DBV TECHNOLOGIES

Corporate Presentation I January 2025

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

VIASKIN is a registered trademark 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

+

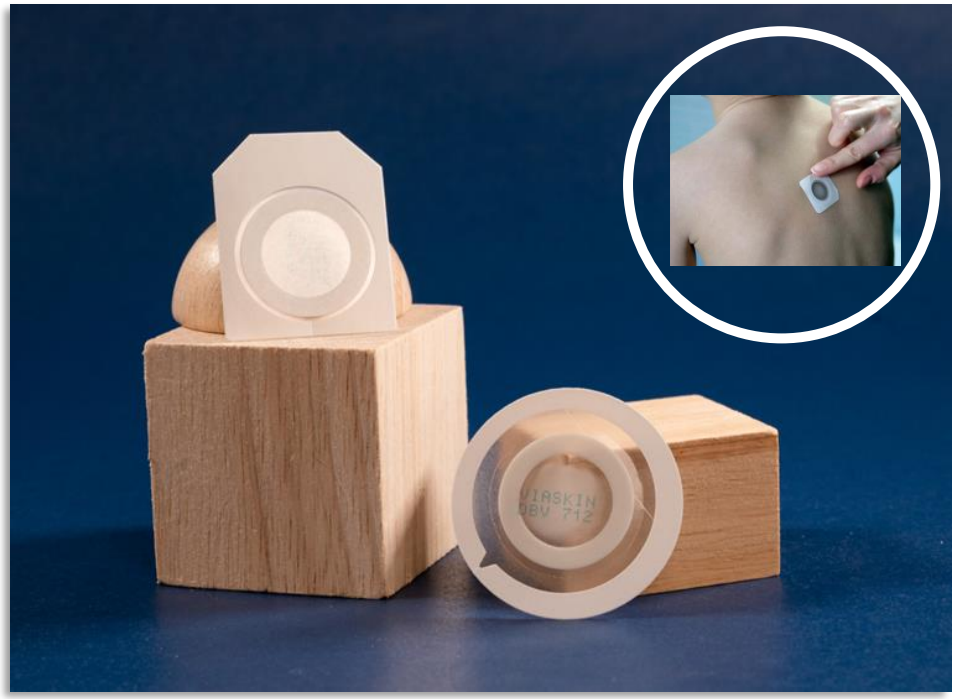
Pioneered VIASKIN® patch technology
DBV's novel approach to epicutaneous immunotherapy

+

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



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

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

The successful EPITOPE Phase 3 study to be supported by a 6-month supplemental safety trial (COMFORT Toddlers) for potential BLA submission under a formalized Accelerated Approval pathway

Ongoing, fully-enrolled 12-month Phase 3 pivotal trial (VITESSE) informed from prior Phase 3 trial in 4–11-YO to be supported by a 6-month supplemental safety trial (COMFORT Children)

Anticipated Clinical & Regulatory Milestones

- Initiation of COMFORT Toddlers anticipated in Q2 ‘25
- BLA submission anticipated for **2H 2026**

- Topline results for VITESSE anticipated in Q4 ’25
- Initiation of COMFORT Children anticipated in Q2 ‘25
- BLA submission anticipated for **2H 2026**

Financial Position

$46.4 M

of Cash and Cash Equivalents as of September 30, 2024

EPIT and DBV’s VIASKIN® patch technology 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.

Company is Led by an Experienced Management Team & Renowned International Board of Directors

Executive Team

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Pharis Mohideen
Chief Medical Officer

Virginie Boucinha
Chief Financial Officer

Kevin P. Malobisky
Chief Operations Officer

Robert Pietrusko
Chief Regulatory Officer

Caroline Danière
Chief Human Resources & Chief of Staff

Michele F. Robertson
Chief Legal Officer

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Board Member

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Board Member

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Board Member

Timothy E. Morris
Board Member

~670K Children Ages 1 to 7 Years Old Have Peanut Allergy in the US[1-3]

Approximately 75% Will Not Outgrow Their Allergy[4,5]

1-3 years old

280,000 Toddlers[2,3]

4-7 years old

390,000 Children[2,3]

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.
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

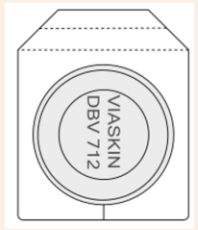
Independent Clinical & Regulatory Paths for VIASKIN® Peanut Patch in Toddlers 1–3 YO & Children 4–7 YO in USA

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

*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.

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

Program	Patch	Core Phase 3 Studies for Each Program/BLA	Key Program Highlights[1]
 1-3		1 epitope **COMPLETED** Efficacy & Safety ✓ Primary endpoint met ✓ Satisfactory to FDA[2] ✓ Published in NEJM[3,4] 2 COMFORT toddlers **6-Month** Supplemental Safety† On-track to initiate in 2Q 2025	✓ FDA provided WR formalizing Accelerated Approval Pathway ✓ FDA confirmed criteria for AA post-marketing study ✓ Aligned on key study elements (inc. adhesion collection methodology & analysis)
 4-7		1 VITESSE **ONGOING** Efficacy & Safety ✓ Enrollment complete[5] (654 participants) 2 COMFORT children **6-Month** Supplemental Safety† On-track to initiate in 2Q 2025	Phase 3 VITESSE topline data anticipated in Q4 2025

†To bring the total number of participants on active treatment close to 600, per ICH guidelines.
WR=Written Response; AA=Accelerated Approval; ICH=International Council for Harmonisation.

1. DBV Technologies Press Release. December 11, 2024; 2. DBV Technologies Press Release. April 21, 2023; 3. Greenhawt M, et al. *N Engl J Med*. 2023; 388:1755-1766.
4. Togias. "Good News for Toddlers". *N Engl J Med*. 2023; 5. DBV Technologies Press Release. September 23, 2024.

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

The unmet need for peanut allergy in Europe is significant:

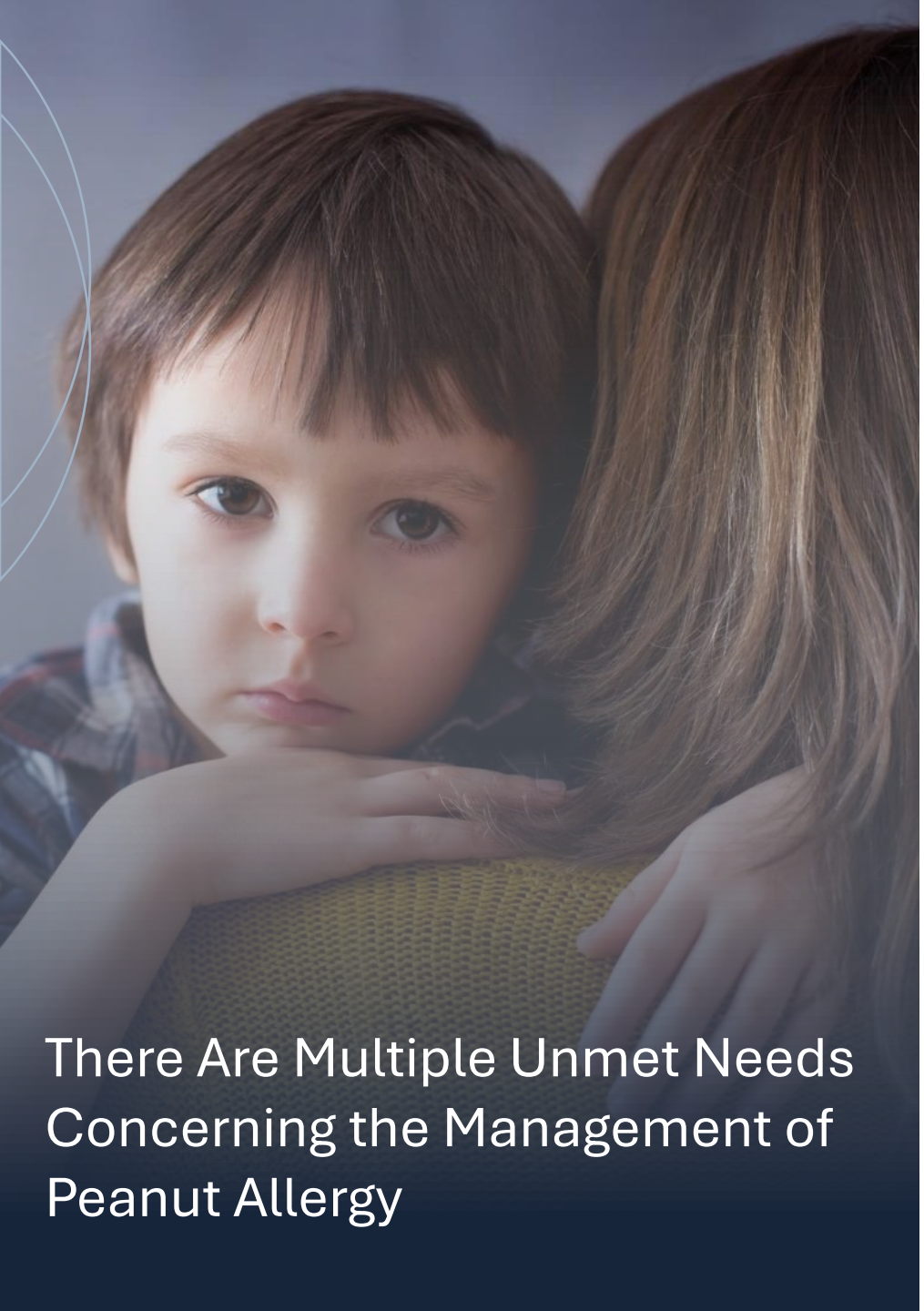
- Estimated that 615,000 children ages 1 – 7 YO in the EU have peanut allergy[1]
- Incidence of new diagnosis of ~81,000 a year[1]

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

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

EMA=European Medicines Agency.

1. Nwaru B, et al. *Allergy*. 2014; 69:62-75; 2. DBV Technologies Press Release. October 22, 2024.



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, NSAID usage, 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.

Current Treatment Options Are Often Not Ideal for Many Patients & Their Families[1-4]

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 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 aged 1-17 YO.

Omalizumab (anti-IgE Monoclonal Antibody)[#]

Fear of injection:

- Requires injection(s) 1-2 times per month[4,5]
- Potentially painful injection site reactions

Not disease modifying[4]

- 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.

1. Chu DK et al. *Lancet*. 2019;393(10187):2222-2232; 2. Mack DP et al. *Clin Exp Allergy*. 2022;52:1391-1402; 3. Plessis AA et al. *Allergy, Asthma & Clinical Immunology*. 2024;20:54; 4. Sampson, H.A. et al. *Ann Allergy Asthma Immunol*. 2024;132: 569-571; 5. XOLAIR. Package insert. Genentech Inc; February 2024; 6. Supplement to: Wood R et al. *N Engl J Med*. 2024;390: 889-899.

Treatment Goals of Physicians, Patients & Their Caregivers

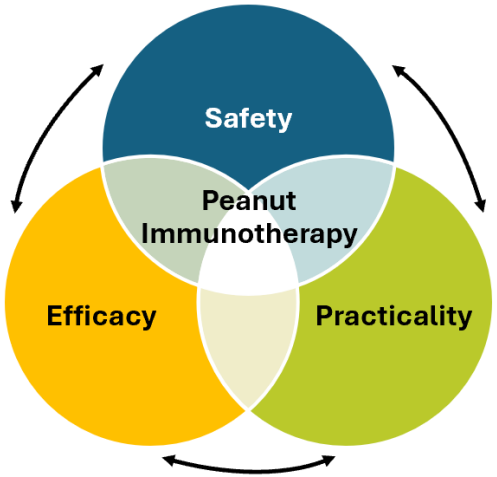
Needs of Physicians, Patients & Their Caregivers/Families

- **90% of allergists see the need for additional options in the treatment of pediatric peanut allergy[1]**
- **Caregivers & physicians are seeking a treatment that[2,3]:**
  - ✓ 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[2,4,5]



Multiple treatment options are desired so families and allergists can together choose the best approach considering patient preference, family lifestyle & medical evidence[4]

1. Based on primary market research conducted by Kaleio on behalf of DBV among 30 allergists in the United States conducted in October 2024. Survey question: "To what extent is there a need for additional options in the treatment of pediatric peanut allergy?"; 2. Greenhawt M, et al. *Ann Allergy Asthma Immunol*. 2018;120:620-625. doi:10.1016/j.anai.2018.03.001; 3. Based on primary market research conducted on behalf of DBV among 100 allergists in the United States. Survey question: If a new peanut allergy desensitization treatment for children 4 to 11 years of age became FDA-approved and available for use, what would be the importance of each of the following attributes to you? Please use a 0- to 7-point scale where 0 means "not at all important to me" & 7 means "very important to me." 4. Anagnostou A, et al. *J Allergy Clin Immunol Pract*. 2020;8:46-51; 5. Ravindran M et al. *Allergy* 2025;80(1):63-76.

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[1-3]

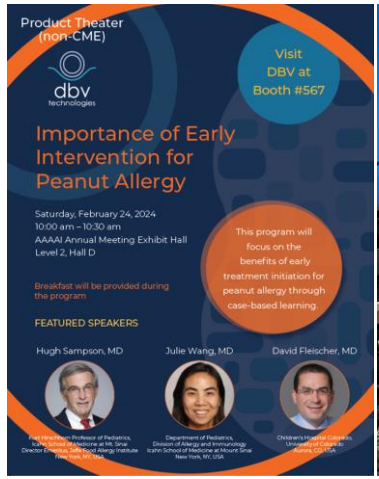
VIASKIN® Peanut Patch is Designed to Meet Treatment Goals of Patients, Caregivers & Clinicians

1. Fleischer 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. *Journal of Allergy Clin Immunol* 2020; 146(4):863-874.
2. Brown-Whitehorn et al. Sustained unresponsiveness to peanut after long-term peanut epicutaneous immunotherapy, *Journal of Allergy Clin Immunol Pract*. Volume 9. 2021; 9(1):524-526.
3. Mondoulet et al. Gata3 hypermethylation & Foxp3 hypomethylation are associated with sustained protection & bystander effect following epicutaneous immunotherapy in peanut-sensitized mice. *Allergy* 2019;74(1):152-164.

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

Three invited review articles published in top allergy journals in 2024 alone[1-3]

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



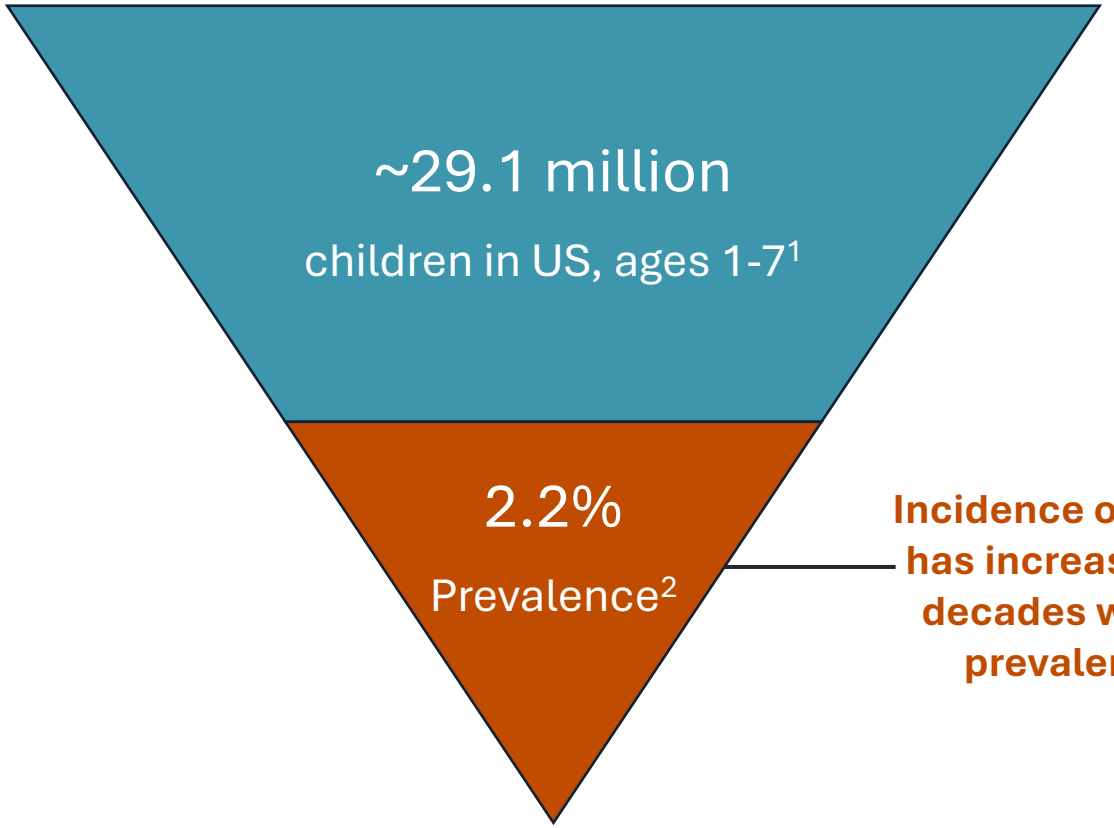
DBV-hosted Product Theater "The Importance of Early Intervention for Peanut Allergy" at AAAAI in Washington D.C. on February 24, 2024

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

1. Dupont C et al. Safety and efficacy of epicutaneous immunotherapy with DBV712 (peanut patch) in peanut allergy. *Expert Rev Clin Immunol*. 2024;20(6):623-633.
2. Sampson H.A. The riddle of response to cutaneous allergen exposure in patients with atopic dermatitis. *Ann Allery Asthma Immunol*. 2024;133(3):244-251.
3. Ravindran M et al. Epicutaneous immunotherapy for the treatment of peanut allergy. *Allergy*. 2025;80(1):63-76. Epub 2024 Sep 28.

VIASKIN® 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



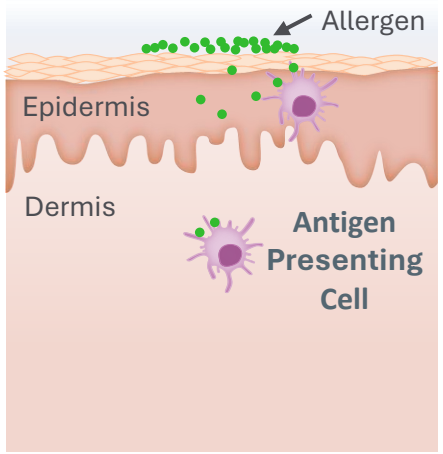
Incidence of peanut allergy has increased over recent decades with a reported prevalence of 2.2%[2]

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

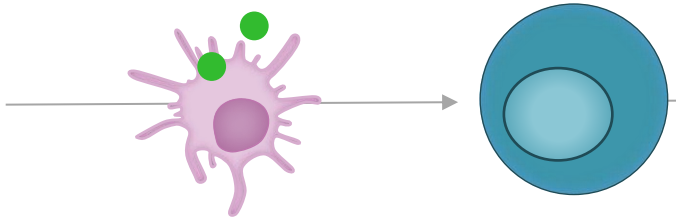
1. CDC National Population Projections 2014-2060 Request.
2. Gupta RS, et al. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States, *Pediatrics;*142, number 6, December 2018:e20181235.

Epicutaneous Immunotherapy (EPIT) Aims to Re-educate the Immune System by Suppressing the Allergic Response[1-7]

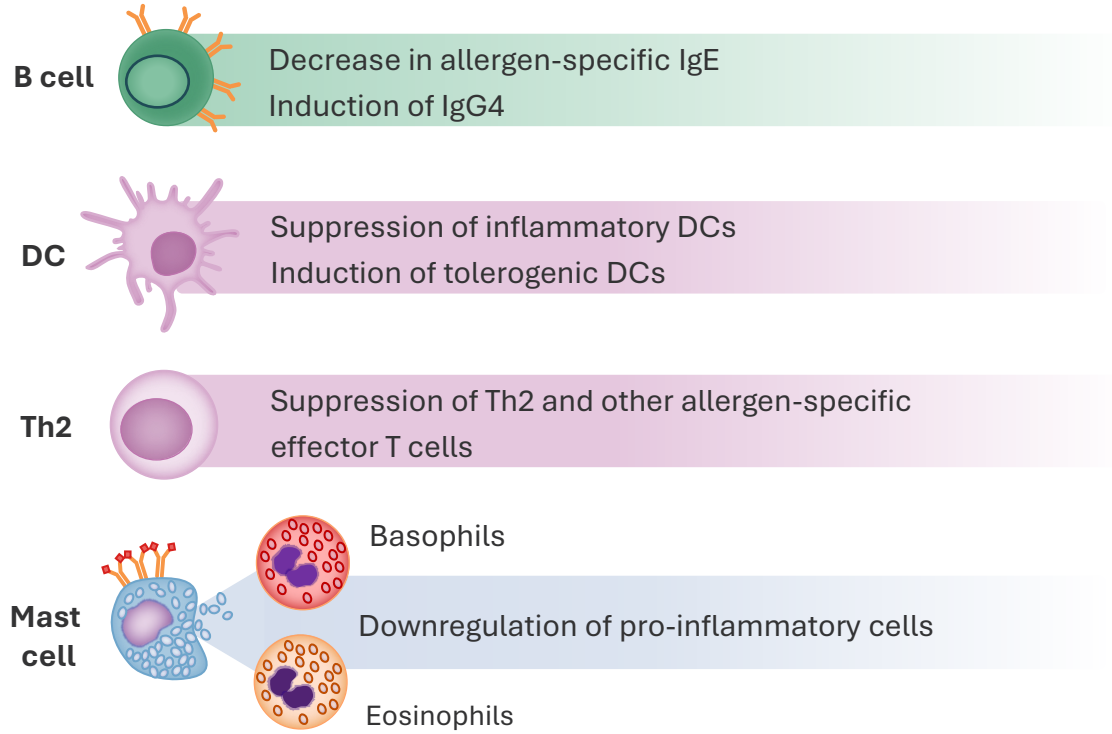
EPIT delivers allergen to the skin



Antigen Presenting Cells capture allergen and induce unique Regulatory T Cells



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

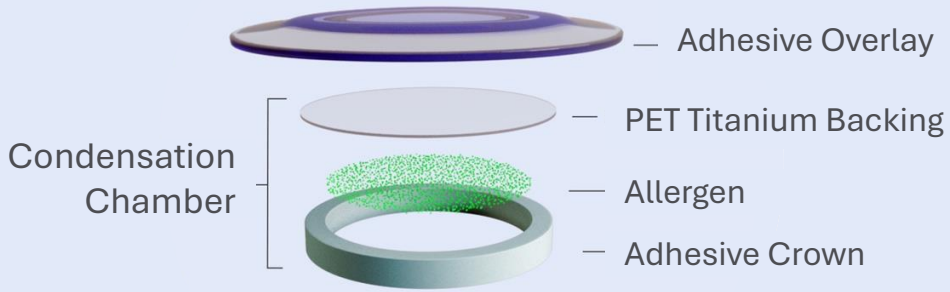


DC=dendritic cell; IgE=immunoglobulin E; IgG4=immunoglobulin G4; Th2=T-helper 2 cell.

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.
7. Reviewed by Hervé et al. Recent advances in epicutaneous immunotherapy and potential applications in food allergy. *Frontiers in Allergy* 2023; Vol 4: https://doi.org/10.3389/falgy.2023.1290003

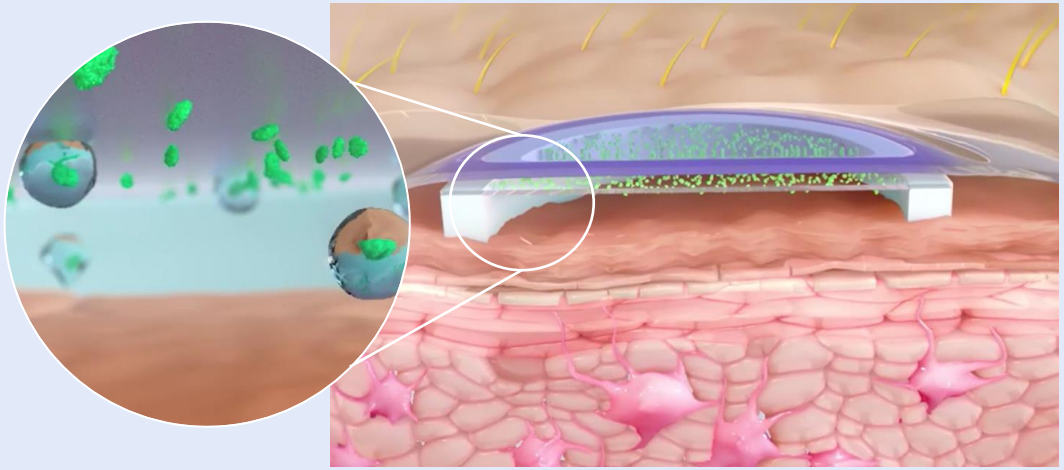
VIASKIN® Patch: Our Innovative Approach to Epicutaneous Immunotherapy[1-3]

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® Patch Uses Minimal Amounts of Allergen to Induce an Immune Response[1-3]

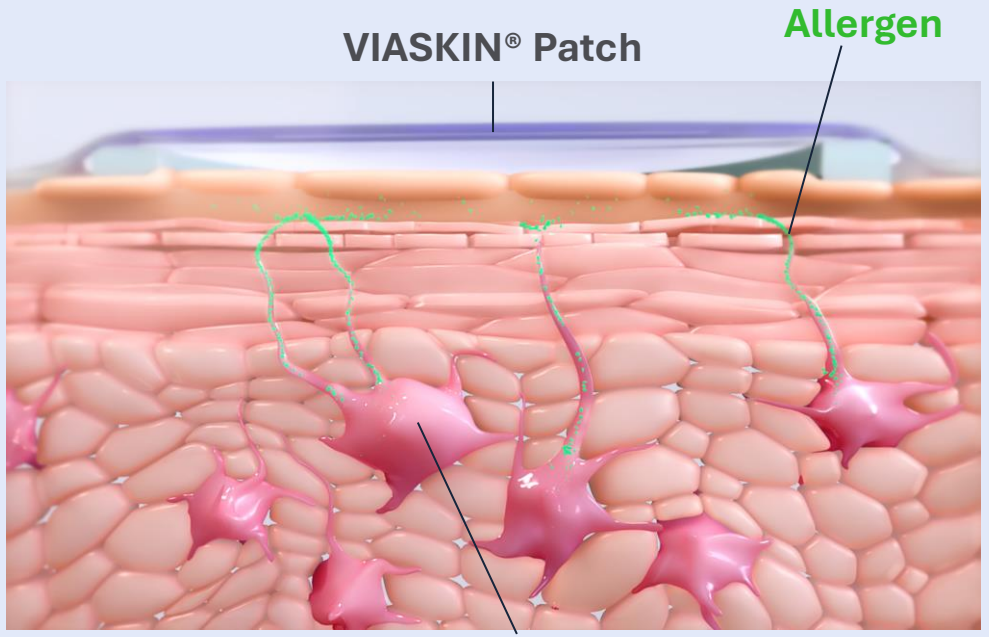
1/1000th of a peanut is applied daily to the skin

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 (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



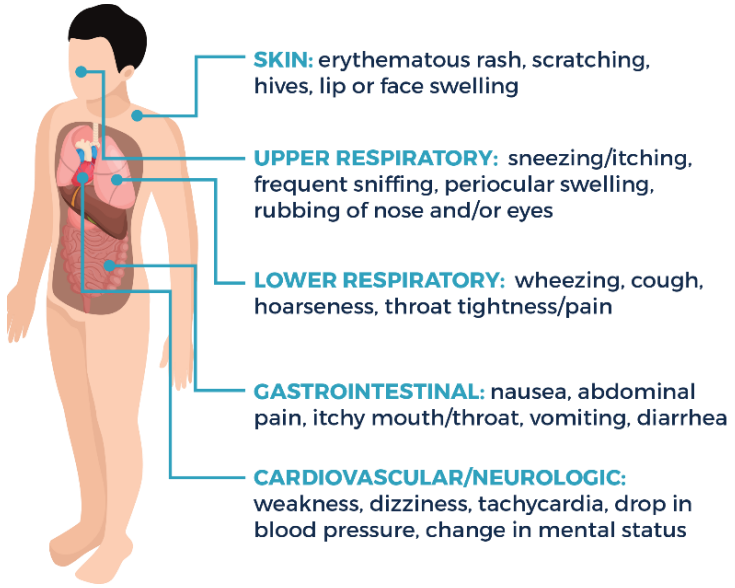
Langerhans Cell
(capturing allergen in the outer layer of the epidermis)

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]:

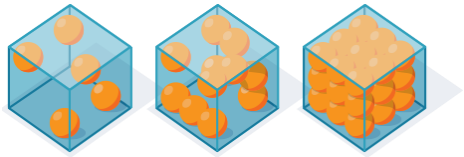


Exposure Dose

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

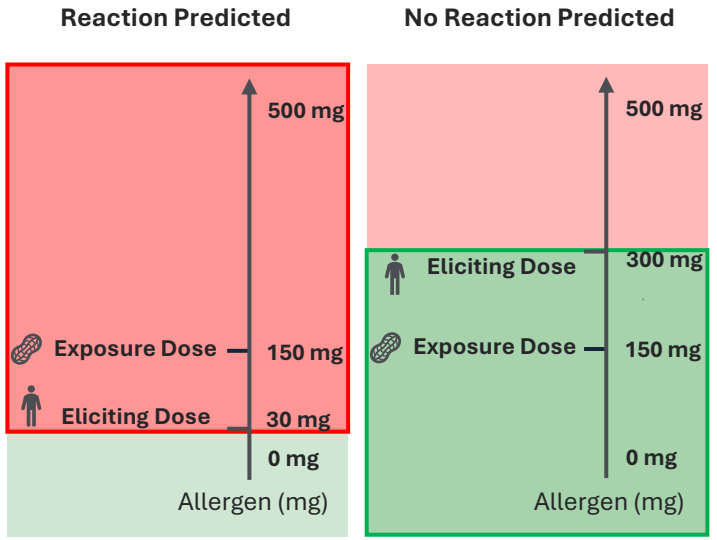
How much food was consumed?

How much allergen was present in the food?

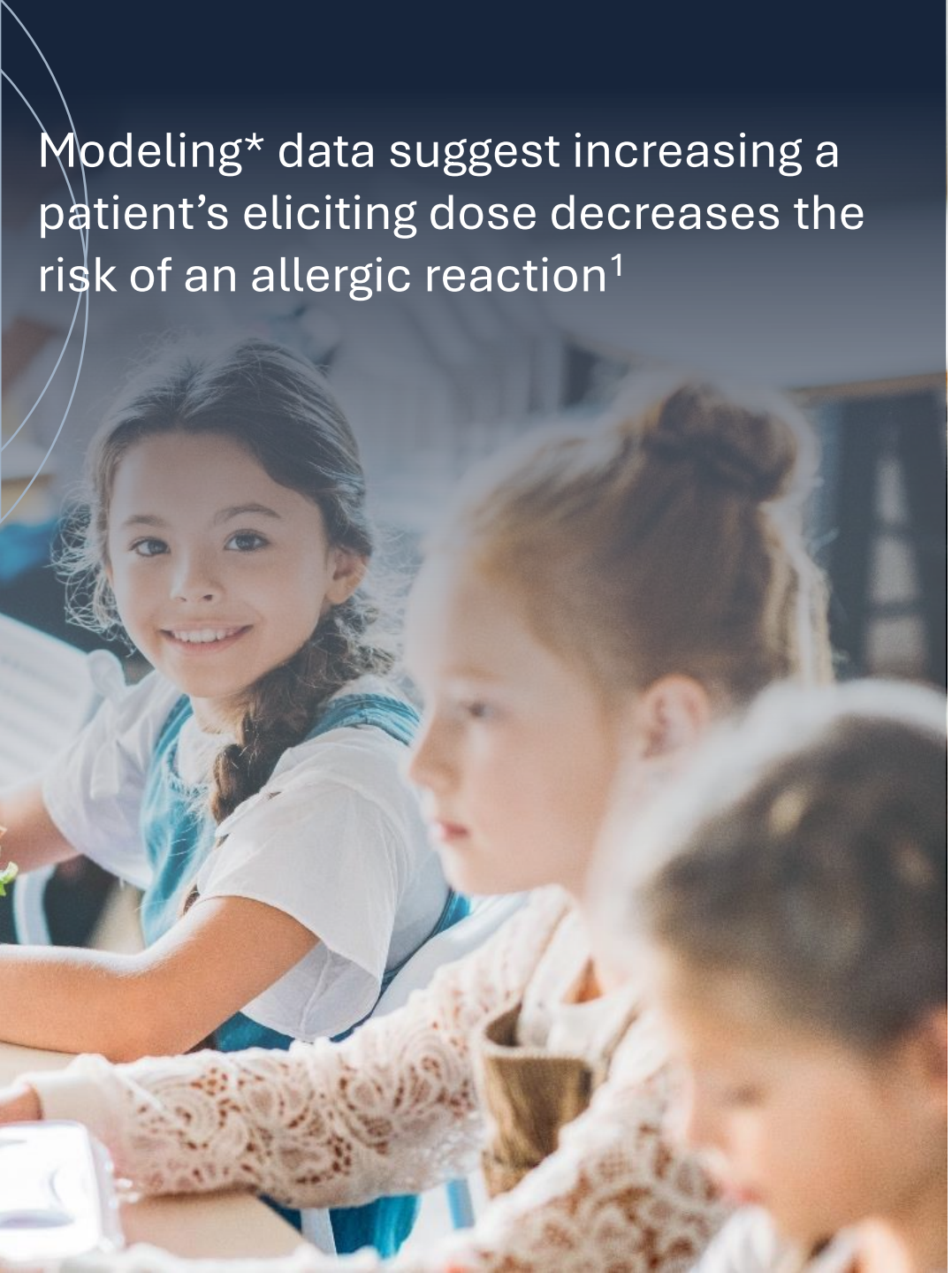


Reaction Prediction

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

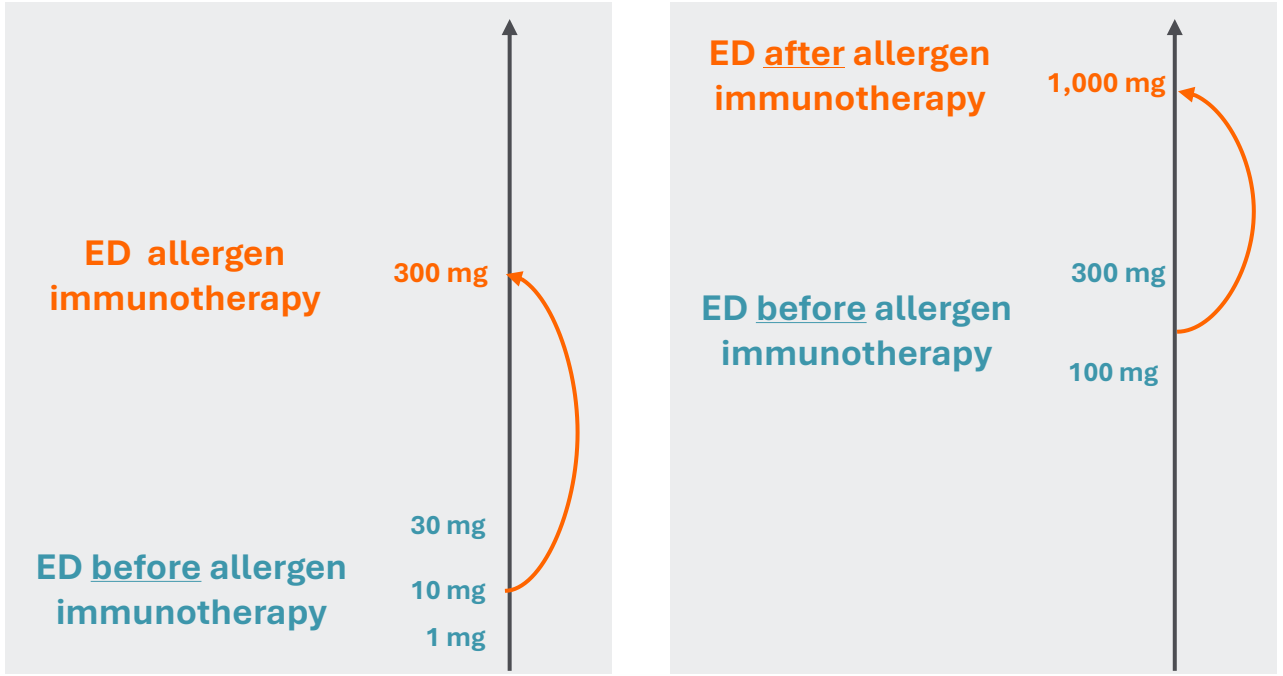


1. Sampson HA, et al. *J Allergy Clin Immunol*. 2012;130:1260-1274; 2. Blom WM, et al. *Food Chem Toxicol*. 2019;125:413-421; 3. Baumert JL, et al. *J Allergy Clin Immunol Pract*. 2018;6:457-465.e4.



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

Decrease in Reaction Risk Following Allergen Immunotherapy



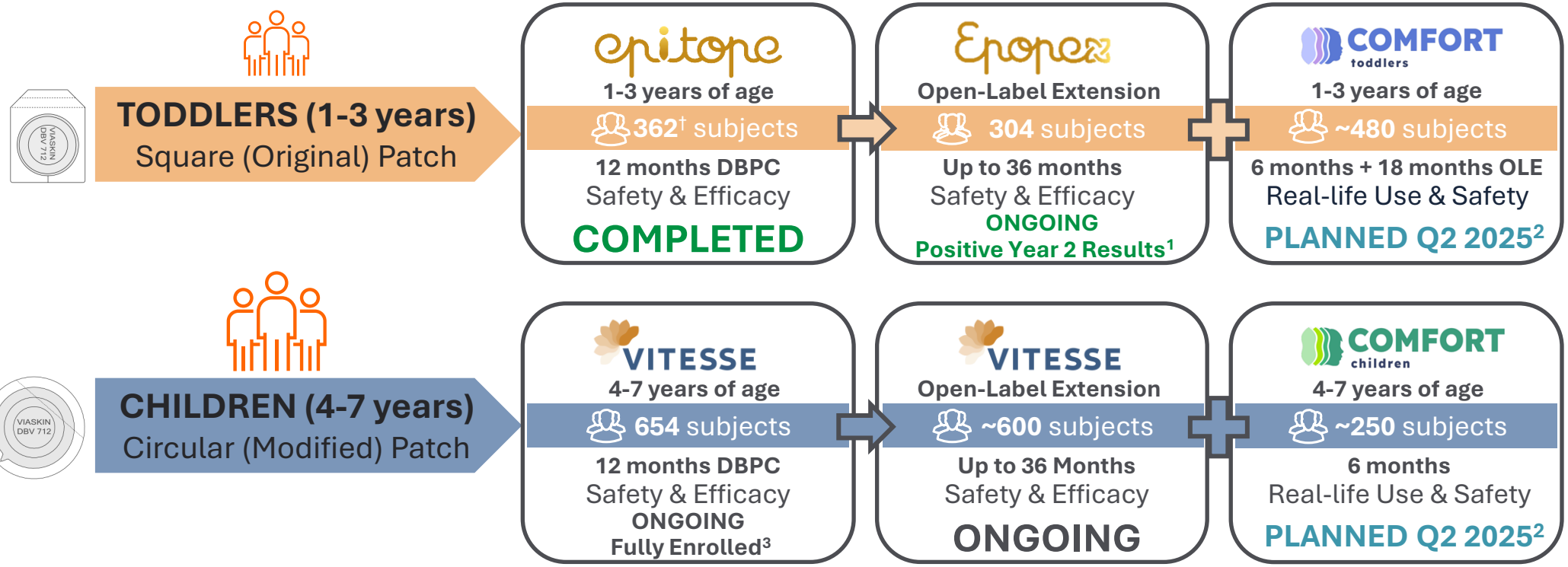
Increasing a patient's eliciting dose from **1**, **10**, or **30 mg** to **300 mg** or **100** or **300 mg** to **1,000 mg** via allergen immunotherapy is predicted to reduce their risk of an allergic reaction by **≥99%**

*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.

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 II – pages 52-58.

†Total number of subjects 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. January 8, 2025; 2 DBV Technologies Press Release. October 22, 2024; 3. DBV Technologies Press Release. September 23, 2024.

DBPC=double-blind, placebo-controlled; OLE=Open-Label Extension; 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)

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

PRIMARY ENDPOINT MET [1-3]

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

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

OTHER ENDPOINTS [1-3]

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

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

≥95% compliance

SAFETY [1-3]

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

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

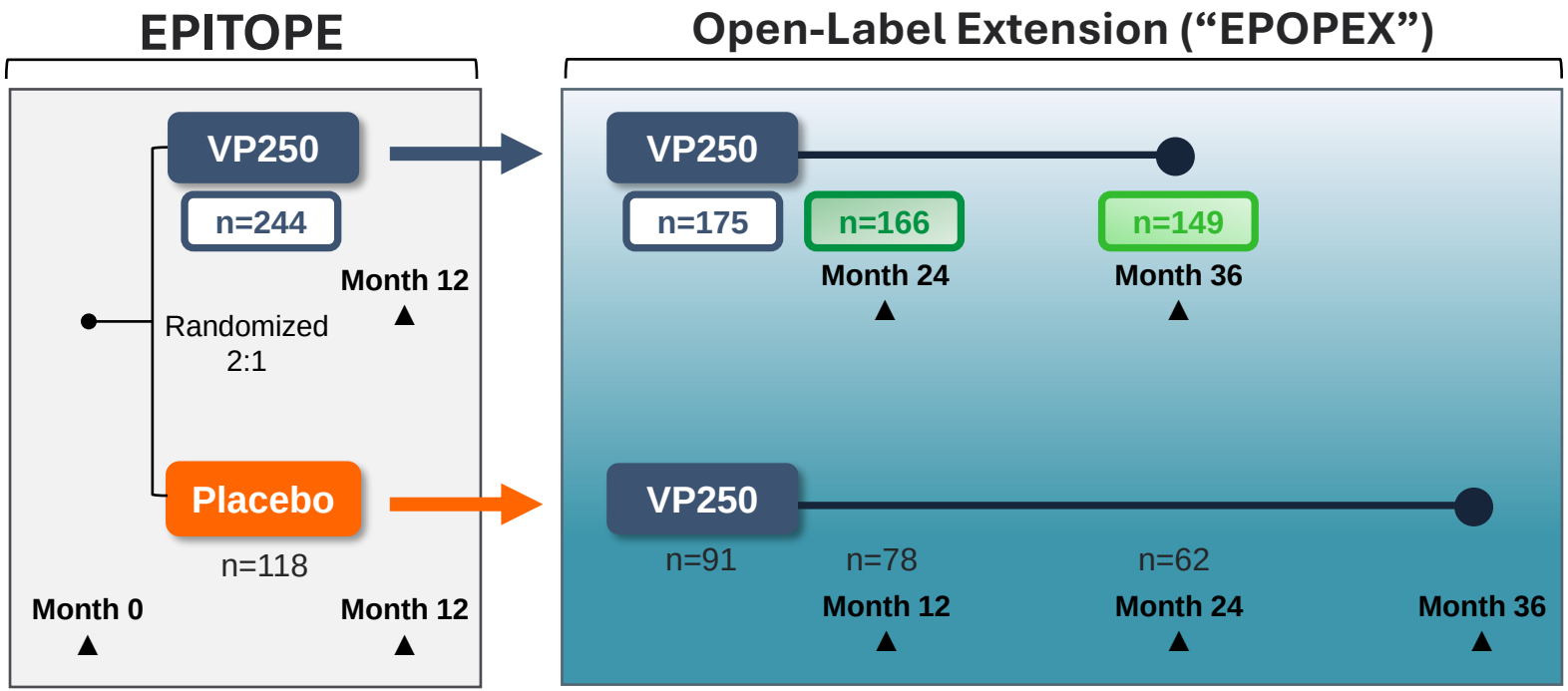
Treatment-related anaphylaxis occurred in 1.6% in the VP250 group and none in the placebo group

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

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 Press Release, April 19, 2023.

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

Study Design for EPITOPE Pivotal Global Study[1] & Open-Label Extension (OLE) to EPITOPE Study[2]



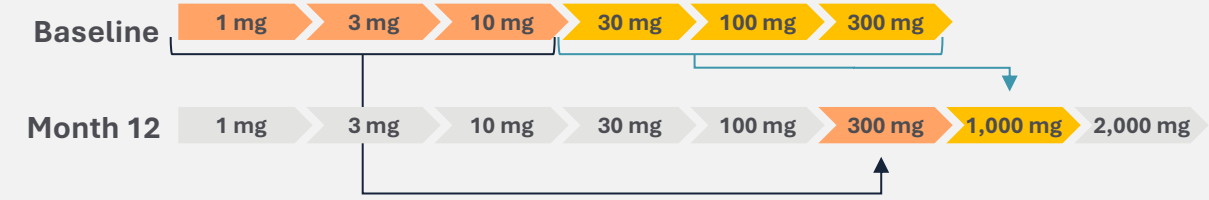
High % of subjects opted to stay on VP250 after Year 1 EPITOPE through 36 Months[3,4]

- 95% of VP250 subjects who entered OLE underwent DBPCFC at Month 24
- 85% of VP250 subjects who entered OLE underwent DBPCFC at Month 36

▲DBPCFC = Double-Blind Placebo-Controlled Food Challenge

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

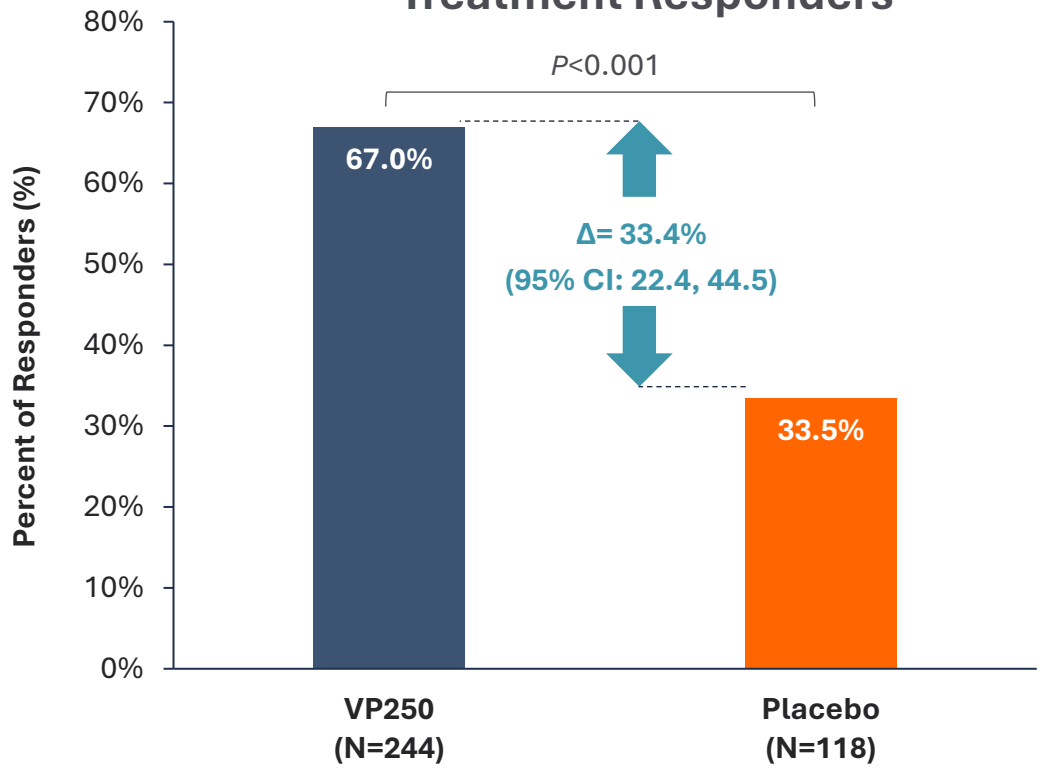
Treatment responder (assessed by DBPCFC) defined as:
If ED ≤10 mg at baseline, responder if ED ≥300 mg at Month 12
If ED >10 mg at baseline, responder if ED ≥1,000 mg at Month 12

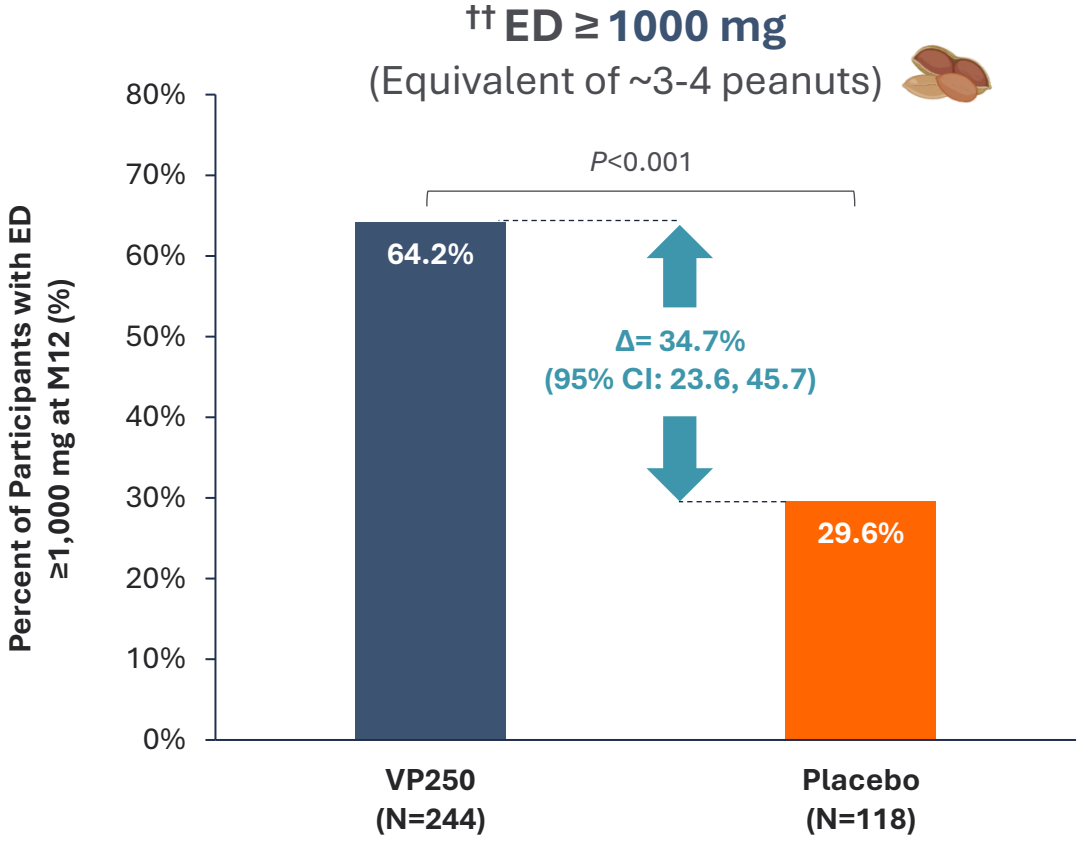


VP250=VIASKIN® Peanut patch 250 µg; ED=eliciting dose.

1. Greenhawt M, et al. Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy. *N Engl J Med*. 2023;388:1755-1766; 2. Greenhawt 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 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.

VIASKIN® Peanut Patch Demonstrated a Statistically Significant Treatment Effect in Toddlers After 12 Months[1,2]





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

†† Versus 100 mg = Median ED at baseline

125 mg = Median dose of peanut protein consumed at accidental consumption[3]

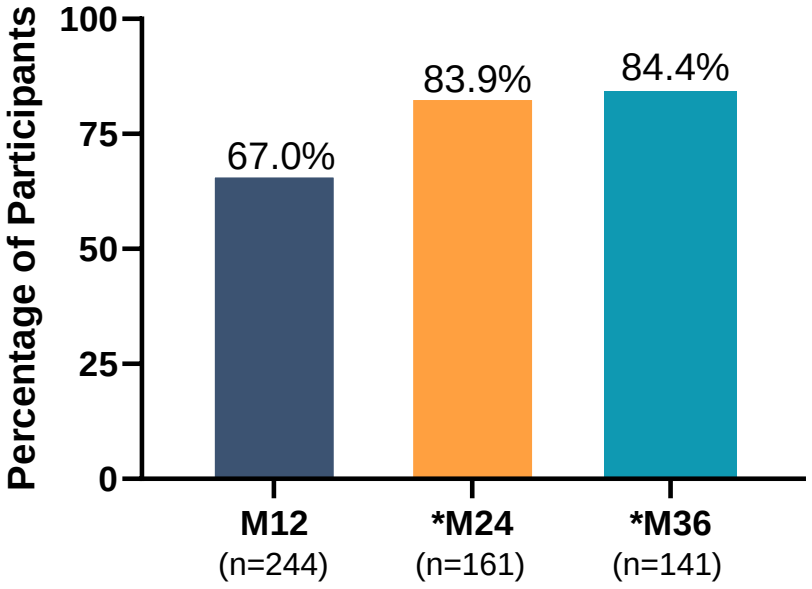
†If ED ≤10 mg at baseline, responder if ED ≥300 mg at M12; If ED >10 mg at baseline, responder if ED ≥1000 mg at M12.
VP250=VIASKIN® Peanut patch 250 µg; CI=Confidence Interval; ED=Eliciting Dose.

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.

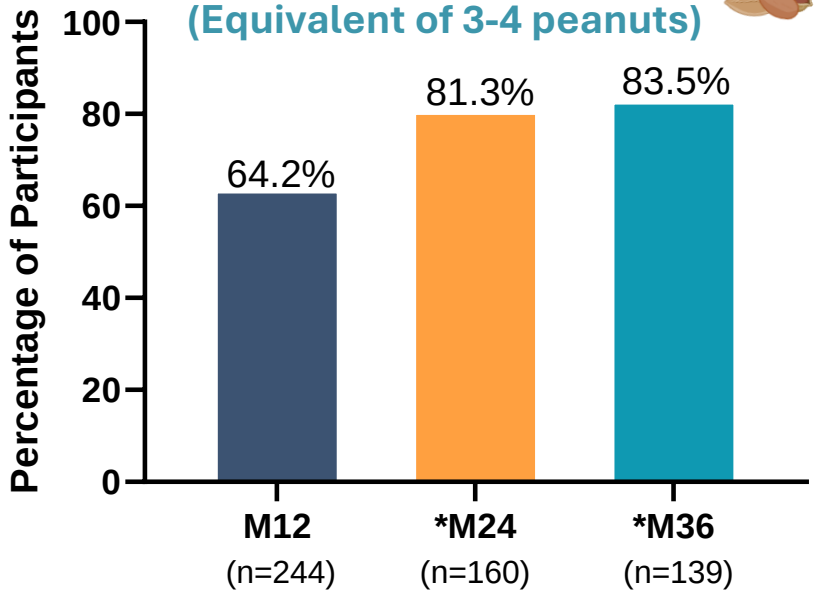
Data from EPITOPE Open-Label Extension Show Continued Improvement in Treatment Response in Toddlers Through 36 Months[1-3]

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

Treatment Responders†



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



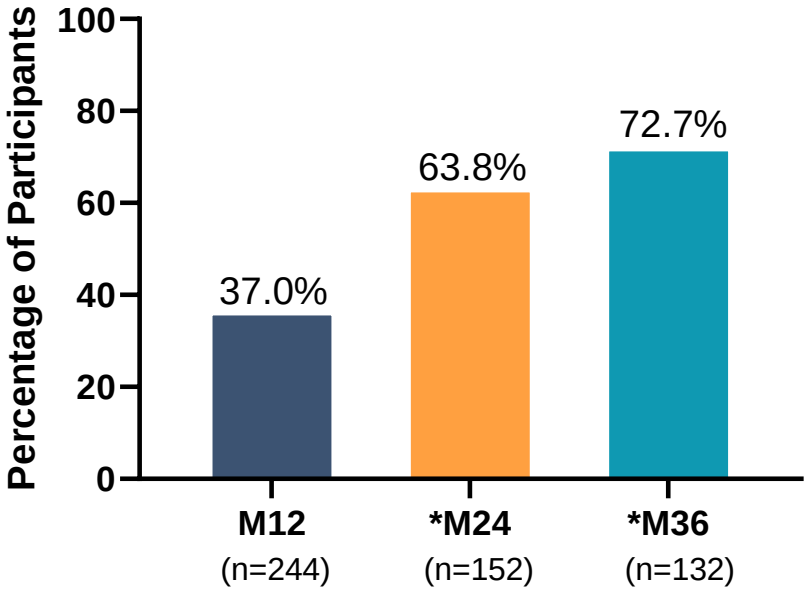
In EPITOPE placebo participants who received treatment with VP250 in the OLE study (2-4 YO), efficacy was consistent with results seen after 12 and 24 months of VP250 treatment in EPITOPE[1-3]

†In EPITOPE, a treatment responder (assessed by DBPCFC) was defined as: If ED ≤10 mg at baseline, responder if ED ≥300 mg at M12; If ED >10 mg at baseline, responder if ED ≥1000 mg at M12.
*Number of subjects with non-missing food challenge endpoint. VP250=VIASKIN® Peanut patch 250 µg; OLE=Open Label Extension; DBPCFC=Double-Blind Placebo-Controlled Food Challenge.

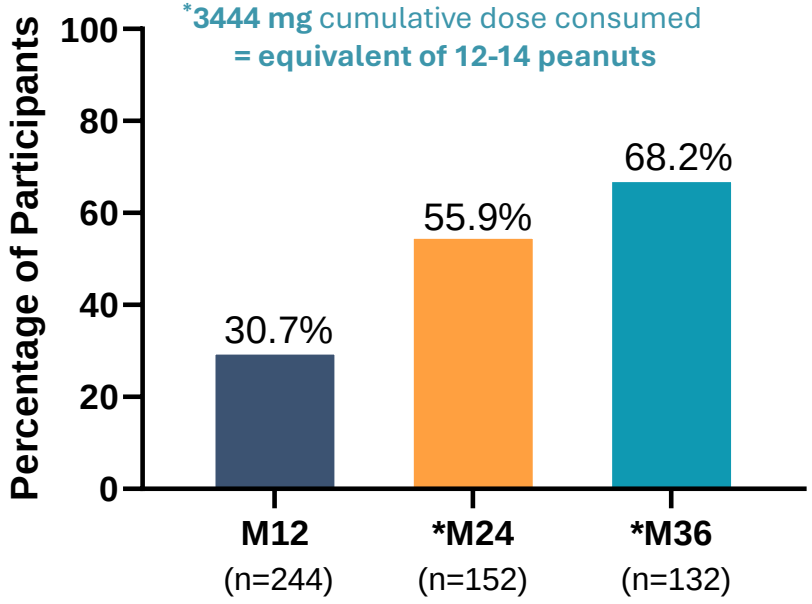
1. Greenhawt et al. EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: 1-year Open-Label Extension to EPITOPE. Oral Presentation at ACAAI Nov 2023; 2. DBV Technologies Press Release, January 8, 2025; 3. Greenhawt et al. EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: Results After 3 Years of Treatment. Presentation at Eastern Food Allergy & Comorbidity Conference. January 9-12, 2025.

Data from EPITOPE Open-Label Extension Show Continued Improvement in Treatment Response in Toddlers Through 36 Months[1-3]

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



Completed Food Challenge* Without Meeting Stopping Criteria



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Study Results of VIASKIN® Peanut Patch Consistently Demonstrate a Favorable Safety & Tolerability Profile in Toddlers[1-4]

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

- Consistent with other studies[5], 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† (EPITOPE) (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 EPITOPE; AE=adverse event; TEAEs=treatment-emergent adverse events. AESI=Adverse event of special interest.
†175 subjects entered OLE study (out of 244 randomized to receive VP250 in EPITOPE).

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. 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. EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: Results After 3 Years of Treatment. Presented 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 presented at AAAAI Annual Meeting, February 2022.

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

April '23

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

- **FDA confirmed EPITOPE data met pre-specified criteria for success;** did not request additional efficacy data to support future BLA
- **Agreement on a supplemental safety study** to augment safety data collected from EPITOPE to bring total number of subjects on active treatment to ~600 (per ICH guidelines)

July '23

Type C Meeting Written Responses on COMFORT Toddlers Study Design[2]

✓ **FDA feedback on KEY study design elements:** 6-month study of approx. 400 subjects randomized 3:1 (active:placebo)

Oct '23

Written Responses Received to DBV's Clarification Request Re. COMFORT Studies Design[3]

- Harmonized, simplified protocol language guiding how the product will be used
- To enroll a population closely aligned with EPITOPE, DBV opted for a DBPCFC at entry

Nov '23

Submission of amended COMFORT Toddlers protocol to FDA for review[4]

March '24

Further discussions between FDA & DBV regarding COMFORT Toddlers study design[4]

– Dialogue focused on adhesion & patch wear-time experience

June '24

COMFORT toddlers

BLA=Biologics License Application; ICH=International Council for Harmonisation; DBPCFC=Double-Blind Placebo-Controlled Food Challenge.

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 labeling approach[1]:

- Crafted on *post-hoc* analysis of EPITOPE efficacy & wear time data to bring efficacy as an essential element of understanding adhesion and wear time with VIASKIN® Peanut patch (VP250)
- Identifies patients most likely to benefit from VP250 based on wear time experience in the first 90 days of treatment (**Outlined on pages 31-37**)

FDA offered guidance on the intermediate clinical endpoint (ICE) to satisfy the 3rd criterion[2]:

DBV agreed to FDA guidance and suggestion on Accelerated Approval (AA) 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

June '24 → **Sep '24** → **Oct '24** → **Dec '24 (3)**

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[2]

VP250 met 1st & 2nd criteria for AA:

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

1. FDA issued WR formalizing AA pathway for VP250 in Toddlers
2. Final alignment on COMFORT Toddlers key study design elements
3. Confirmed criteria for the post-marketing study design

VP250=VIASKIN® Peanut patch 250 µg; AA=Accelerated Approval; WR=Written Response.

1. DBV Technologies Press Release July 30, 2024; 2. DBV Technologies Press Release October 22, 2024; 3. DBV Technologies Press Release December 11, 2024.

DBV's Proposed Labeling Strategy

A Practical Solution to Address FDA's Remaining Questions Around Patch Adhesion

Question was raised by FDA during dialogue re. COMFORT Toddlers' protocol:

What should prescribers tell their patients if there is day-to-day variability in patch wear time?

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

↓

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

↓

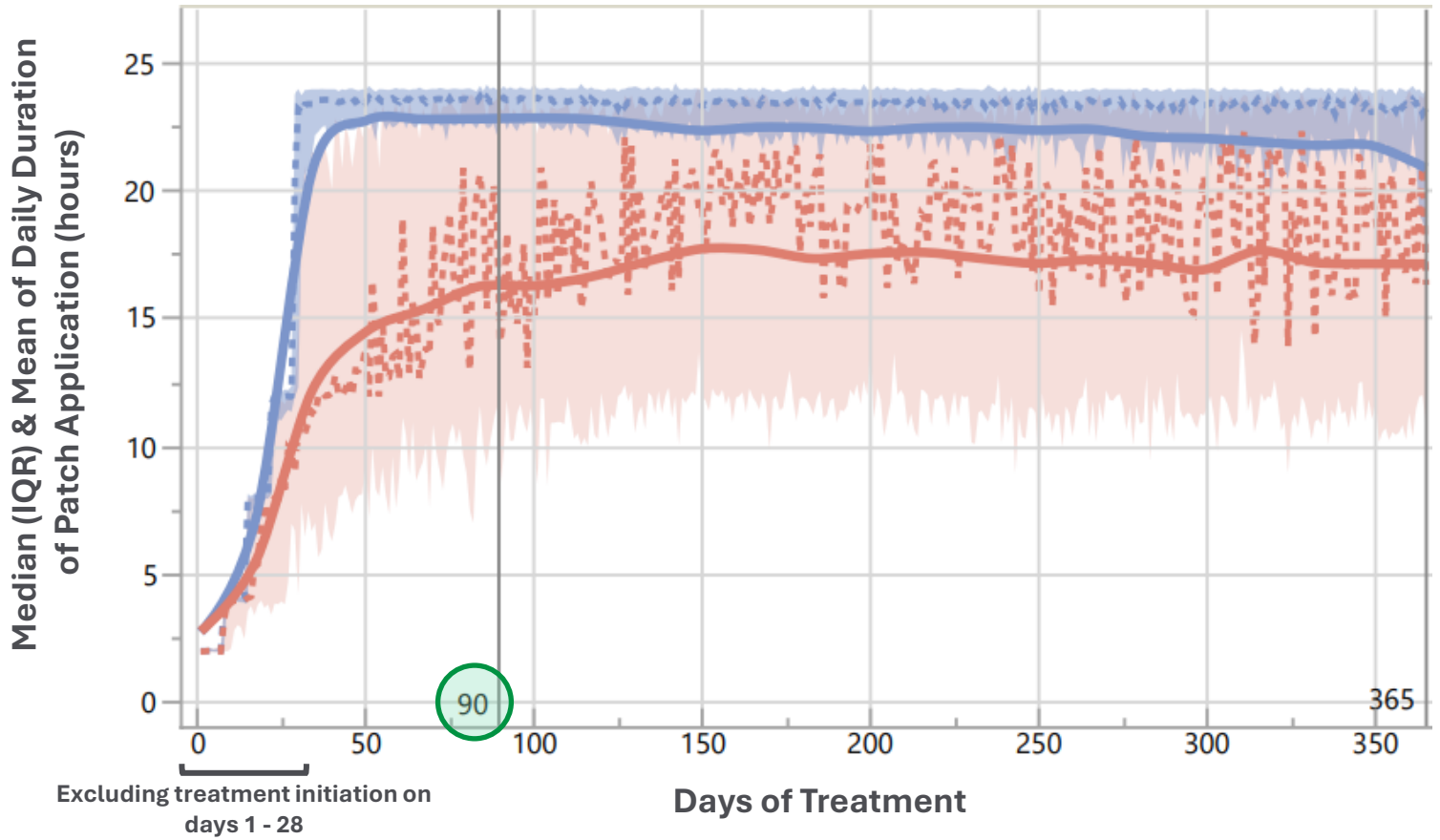
Identifies patients who would have the highest potential clinical benefit at Month 12 based on wear-time experience in the first 90 days of treatment

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

1. DBV Technologies Press Release, July 30, 2024; 2. DBV Technologies Press Release, January 8, 2025.

Two Groups of Subjects Treated with VIASKIN® Peanut Patch Are Readily Distinguished Based on Average Daily Wear-Time (ADWT)[1,2]

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



LOW day-to-day wear time variability (≥20h ADWT), n=167

HIGH day-to-day wear time variability (<20h ADWT), n=77

Dashed Lines = Median (IQR Band)

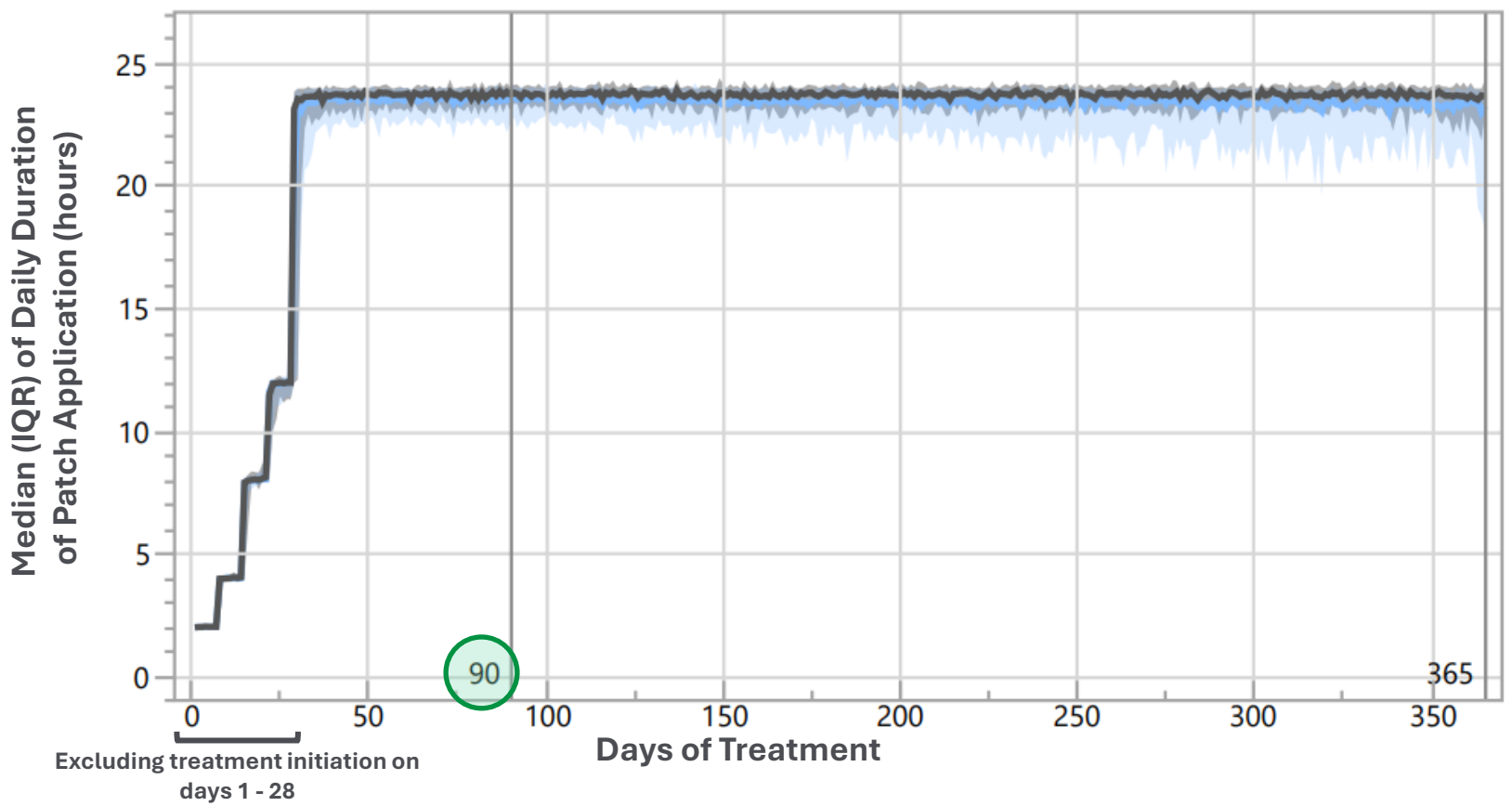
Solid lines = Mean

ADWT within first 90 days of treatment is highly predictive (R=0.81) of ADWT over a 12-MO treatment period

1. Kim, E et al. VP250 Average Daily Wear Time: Impact on Efficacy and Safety in the Phase 3 EPITOPE Study. Presentation at Eastern Food Allergy & Comorbidity Conference, January 9-12, 2025.
2. DBV Technologies Press Release. January 8, 2025.

Similar Wear-Time Experience Observed in Participants Achieving ≥20 hours ADWT as Placebo Subjects[1,2]

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



=IQR Band (VP250 ≥20h ADWT)

=IQR Band (Placebo)

VP250 ≥20h ADWT	22.9 hours Median ADWT
Placebo	23.7 hours Median ADWT

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

1. Kim, E et al. VP250 Average Daily Wear Time: Impact on Efficacy and Safety in the Phase 3 EPITOPE Study. Presentation at Eastern Food Allergy & Comorbidity Conference, January 9-12, 2025.
2. DBV Technologies Press Release. January 8, 2025.

Subjects with ADWT <20h Reported More Scratching as a Reason for Patch Detachment Versus Subjects with ADWT ≥20h Despite Similar Baseline Characteristics

IMPLICATION – Lower Tolerability to Peanut Allergen ("More Itchiness") in Subjects with ADWT <20h[1-2]

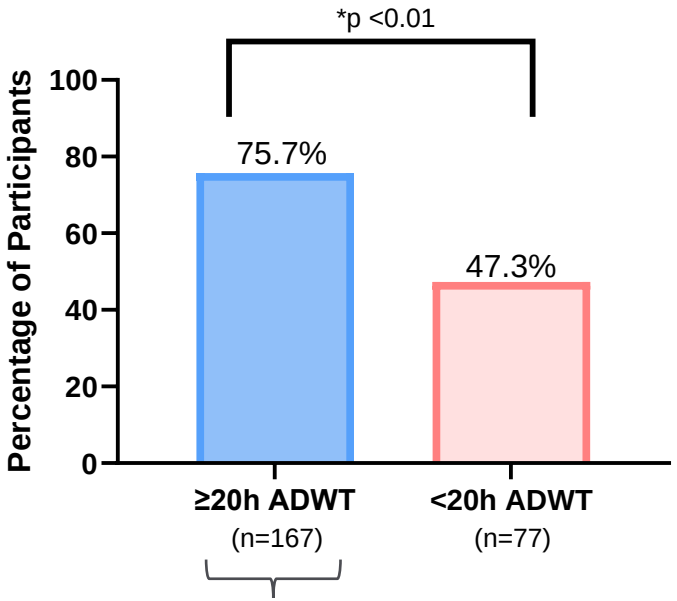
Baseline characteristics & in-study factors which may influence system wear time & adhesion	≥20h ADWT (n=167)	<20h ADWT (n=77)
Baseline sIgE, median (mean)	**13.3 (66.1)**	**13.9 (50.8)**
Baseline Ara h 2, median (mean)	**8.1 (38.9)**	**9.6 (32.7)**
Baseline ED, median	**100 mg**	**100 mg**
Baseline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

sIgE=peanut-specific IgE; Ara h 2=a major peanut allergen; ED=Eliciting Dose; SCORAD=SCORing Atopic Dermatitis; AEs=Adverse events.
*Score of 2=partially detached; score of 3=detached

1. Kim, E et al. VP250 Average Daily Wear Time: Impact on Efficacy and Safety in the Phase 3 EPITOPE Study. Presentation at Eastern Food Allergy & Comorbidity Conference, January 9-12, 2025.
2. DBV Technologies Press Release. January 8, 2025.

Average Daily Wear-Time (ADWT) within First 90 Days Correlates with Clinical Response at Month 12 [1,2]

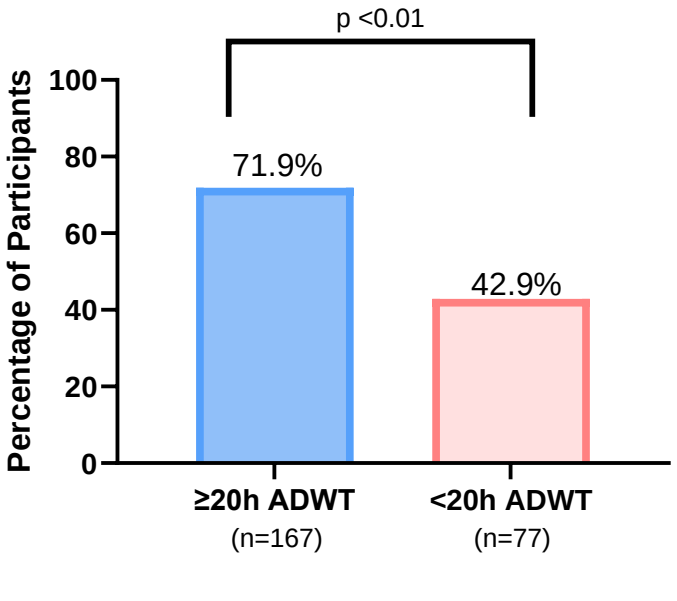
Responder Primary Analysis



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

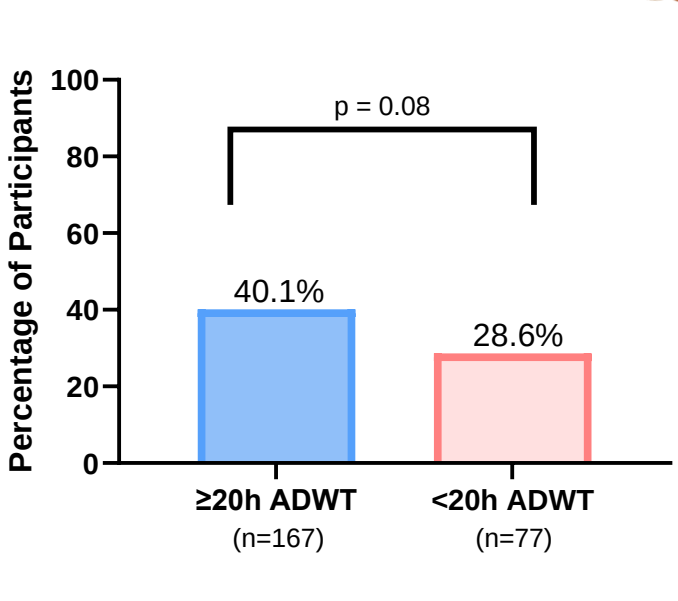
Eliciting Dose ≥1000 mg

(Equivalent of 3-4 peanuts)



Eliciting Dose ≥2000 mg

(Equivalent of 6-8 peanuts)



*Multiple imputation.

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

Lower Rate of Key Safety Outcomes in Subjects with ADWT ≥20 Hours Versus Subjects with ADWT of ≤20 Hours[1,2]

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

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

VP250=VIASKIN® Peanut patch 250 µg; ADWT=Average Daily Wear-Time.
TEAEs=treatment-emergent adverse events.
AESI=Adverse event of special interest.

1. Kim, E et al. VP250 Average Daily Wear Time: Impact on Efficacy and Safety in the Phase 3 EPITOPE Study. Presentation at Eastern Food Allergy & Comorbidity Conference, January 9-12, 2025.
2. DBV Technologies Press Release. January 8, 2025.

DBV's Labeling Strategy: A Practical Tool to Guide Shared Decision-Making

In EPITOPE, participants could be readily distinguished based on ADWT

- Those with LOW day-to-day variability (≥20 hours ADWT)
- Those with HIGH day-to-day variability (<20 hours ADWT)

Subjects with LOW day-to-day variability have a very similar wear time experience to placebo patients (median ADWT of 22.9 hours vs 23.7 hours, respectively)

vs

Subjects with ADWT of ≥20 hours vs ADWT <20 hours have highly comparable baseline immunological profiles AND a similar incidence & severity of local site reactions

Participants with ADWT <20 hours reported more scratching leading to patch detachment – suggesting that these subjects experience lower tolerability (i.e., higher degree of "itchiness") to peanut-induced local skin immune response

- ✓ ADWT within the first 90 days of treatment is highly predictive of clinical efficacy at Month 12 AND highly predictive of ADWT over a 12-month treatment period
- ✓ ADWT is a practical approach that could be adopted to guide shared decision-making and optimal use of VIASKIN® Peanut patch if approved

dbv technologies

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:

FDA Confirms an AA Pathway for VIASKIN® Peanut Patch in 1-3 YO[1]

1. **Product treats a serious disease** → FDA states it is met[2]
2. **Generally provides a meaningful advantage over available therapies†** → FDA states it is met[2]
3. **Demonstrates an effect on an intermediate clinical endpoint (ICE) that is reasonably likely to predict clinical benefit** → FDA states it is met via Written Response Letter[1]

- ✓ 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.

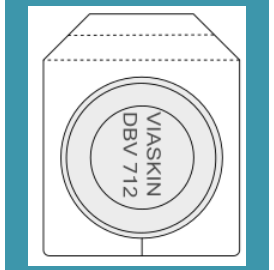
† PALFORZIA and XOLAIR are FDA-approved for the treatment of peanut allergy.

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

Alignment on COMFORT Toddlers Supplemental Safety Study

Intends to Generate Supplemental Safety & Adhesion Data in Peanut Allergic Toddlers, Ages 1-3 YO

- 6-month study with an optional 18-month open-label extension
- Key study inclusion criteria include skin/serum sensitization to peanut and reaction on DBPCFC (at screening) to an eliciting dose of 300 mg or less of peanut protein
- **Aligned on a patch wear time collection methodology, analysis and study objective hierarchy in the COMFORT Toddlers study[1]**
- The agreed-upon adhesion data collection methodology provides a practical approach for subjects, families, and investigators AND is intended to generate sufficient data to support a BLA submission under the Accelerated Approval pathway (i.e., collecting patch adhesion data with a focus on daily wear time at relevant time points)
- **Start-up activities have begun with trial initiation anticipated in Q2 2025 [1,2]**



COMFORT toddlers

1. DBV Technologies Press Release, December 11, 2024.
2. DBV Technologies Press Release, October 22, 2024.

US Regulatory Pathway for Toddlers, Ages 1-3 YO

Clear & Well-Defined Regulatory Pathway for the VIASKIN® Peanut Patch Program in Toddlers

Under The Accelerated Approval (AA) Pathway

1 **epitope**

COMPLETED Efficacy & Safety

The successful Phase 3 trial in 1-3 YO[1]

†Clinical patch

+

2 **COMFORT toddlers**

6-Month DBPC Supplemental Safety††

To augment safety data collected in EPITOPE

Anticipated to be initiated in Q2 2025

†Commercial patch

=

Could constitute a BLA submission for a 1-3 YO indication using the original square patch

+

Commitment to a Post-Marketing Confirmatory Study in 1-3 YO

To be initiated at the time of BLA submission (with Commercial patch)

BLA Under AA Pathway Anticipated to be Submitted in 2H 2026[2]

Written Confirmation from FDA Regarding Study Criteria[2] (*)

†The components in contact with the patients' skin, as well as the condensation chamber, and active pharmaceutical ingredient (API) are unchanged. Minor changes were made to the commercial patch with the aim to ease application of the patch by the caregiver; as illustrated on page 51 (Appendix I).

††The company anticipates enrolling ~360 subjects on active treatment into the COMFORT Toddlers safety study[2], which would bring the total VIASKIN® Peanut patch safety database in toddlers to ~600 subjects (i.e., when combined with toddlers on active treatment in EPITOPE), consistent with prior FDA guidance.

(*) The post-marketing confirmatory study will include[2]: (1) a DBPCFC; (2) the same statistical criteria for success (i.e., lower bound of the 95% CI ≥15%) as used in the Phase 3 EPITOPE efficacy study; (3) adhesion data will be collected in a similar manner as COMFORT Toddlers; (4) further analyses will also be conducted to support the importance of average daily wear time as it relates to efficacy & labeling.

DBPC=Double-Blind, Placebo-Controlled; BLA=Biologics License Application; CI=Confidence Interval.

1. Greenhawt M, et al. *N Engl J Med*. 2023; 388:1755-1766; 2. DBV Technologies Press Release. December 11, 2024.

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 ≥4 YO, as requested by FDA[1]**
- ✓ **The modified CIRCULAR VIASKIN® patch was selected based on adhesion data collected from a Phase 1 study conducted in healthy adults[2]**

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[3]

VITESSE MODELED ON PRIOR PHASE 3 PIVOTAL TRIAL IN 4-11 YO[4]

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 ($p<0.001$)[5]

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

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, September 7, 2022; 5. 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.

VITESSE Study Design Schematic with Open-Label Extension Targeting a Younger, More Sensitive Patient Population[1]

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

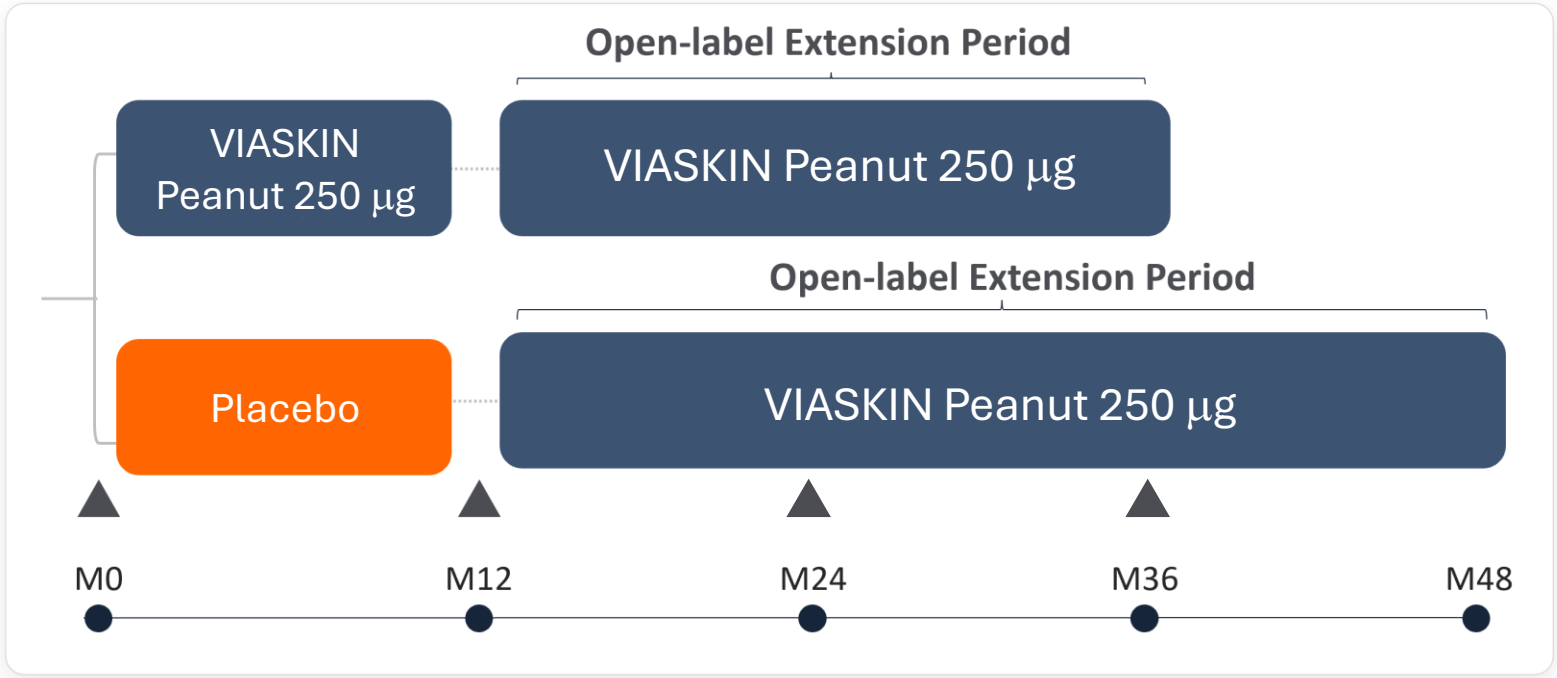
Global Phase 3 Trial

Randomized, double-blind, placebo-controlled

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

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

Treatment responder (assessed by DBPCFC) defined as:
If ED ≤30 mg at baseline, responder if ED ≥300 mg at M12
If ED=100 mg at baseline, responder if ED ≥600 mg at M12



▲ DBPCFC=Double-Blind Placebo-Controlled Food Challenge

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.
2. DBV Technologies Press Release, September 23, 2024; 3. DBV Technologies Press Release, October 22, 2024.

VIASKIN® Peanut Patch 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[1]

+

2

COMFORT children

6-Month DBPC Supplemental Safety†

- Anticipate ~250 subjects in total
- 3:1 randomization
- No Food Challenge required
- **Start-up activities have begun**

– Study expected to be initiated in Q2 2025[2]

=

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

BLA Filing Anticipated in 2H 2026[2]

DBPC=Double-blind, placebo-controlled; †To achieve FDA Guideline of ~600 subjects on active treatment for at least 6 months

dbv technologies

1. DBV Technologies Press Release. October 22, 2024; 2. DBV Technologies Press Release. December 11, 2024.

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

1. 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.
2. Spergel JM et al. Efficacy of Epicutaneous Immunotherapy in Children With Milk-Induced Eosinophilic Esophagitis *Clin Gastroenterol Hepatol*. 2020 Feb;18(2):328-336.

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

† 2034 expiration date assumes full 5-year patent term extension ("PTE") is granted post-marketing approval.
NOTE this applies to the US only; other expiration dates may apply in other countries.

Patch Manufacturing Capabilities

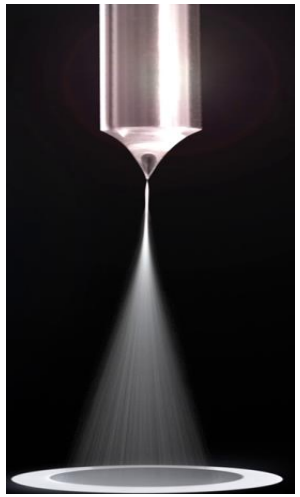
Integrated End-to-End Patch Manufacturing in Place

Source Material

Active Pharmaceutical Ingredient (API)

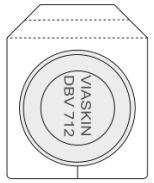
Final Product Process

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)

- 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)

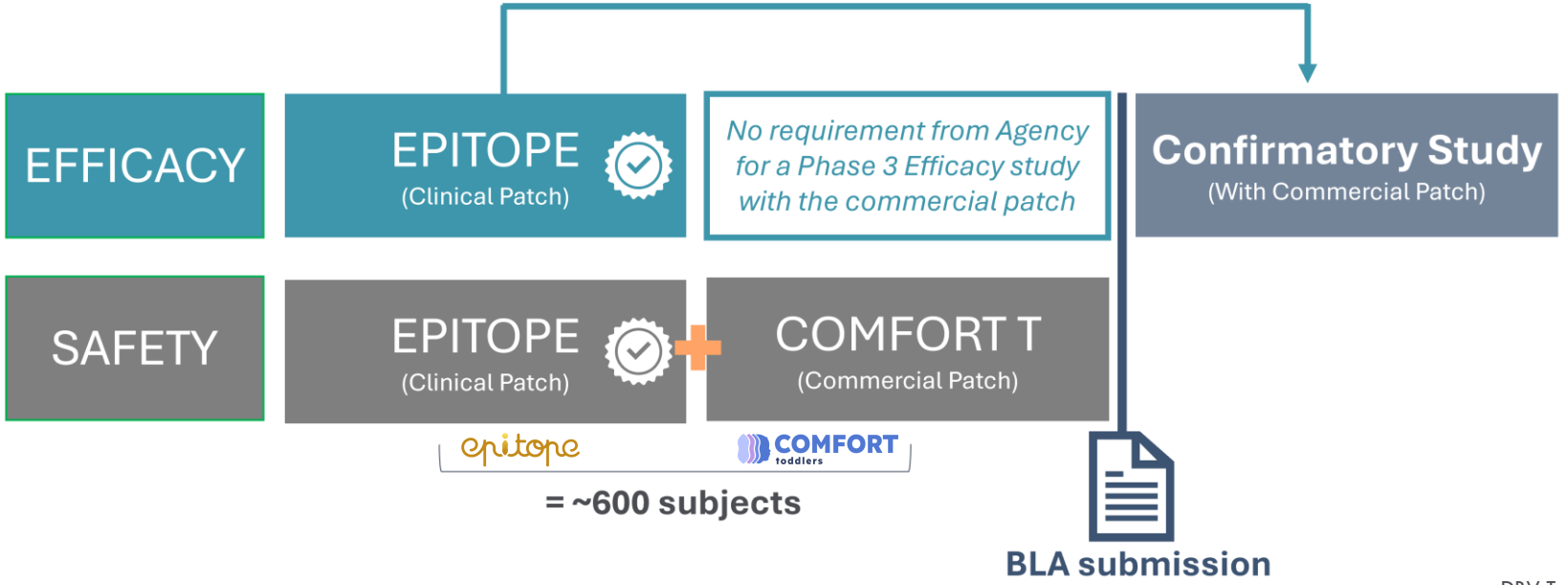
- Initiation of COMFORT Children anticipated in Q2 2025
- Continue to advance VITESSE with topline data anticipated in Q4 2025

APPENDIX I:
VIASKIN Peanut Program in Toddlers (1–3-Year-Olds)

Accelerated Approval Pathway

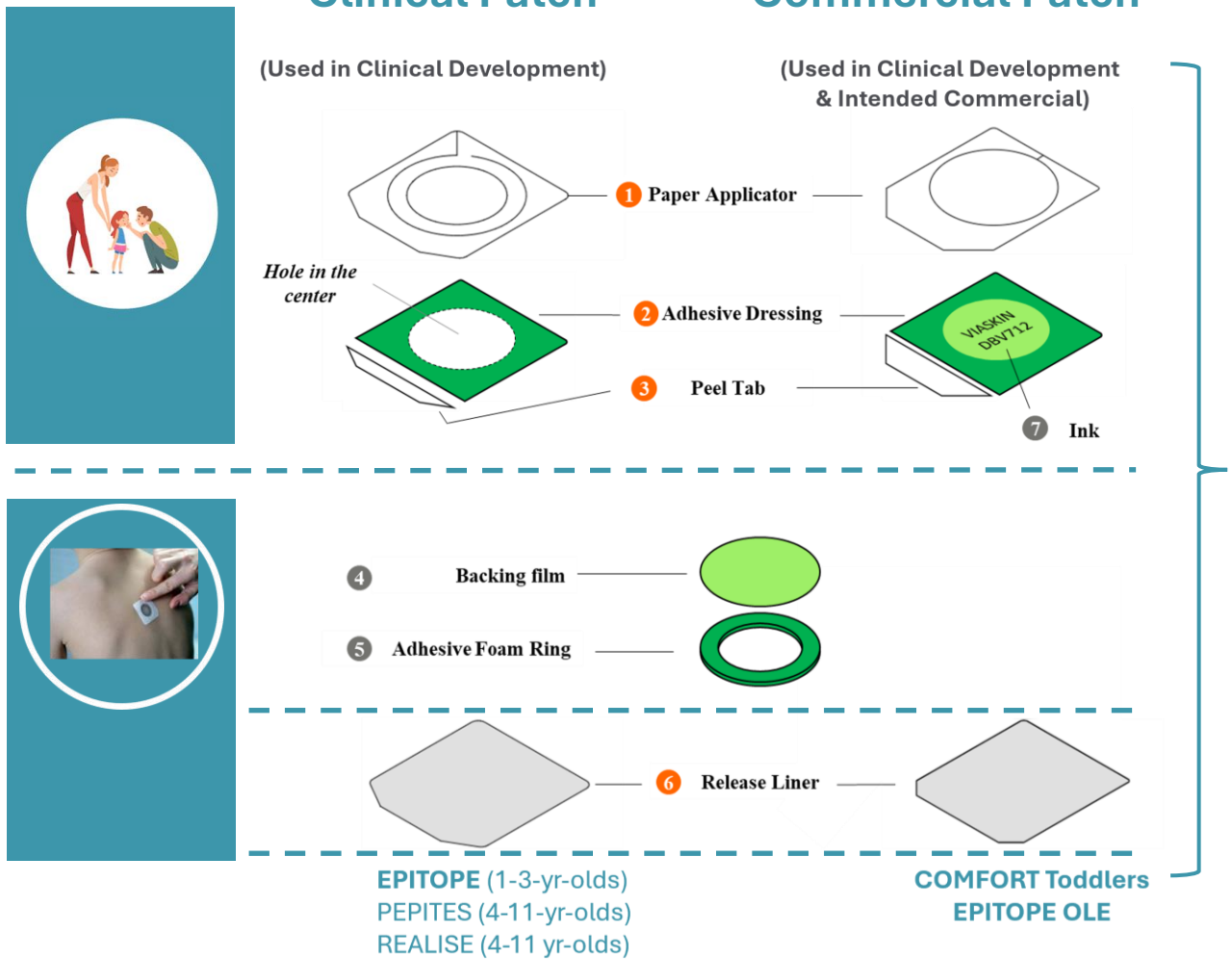
A Creative & Reasonable Solution Making use of Existing Regulations to Accelerate Availability of VIASKIN® Peanut Patch to Patients

- **VIASKIN® Peanut patch has breakthrough designation**
- Demonstrated efficacy with EPITOPE "clinical patch" is predictive of efficacy with the "commercial patch"
- No need to generate safety data in 600 patients with the "commercial patch"
- **Accelerated Approval is the fastest pathway to make VIASKIN® Peanut patch available to patients**



Minor Alterations to EPITOPE Patch to Evolve Towards Commercialization

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



Components in contact with patients' skin and condensation chamber are UNCHANGED

Changes made to ease application without impacting components in contact with patient's skin:

Paper Applicator (1), Peel Tab (3) and Release Liner (6): Cut & Size

Changes aimed to facilitate the manipulation of the system by caregivers and make the removal of the paper applicator easier

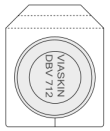
Adhesive Dressing (2)

Adhesive Dressing covers the Backing Film (4); allowing the product name to be printed (7) on inside of the dressing and protected against erasure

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

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

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



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 Patch 250 µg in Children 4–11 YO

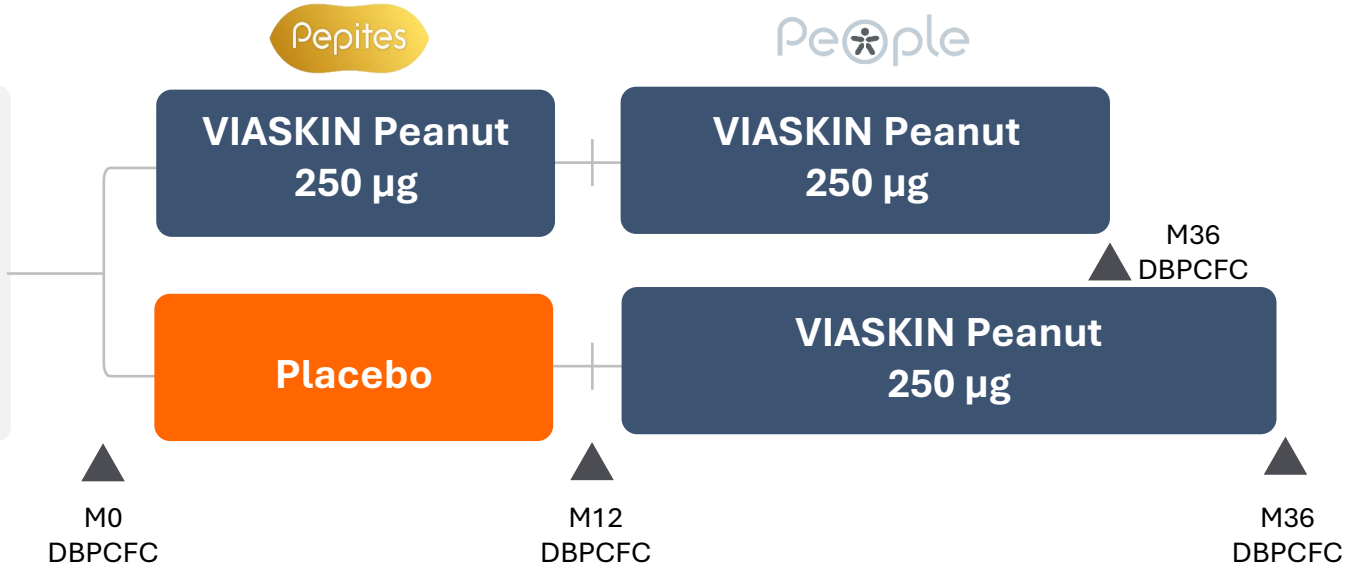
Results Published in JAMA (PEPITES)[1] & Journal of Allergy & Clinical Immunology (PEOPLE)[2]

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

Treatment responder (assessed by DBPCFC) defined as:

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

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

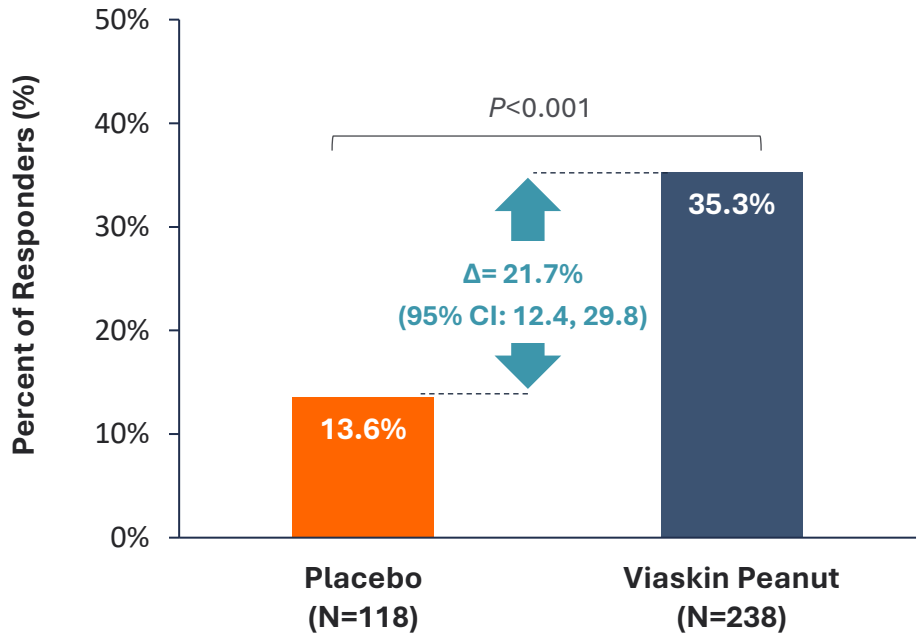
*Confirmed peanut allergy by SPT ≥6 mm for 4- to 5-year-olds or ≥8 mm for 6- to-11-year-olds and sIgE levels (>0.7 kUA/L).
DBPCFC=Double-Blind Placebo-Controlled Food Challenge; ED=Eliciting Dose.

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

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

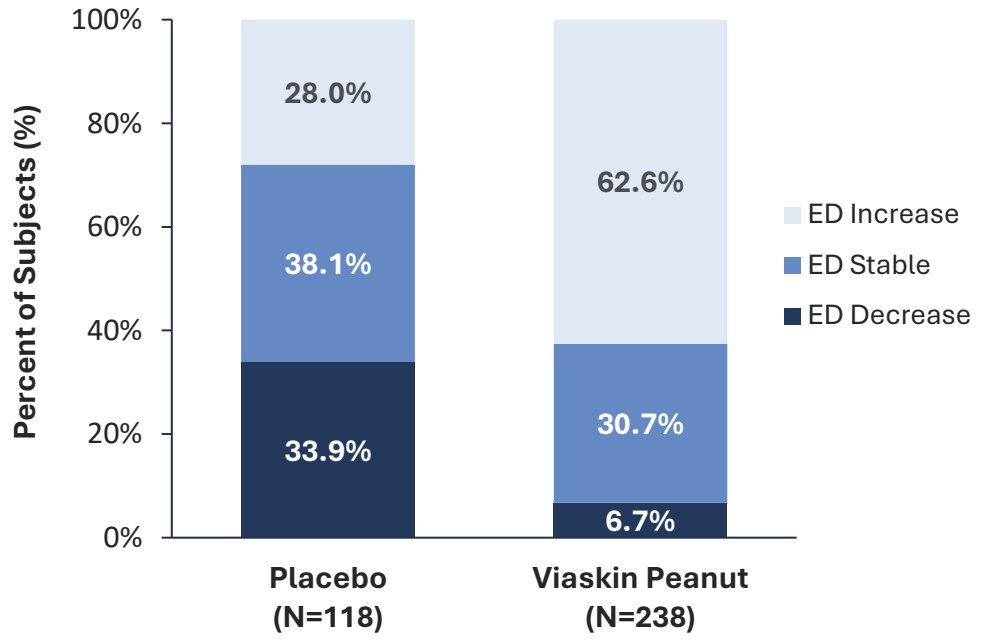
Primary Efficacy Outcome Showed Statistically Significant Treatment Benefit

Response Rate after 12 Months



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

Change in Eliciting Dose after 12 Months*



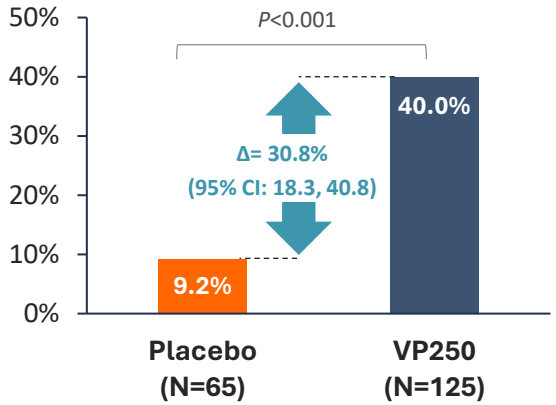
An increase in ED was >4 times more likely to occur in the VIASKIN® Peanut patch group compared with placebo

*Based on ITT population; missing data calculated using mBOCF. DBPCFC=Double-Blind Placebo Controlled Food Challenge; ED=Eliciting Dose.

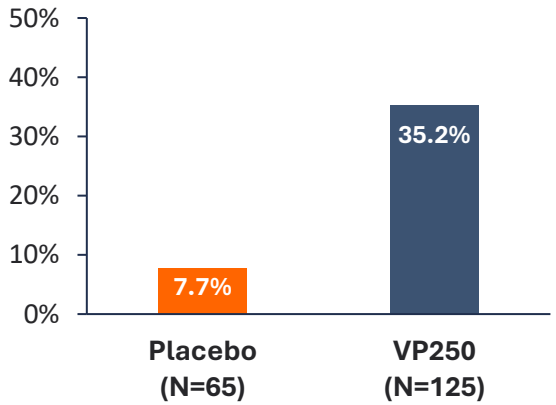
1. Fleischer DM, et al. Effect of Epicutaneous Immunotherapy vs Placebo on Reaction to Peanut Protein Ingestion Among Children With Peanut Allergy: The PEPITES Randomized Clinical Trial. *JAMA*. 2019;321:946-955.

Post-Hoc Analysis of PEPITES Data Supports Concept That Greater Gains in Desensitization May Be Achieved in Younger Versus 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 patch 250 µg (VP250) versus placebo was demonstrated

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

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

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 Patch[1]

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

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

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

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

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

Conclusion

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

*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

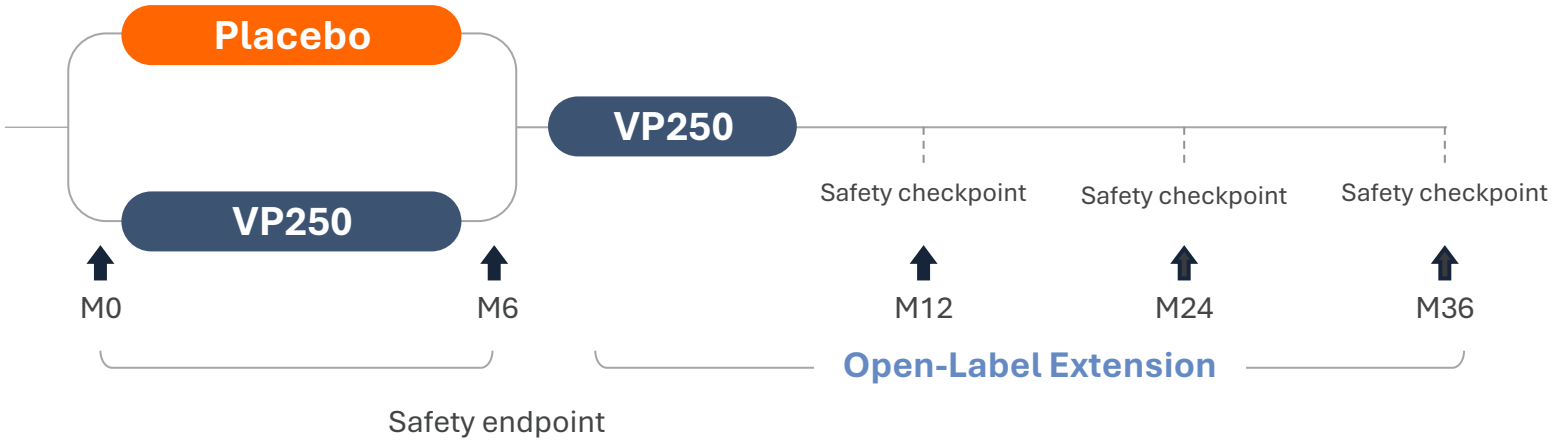
Children 4–11 Years Old

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

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

32 centers in the US and Canada

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



- REALISE met its primary endpoint in the 6-month blinded portion of the study, demonstrating that VIASKIN® Peanut patch was tolerated with no new or unexpected 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 patch 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.

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