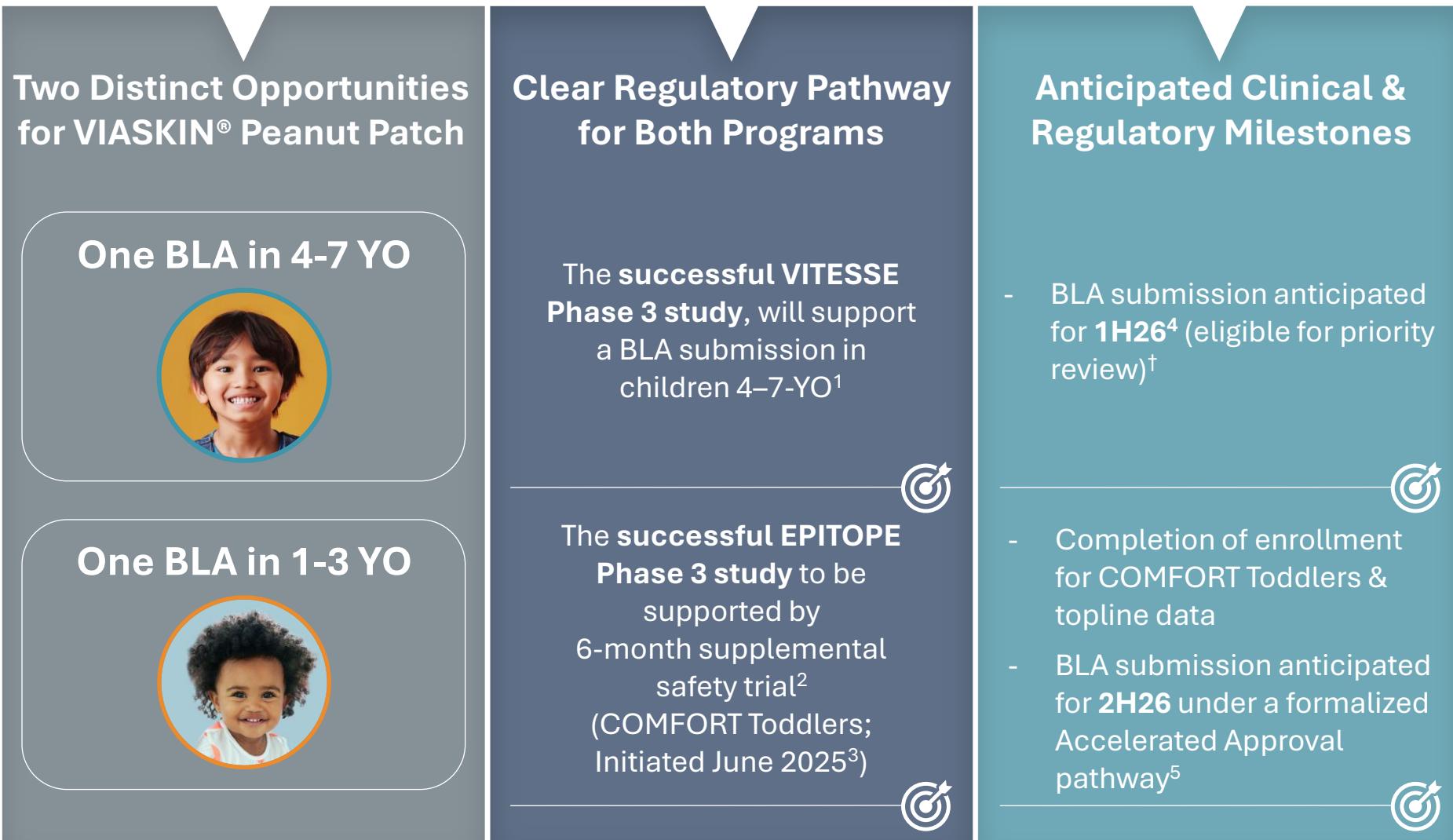
Science-driven leadership team with deep regulatory & commercial experience



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



Regulatory Overview (US)





Significant Market Opportunity for VIASKIN® Peanut Patch

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



1-3 years old

280,000 Toddlers¹⁻³



4-7 years old

390,000 Children¹⁻³

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.



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

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



Square and Circular VIASKIN® peanut patches have the same condensation chamber (foam ring & dose). Patches differ only in the size (circular patch is ~50% larger) and shape of the overlay

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

Under Accelerated Approval Pathway¹

Accelerated Timeline for BLA Submission²



Anticipated Near-Term Milestones

Upcoming Milestones & Catalysts Anticipated in 2026



CHILDREN (4-7 years)

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

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 2026¹





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

The unmet need for peanut allergy in Europe is significant:

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

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

3

DBV 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 11/17/25¹

92%

of peanut allergy cases
emerge by age of 7²; ~80%
are lifelong³

41%

have an accidental exposure
within 3 years of diagnosis⁴

- ✓ Reactions unpredictable and can be life-threatening
- ✓ Annual economic impact \$25B⁵; impact to quality of life for caregivers/children⁶
- ✓ 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 Families¹⁻⁴



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



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



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



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



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

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



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



Omalizumab (anti-IgE Monoclonal Antibody)[#]



Fear of injection:

- Requires injection(s) 1-2 times per month^{4,5}
- Potentially painful injection site reactions⁵



Not disease modifying⁴

- Patient needs to continue therapy indefinitely

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

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

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

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



Potential Benefits of Epicutaneous Immunotherapy with VIASKIN® Peanut Patch

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

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



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



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

PEANUT ALLERGY MARKET DYNAMICS



The Patients

670K Children

ages 1 to 7 years old ^{1,2}

DBV will leverage its strong
relationships with Advocacy Groups



The Prescribers

4,500 Allergists

in the US^{1,2}

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 3 regional meetings with allergist MD/DOs - 1 per MSL region
- Assume up to 1 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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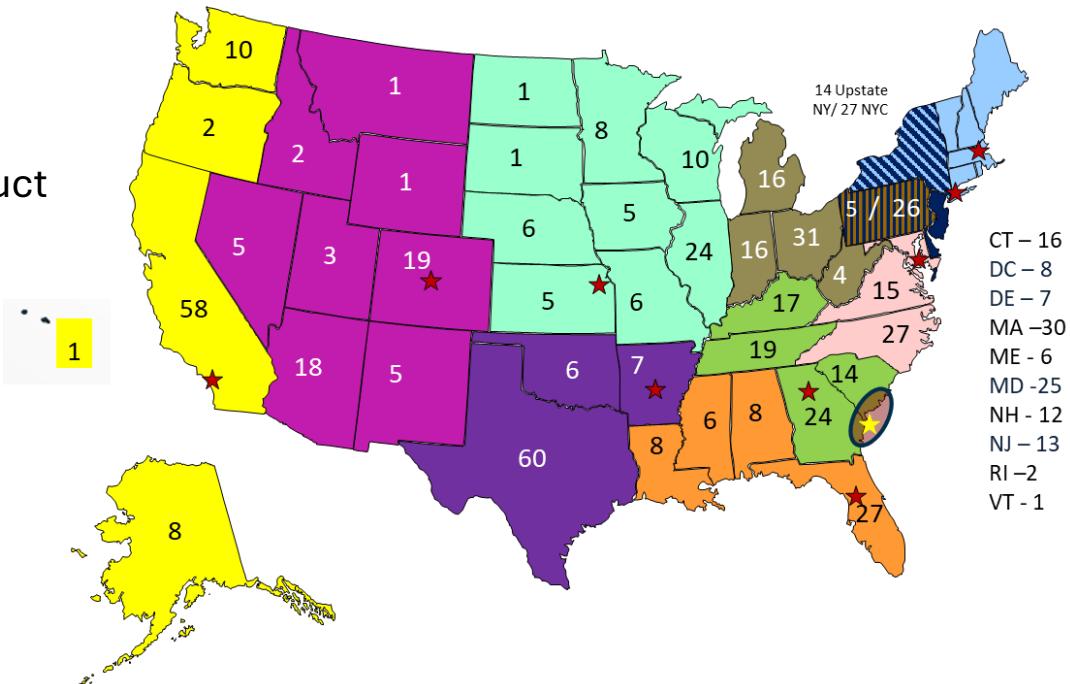
Assembling a Launch Excellence Advisory Board

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[†]



†. Subject to modification

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:

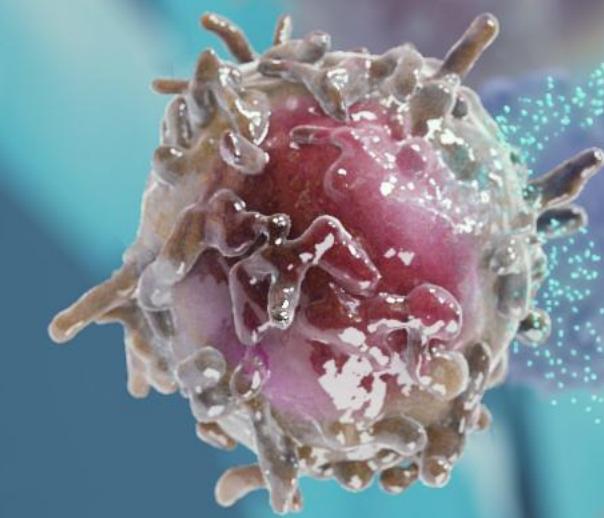
Allergists see a significant role for VP, as a complement with avoidance and epi to desensitize EARLY in a child's life

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:

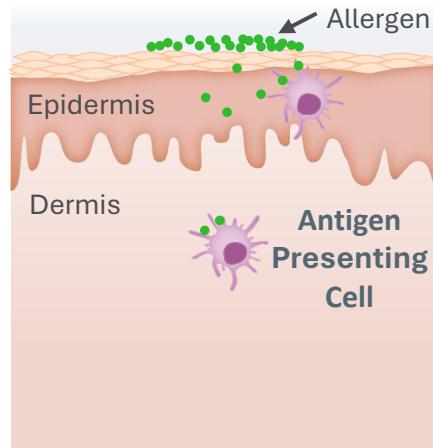
Payer dynamics and early research suggest favorable access and value potential for VIASKIN Peanut



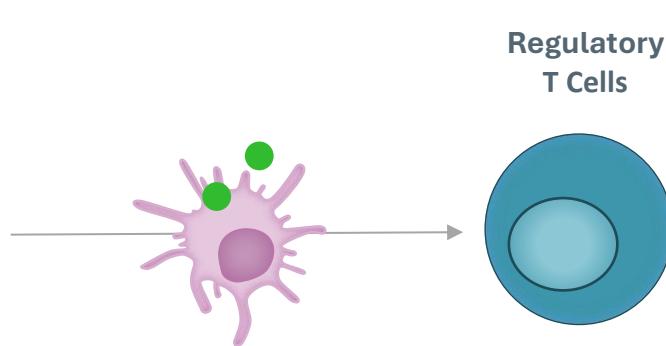
THE SCIENCE OF EPICUTANEOUS IMMUNOTHERAPY (EPIT)

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

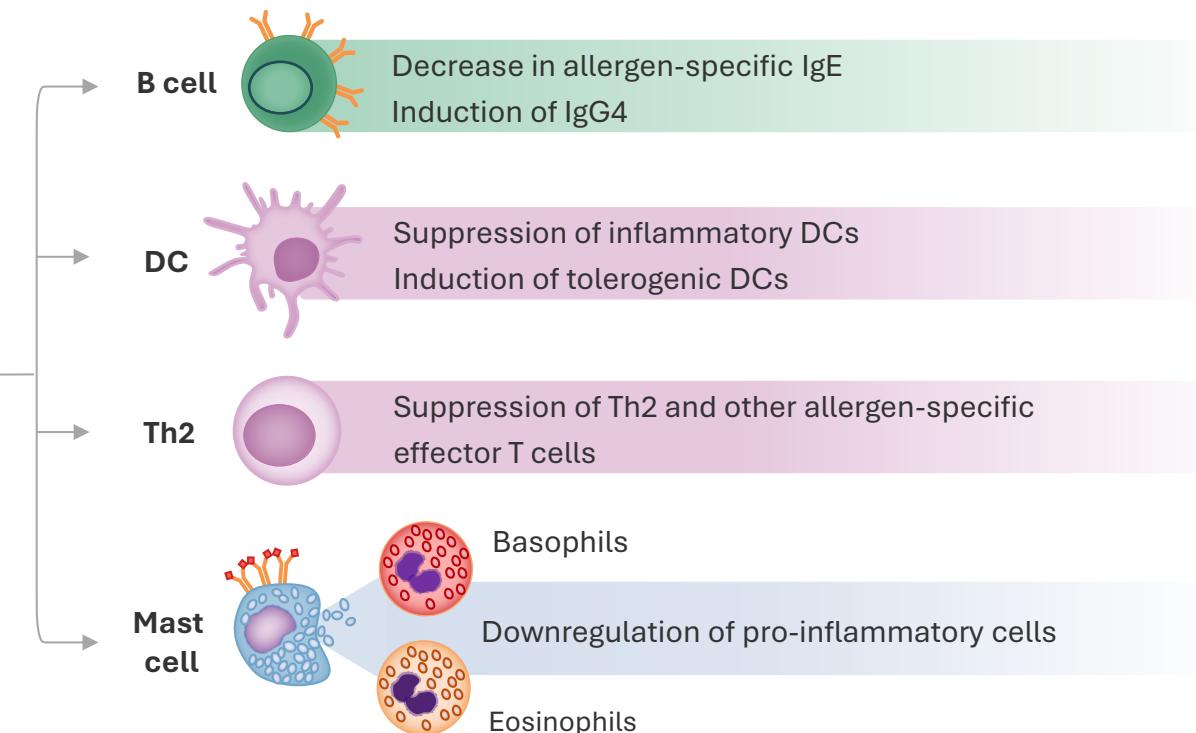
EPIT delivers allergen to the skin



Antigen Presenting Cells capture allergen and induce unique Regulatory T Cells



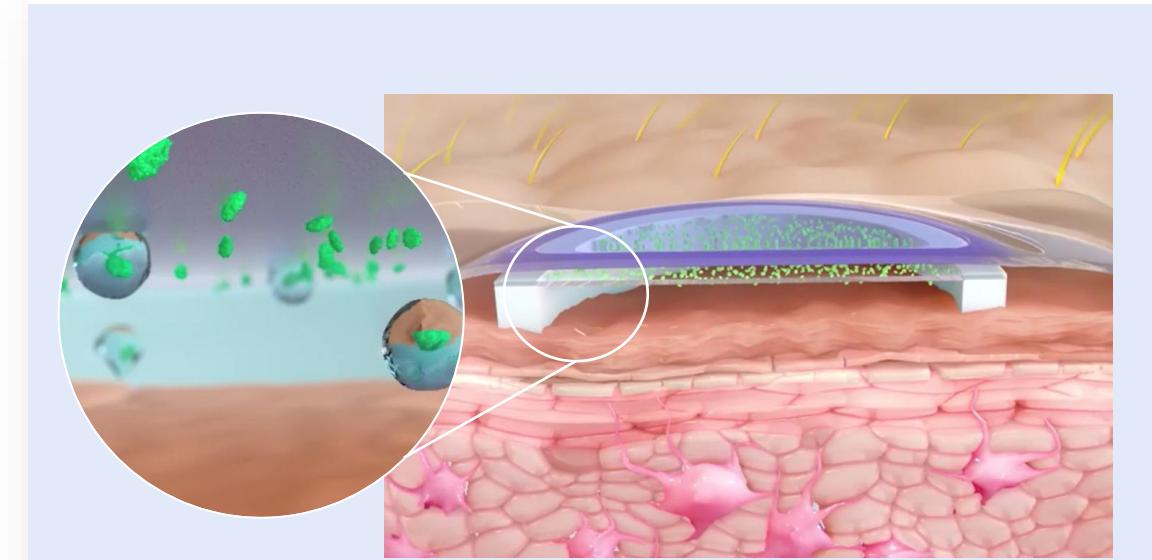
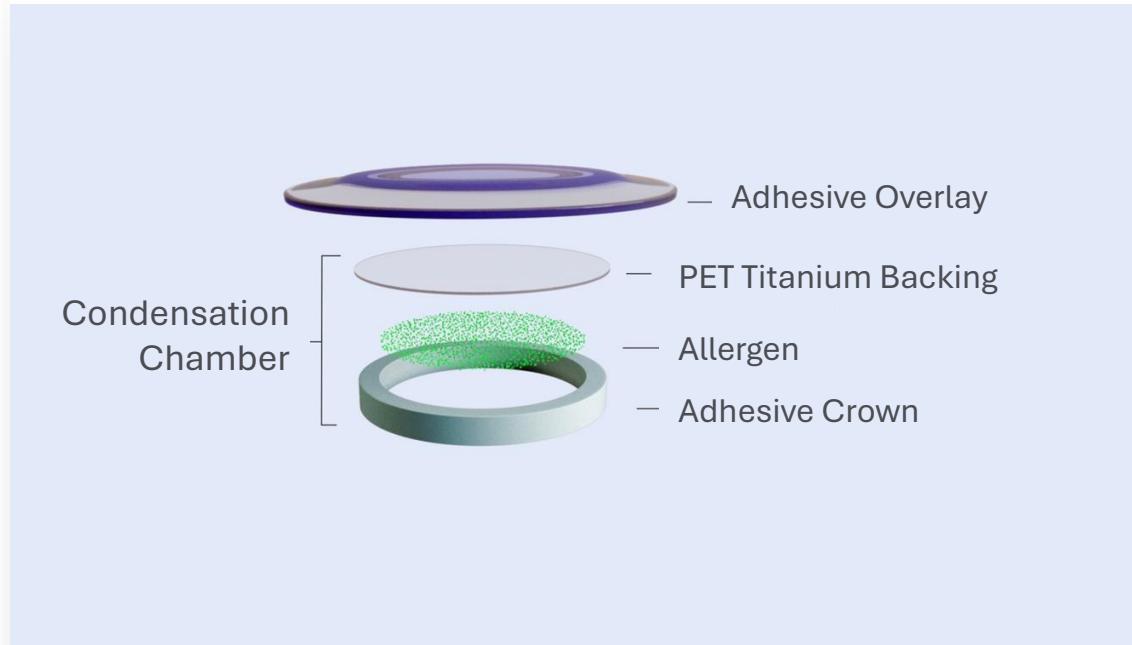
Regulatory T Cells act on the immune system to suppress the allergic response



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

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

A Novel Drug-Device Combination for Delivering Allergen Immunotherapy



Condensation Chamber

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

Allergen Solubilization

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

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

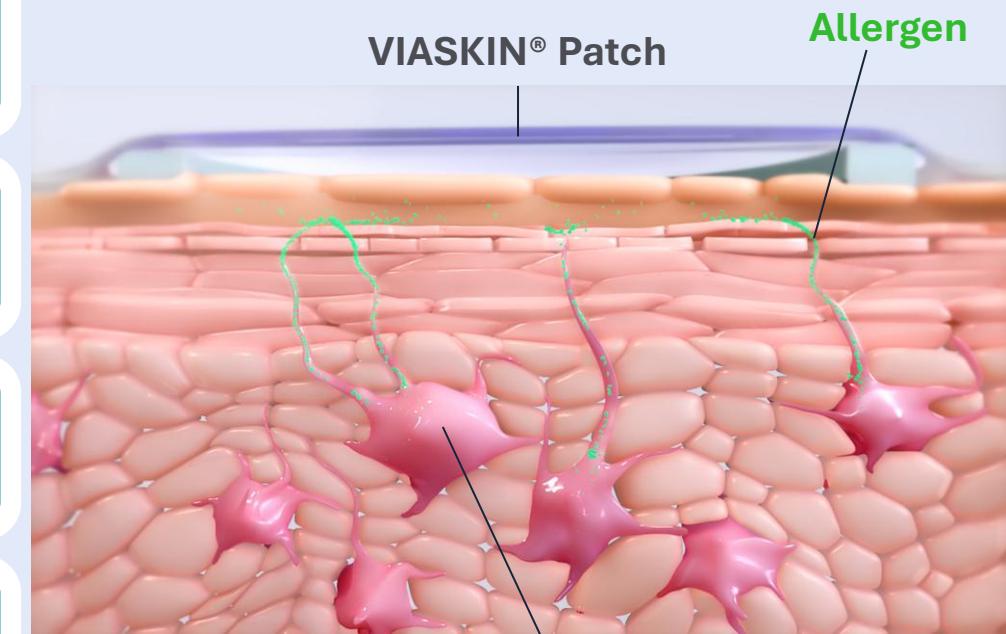
1/1000th of a peanut is applied daily to the skin

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

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

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

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

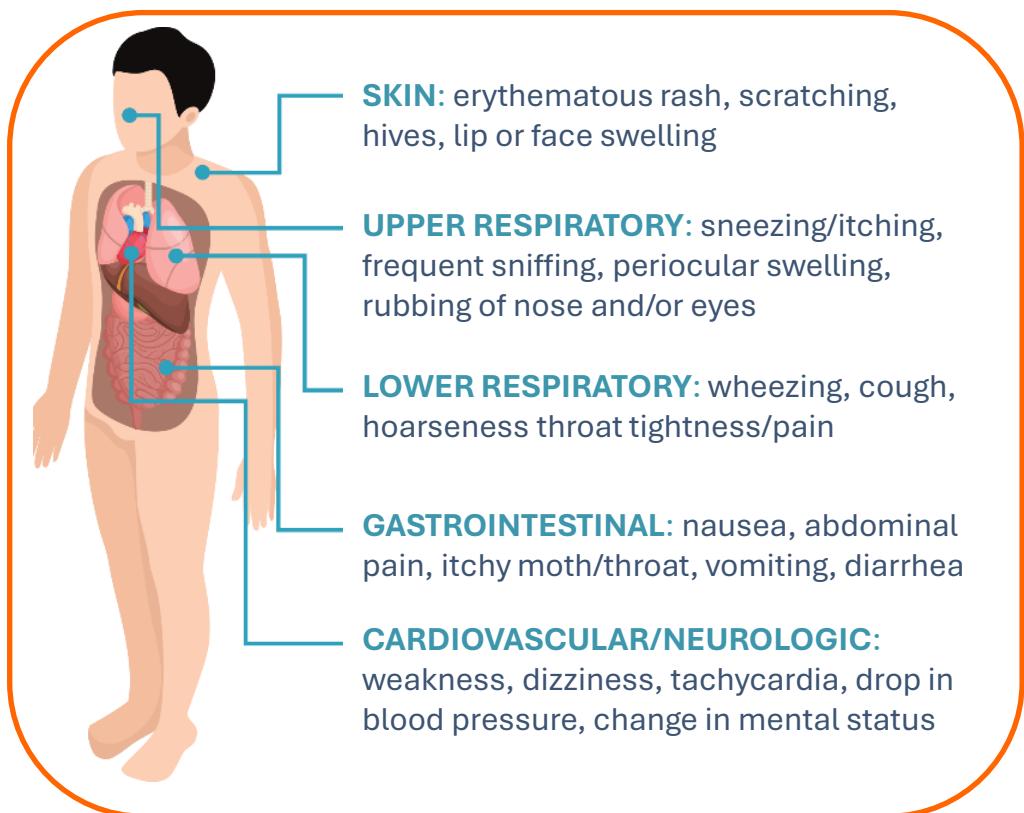


Langerhans Cell

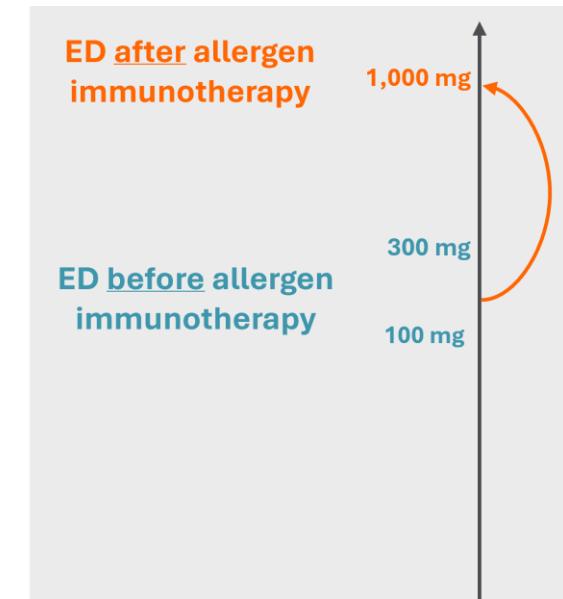
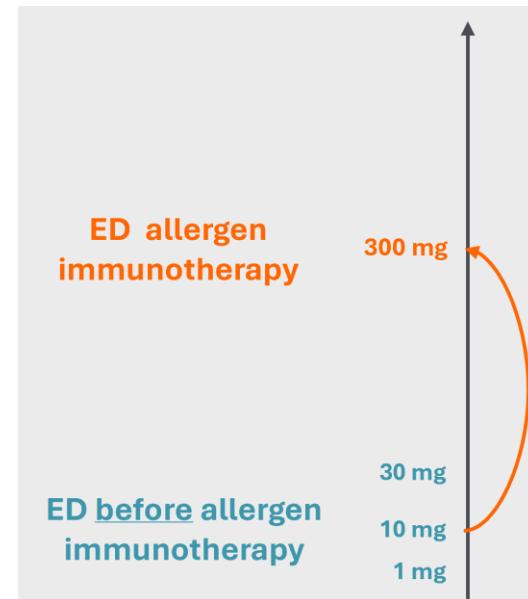
(capturing allergen in the outer layer of the epidermis)

Desensitization is Measured by Increases in Eliciting Dose (ED)

ED = the amount of allergen that induces allergic symptoms¹:



Decrease in Reaction Risk with Increased ED Following Allergen Immunotherapy



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

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

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





VITESSE Study Design

- 654 subjects ages 4-7 YO (vs target enrollment of 600¹)
- Largest immunotherapy clinical trial for this patient population²
- 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

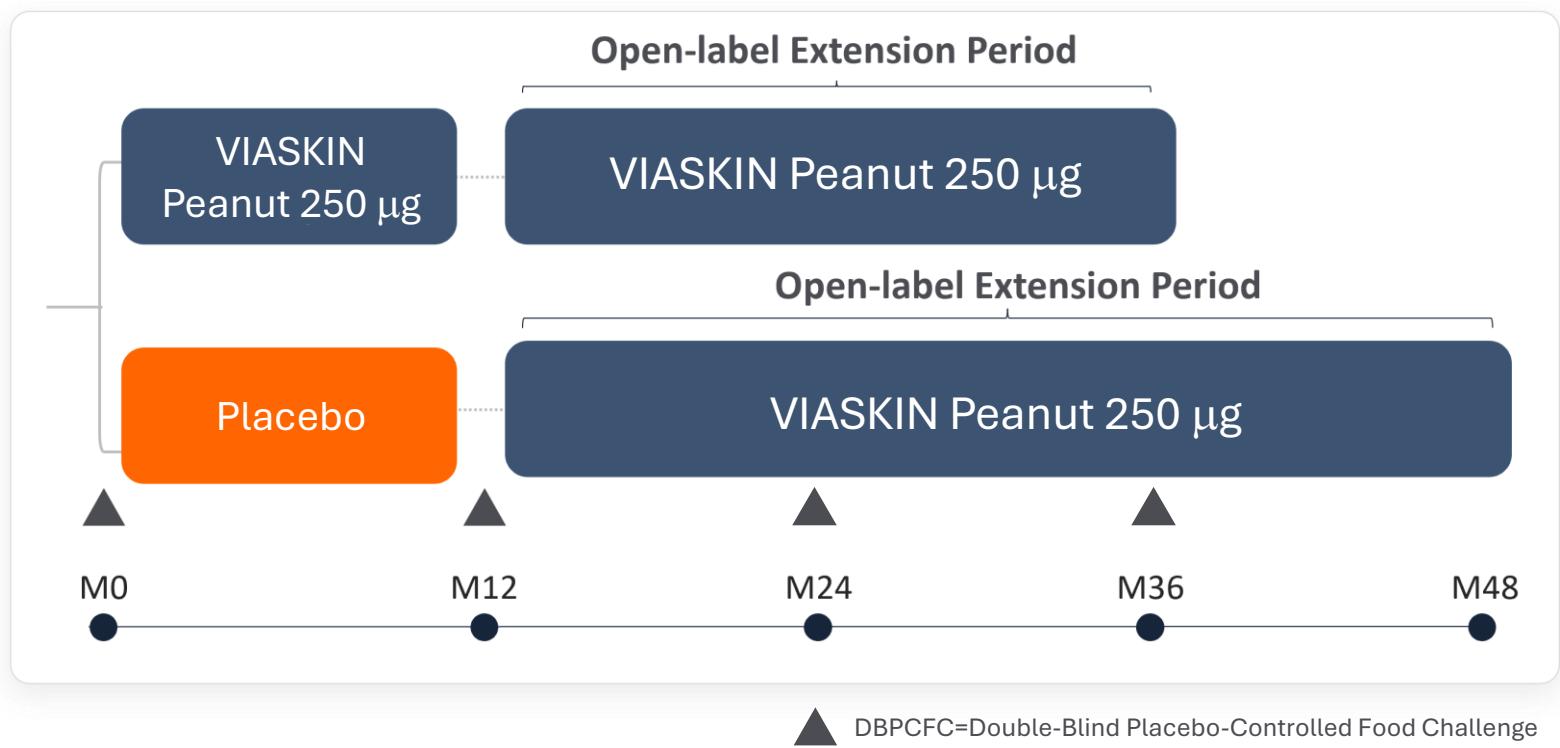
Primary endpoint:

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

Treatment responder (assessed by DBPCFC) defined as:

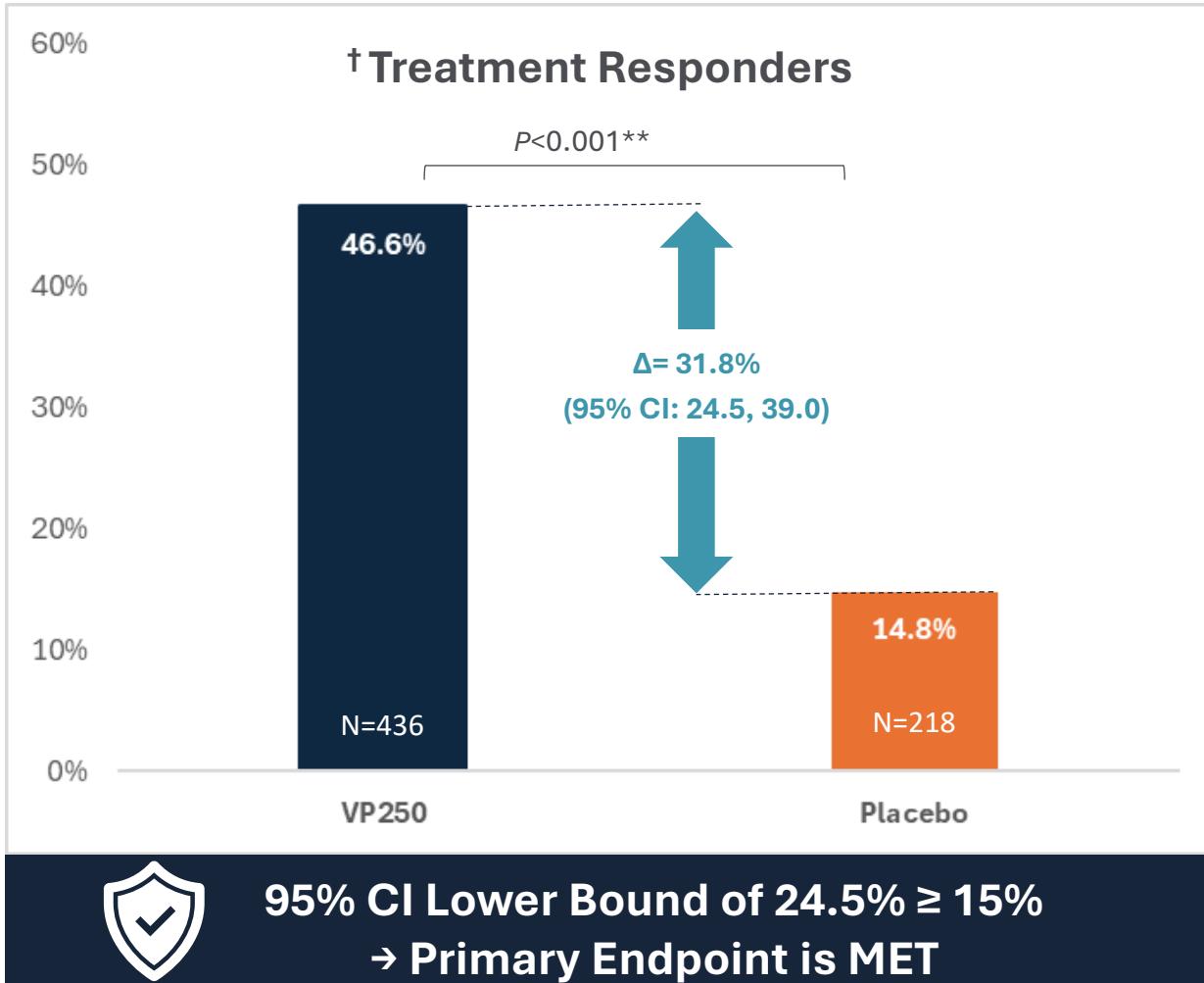
If ED \leq 30 mg at baseline, responder if ED \geq 300 mg at M12

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% 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 tied back, wearing a light-colored patterned dress, is holding a young child in a park. The child is wearing a light blue t-shirt and green shorts. They are standing on a wooden deck or boardwalk. In the background, there are trees and a paved path. The lighting suggests a sunny day.

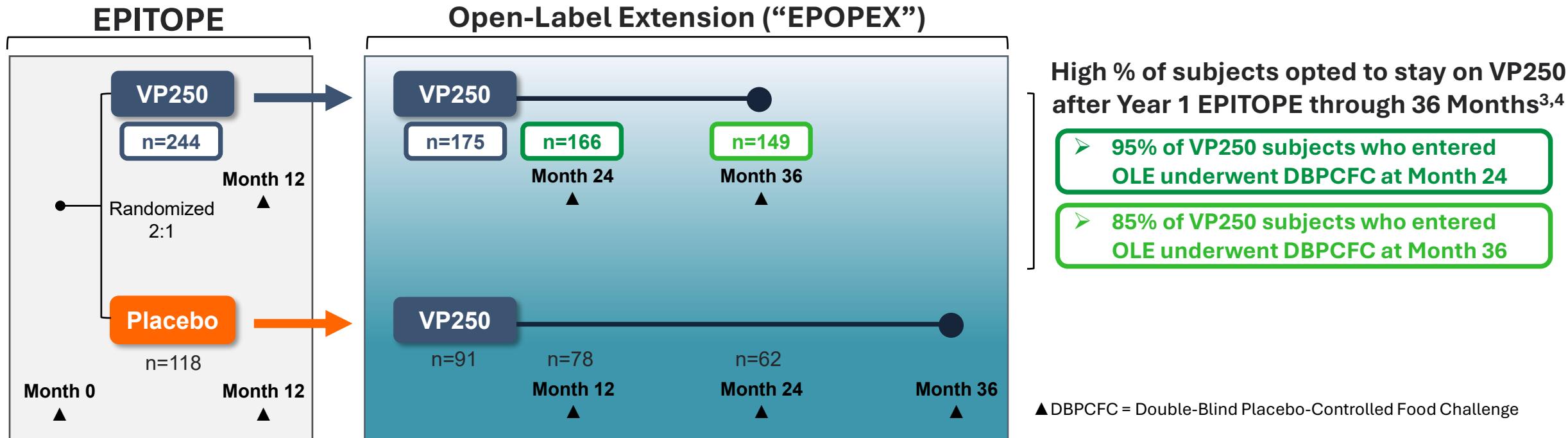
epitone
 **COMFORT**
toddlers

**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 Study¹ & Open-Label Extension (OLE) to EPITOPE Study²



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

Treatment responder (assessed by DBPCFC) defined as:

If ED ≤ 10 mg at baseline, responder if ED ≥ 300 mg at Month 12

If ED > 10 mg at baseline, responder if ED ≥ 1,000 mg at Month 12



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

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



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



PRIMARY ENDPOINT MET ¹⁻³



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



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

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



OTHER ENDPOINTS ¹⁻³

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

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



\geq 95% compliance



SAFETY ¹⁻³

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

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

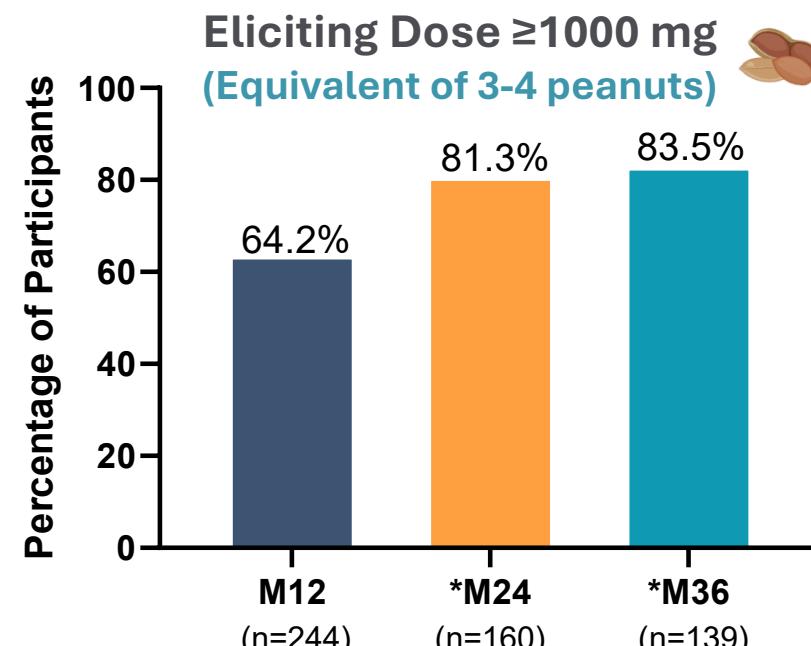
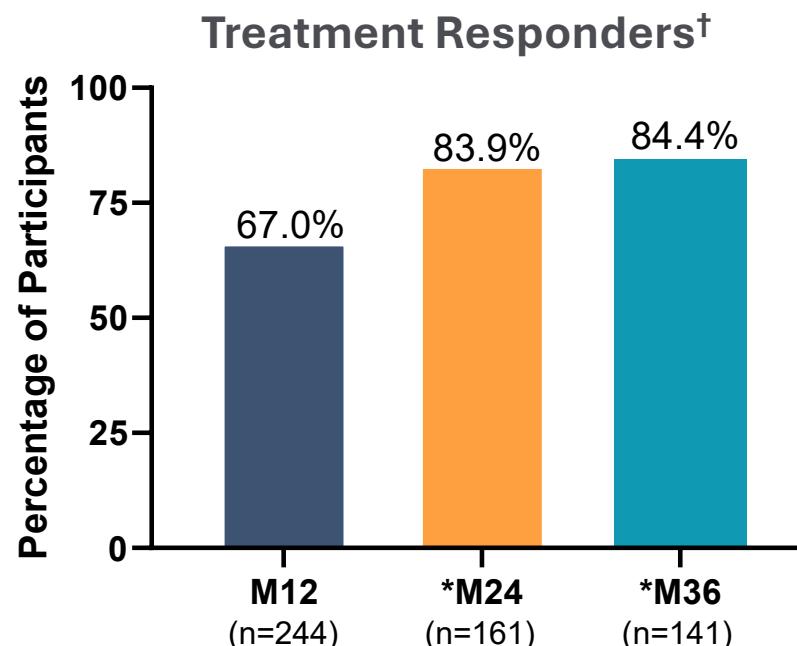
Treatment-related anaphylaxis occurred in 1.6% in the VP250 group and none in the placebo group

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. DBV Technologies Press Release. April 19, 2023.



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

- 175 subjects entered OLE study (out of 244 randomized to receive VP250 in EPITOPE¹)
- 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® Peanut patch in the OLE study showed consistent improvement in efficacy over the course of 36 months²⁻⁴

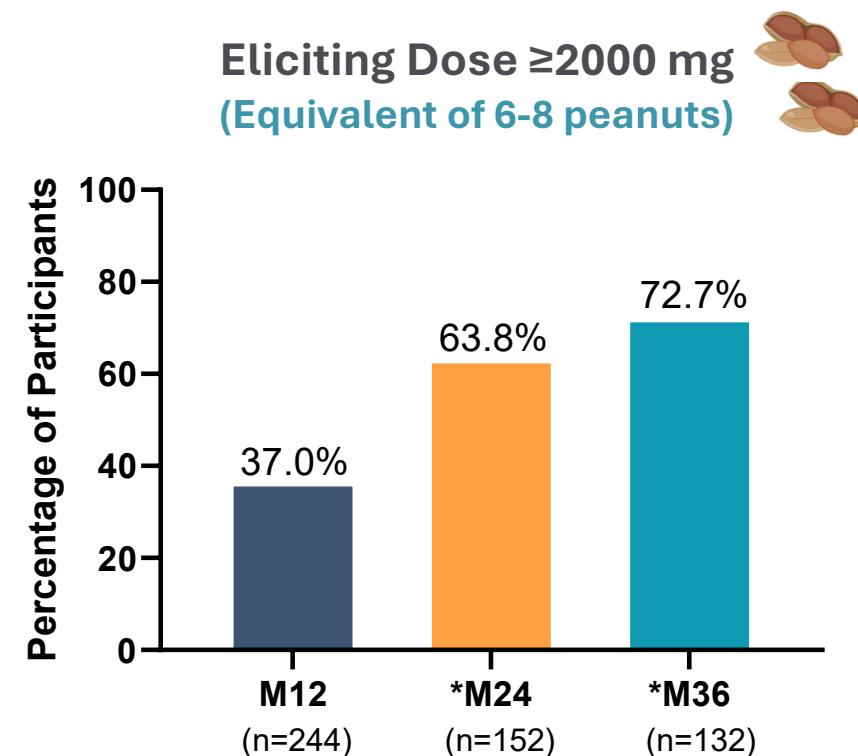
[†]In EPITOPE, a treatment responder (assessed by DBPCFC) was defined as: If ED \leq 10 mg at baseline, responder if ED \geq 300 mg at M12; If ED $>$ 10 mg at baseline, responder if ED \geq 1000 mg at M12.

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

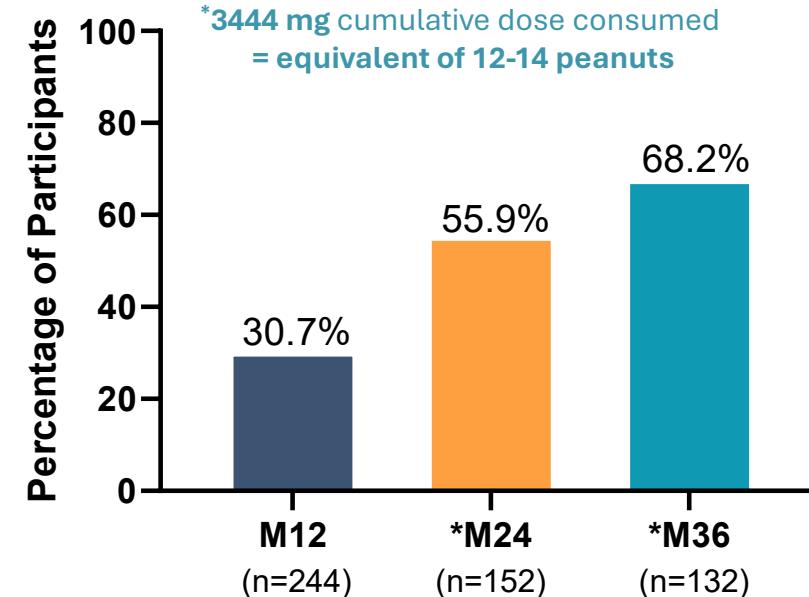
1. Greenhawt M, et al. Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy. *N Engl J Med.* 2023;388:1755-1766; 2. Greenhawt M, et al. Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Toddlers: Open-Label Extension to EPITOPE. *J Allergy Clin Immunol Pract.* 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 MO¹⁻⁴



Completed Food Challenge* Without Meeting Stopping Criteria



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 months²⁻⁴

¹In 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.

²Number of subjects with non-missing food challenge endpoint. VP250=VIASKIN® Peanut patch 250 µg; 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 Toddlers¹⁻⁴

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

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

Adverse Event Category, n (%)	Year 1 [†] (EPIPOPE) (N=175)	Year 2 (OLE) (N=175)	Year 3 (OLE) (N=165)
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 EPIPOPE; AE=adverse event; TEAEs=treatment-emergent adverse events. AESI=Adverse event of special interest.

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

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 et al. Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-Allergic Toddlers: Open-Label Extension to EPIPOPE. *J Allergy Clin Immunol Pract*. 2025;13:1176-1187; 3. DBV Technologies Press Release. January 8, 2025;
4. Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: Results After 3 Years of Treatment. Presented by Dr. M. Greenhawt at Eastern Food Allergy and Comorbidity Conference, January 9-12, 2025; 5. Pooled Safety Data from Phase 3 Studies of Epicutaneous Immunotherapy for Peanut Allergy in Children Aged 4-11 Years – Rachel Robison, MD. Presented at AAAAI Annual Meeting, February 2022.



Accelerated Approval Pathway for VIASKIN® Peanut Patch in Toddlers



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

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

1

Product treats a serious disease



2

Generally provides a meaningful advantage
over available therapies[†]



3

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



FDA Confirms an AA Pathway for
VIASKIN® Peanut Patch in 1-3 YO¹



FDA states it is met²



FDA states it is met²



FDA states it is met via
Written Response Letter¹

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

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

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

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

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



SUMMARY:

VIASKIN Peanut – A Novel Drug-Device with Blockbuster Potential



High unmet need: medical consequence of accidental peanut consumption plus the ever-present impact on child and family's quality of life



Significant market size in BOTH indications



Designed to meet outcome objectives of Immunotherapy: efficacy, safety, and practicality



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



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

Robust Intellectual Property Portfolio

IP Protection in Various Countries, Encompassing:

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

Patch Manufacturing Capabilities

Integrated End-to-End Patch Manufacturing in Place



Source Material



Active Pharmaceutical Ingredient (API)



Final Product Process

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



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