DBV TECHNOLOGIES

Corporate Presentation I May 2025

Euronext Paris: DBV I Nasdaq: DBVT

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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.

Summary Overview of DBV Technologies

Our Mission is to Develop Novel Treatments for Pediatric Food Allergy

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

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

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

Investment Highlights (US)

Two Distinct Opportunities for VIASKIN® Peanut Patch

One BLA in 4-7 YO

One BLA in 1-3 YO

Clear Clinical Pathway for Both Programs

Ongoing, fully-enrolled 12-month Phase 3 pivotal trial (VITESSE) in 4–7-YO for potential BLA submission in children[1]

The successful EPITOPE Phase 3 study to be supported by a 6-month supplemental safety trial[2] (COMFORT Toddlers)

Anticipated Clinical & Regulatory Milestones

- Topline results for VITESSE anticipated in **4Q25**[3]
- BLA submission anticipated for **1H26**[4] (eligible for priority review)†

- FPI for COMFORT Toddlers anticipated in **2Q25**[5]
- BLA submission anticipated for **2H26** under a formalized Accelerated Approval pathway[5]

Transformational March ’25 Financing

Up to $306.9 million ($125.5 million upfront)[6]

Expected to fund operations through BLA submission for VIASKIN® Peanut patch in 4-7 YO & commercial launch, if approved

1. DBV Technologies Press Release. September 23, 2024; 2. DBV Technologies Press Release. April 19, 2023; 3. DBV Technologies Press Release. October 22, 2024; 4. DBV Technologies Press Release. March 24, 2025; 5. DBV Technologies Press Release. December 11, 2024; 6. DBV Technologies Press Release. March 27, 2025.
†VIASKIN® Peanut patch has breakthrough designation.

Transformational Financing (Announced March 27, 2025) Provides Runway Through Potential Approval & Launch of VIASKIN® Peanut Patch

March 2025 Financing

Financing led by several large dedicated healthcare funds[1]

Upfront	$125.5 M
Proceeds from exercise of all warrants following release of VITESSE topline data (anticipated in Q4 2025)	$181.4 M
Total Financing	$306.9 M

DBV is sufficiently funded through the expected Biologics License Application (BLA) submission for the VIASKIN® Peanut patch in 4-7 YO & commercial launch, if approved

1. DBV Technologies Press Release. March 27, 2025.

Significant Market Opportunity for VIASKIN® Peanut Patch

~670K Children Aged 1-7 Years Have Peanut Allergy in US[1-3]

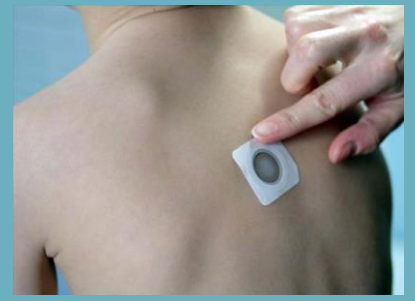
1-3 years old	4-7 years old
280,000 Toddlers[1-3]	390,000 Children[1-3]

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.

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 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 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)

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.

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 Formalized Accelerated Approval Pathway[1]	**ACCELERATED Timeline for BLA Submission[2]**

1. DBV Technologies Press Release. December 11, 2024; 2. DBV Technologies Press Release. March 24, 2025.

Accelerated Timeline for VIASKIN Peanut in Children, Ages 4 –7 YO

Agreement with FDA on Safety Exposure Data for BLA Filing, Obviating Need for COMFORT Children Trial

Program	Patch	(Originally) Planned Phase 3 Studies to Support a BLA in Children		
		VITESSE 12-Month Efficacy & Safety TOPLINE DATA ANTICIPATED 4Q25[1]	VITESSE 3 Year Open-Label Extension *Ongoing*	COMFORT children 6-Month Supplemental Safety NO LONGER REQUIRED[2]

ICH guidelines typical safety database should consist of 300-600 subjects[3]

>400 subjects randomized to receive VIASKIN Peanut patch in VITESSE

+

Placebo-cross over subjects in OLE (>200 subjects randomized to receive placebo in VITESSE)

=

~500 subjects anticipated on active treatment for at least 6 months to support a BLA submission

- Anticipated BLA submission in H1'26[2]; BLA may be eligible for priority review*
- DBV anticipates this path may accelerate potential launch, if approved by FDA, by ~1 year[2]

1. DBV Technologies Press Release. September 23, 2024; 2. DBV Technologies Press Release. March 24, 2025; 3. ICH Harmonized Tripartite Guideline.
*VIASKIN® Peanut patch has breakthrough designation.

US Regulatory Pathway for VIASKIN Peanut in Toddlers, Ages 1 –3 YO

Agreement with FDA on a Formalized Accelerated Approval (AA) Pathway for Toddlers Program[1]

Program	Patch	Core Phase 3 Studies for BLA Under AA Pathway			
		1 epitope **COMPLETED** Efficacy & Safety ✓ Primary endpoint met ✓ Satisfactory to FDA[2] ✓ Published in NEJM[3,4]	+	2 COMFORT toddlers **6-Month DBPC** Supplemental Safety Anticipated to start in 2Q25[1]	= Constitute a BLA Submission for a 1-3 YO Indication with Original Patch + Commitment to a Post-Marketing Confirmatory Study in 1-3 YO† † To be initiated at the time of BLA submission

BLA for 1-3 YO under formal AA pathway anticipated to be submitted in 2H26[5]

DBV has received written confirmation from FDA regarding study criteria for Post-Marketing Confirmatory study[1]

BLA=Biologics License Application; DBPC=Double-Blind, Placebo-Controlled

1. DBV Technologies Press Release. December 11, 2024; 2. DBV Technologies Press Release. April 19, 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. January 8, 2025.

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

The unmet need for peanut allergy in Europe is significant:

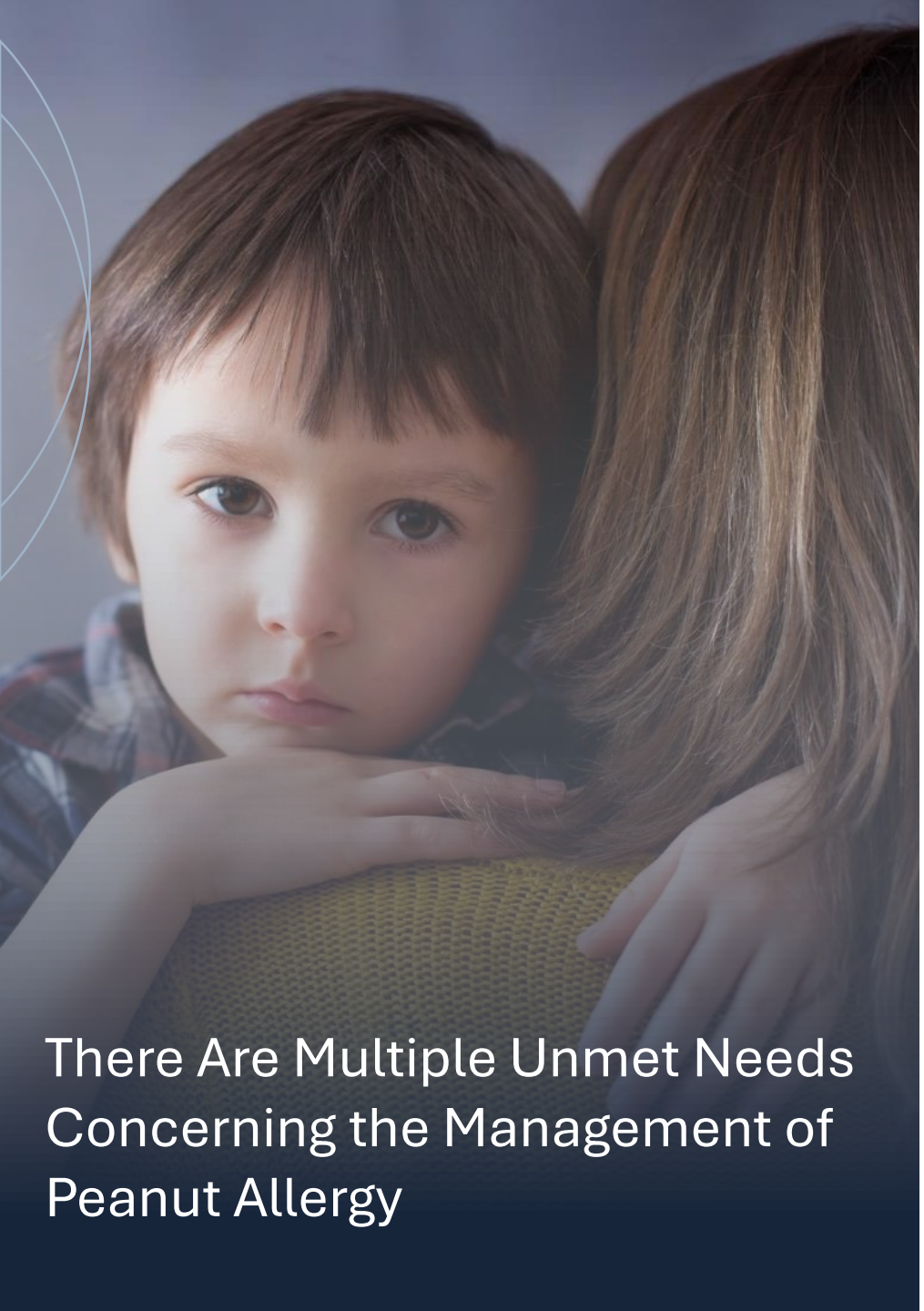
- Estimated that 615,000 children ages 1 – 7 YO in the EU have peanut allergy[1]
- Incidence of new diagnosis of ~81,000 a year[1]

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 design 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 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 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.

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.

90% of allergists see the need for additional options in the treatment of pediatric peanut allergy[7]

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; 7. 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?"

Treatment Must Be Effective, Safe, and Practical to Use to Achieve Outcomes with Immunotherapy

Peanut Allergy Treatment Must Balance 3 Key Elements[1-4]

Reduces likelihood of an allergic reaction in case of accidental exposure

Low risk of a serious reaction caused by the treatment & low risk of side effects

Accepted by caregiver & child

Purposely Designed to Meet the Outcome Objectives of Immunotherapy

1
- ✓ Primary endpoint met in pivotal trial in 1-3 YO[5,6] with further gains in desensitization through 36 MO[7]
- ✓ Efficacy endpoint in ongoing 4-7 YO trial modeled from 4-11 YO pivotal trial[8]

2
- ✓ Daily exposure to 1/1000th of a peanut kernel
- ✓ Consistently favorable safety & tolerability profile[5,7,9] with ~1M patches administered to >1300 children

3
- ✓ Applied once a day at home; no treatment escalation; no restriction on activities in trials
- ✓ High Tx compliance across trials (93% out to 5 years[10])

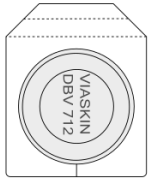
1. Greenhawt M, et al. *Ann Allergy Asthma Immunol.* 2018;120:620-625. doi:10.1016/j.anai.2018.03.001; 2. Based on primary market research conducted on behalf of DBV among 100 allergists in the United States. Survey question: If a new peanut allergy desensitization treatment for children 4 to 11 years of age became FDA-approved and available for use, what would be the importance of each of the following attributes to you? Please use a 0- to 7-point scale where 0 means "not at all important to me" & 7 means "very important to me." 3. Anagnostou A, et al. *J Allergy Clin Immunol Pract.* 2020;8:46-51; 4. Ravindran M et al. Allergy 2025;80(1):63-76; 5. Greenhawt M, et al. *N Engl J Med*. 2023; 388:1755-1766; 6. DBV Technologies Press Release. April 19, 2023; 7. Greenhawt 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; 8. 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; 9. 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; 10. Fleischer, D.M. Long-term Efficacy Results of Epicutaneous Immunotherapy with VIASKIN® Peanut Patch in Peanut-Allergic Children Ages 4-11 Years in the Phase 3 PEOPLE Study. Presented at AAAAI, March 3, 2025.

Anticipated Near-Term Milestones

Upcoming Milestones & Catalysts Anticipated Over Next 18 Months

CHILDREN (4-7 years)

- **VITESSE topline data anticipated in Q4 2025**
- **BLA submission for 4-7 YO anticipated for 1H 2026[1]**



TODDLERS (1-3 years)

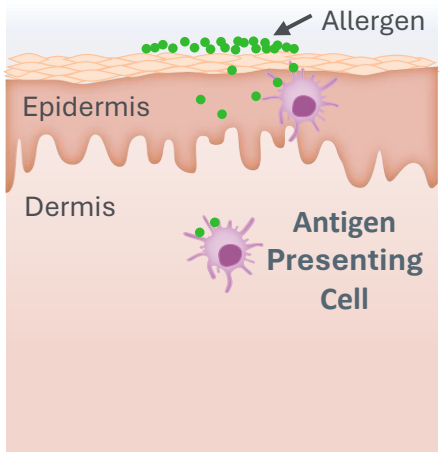
- **Initiation of COMFORT Toddlers safety trial anticipated in Q2 2025**
- **BLA submission for 4-7 YO anticipated for 2H 2026[1]**

1. DBV Technologies Press Release. March 24, 2025.

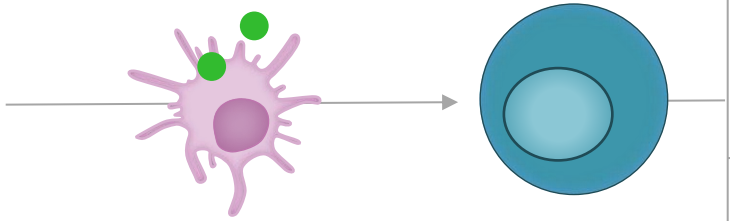
THE SCIENCE OF EPICUTANEOUS IMMUNOTHERAPY (EPIT)

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

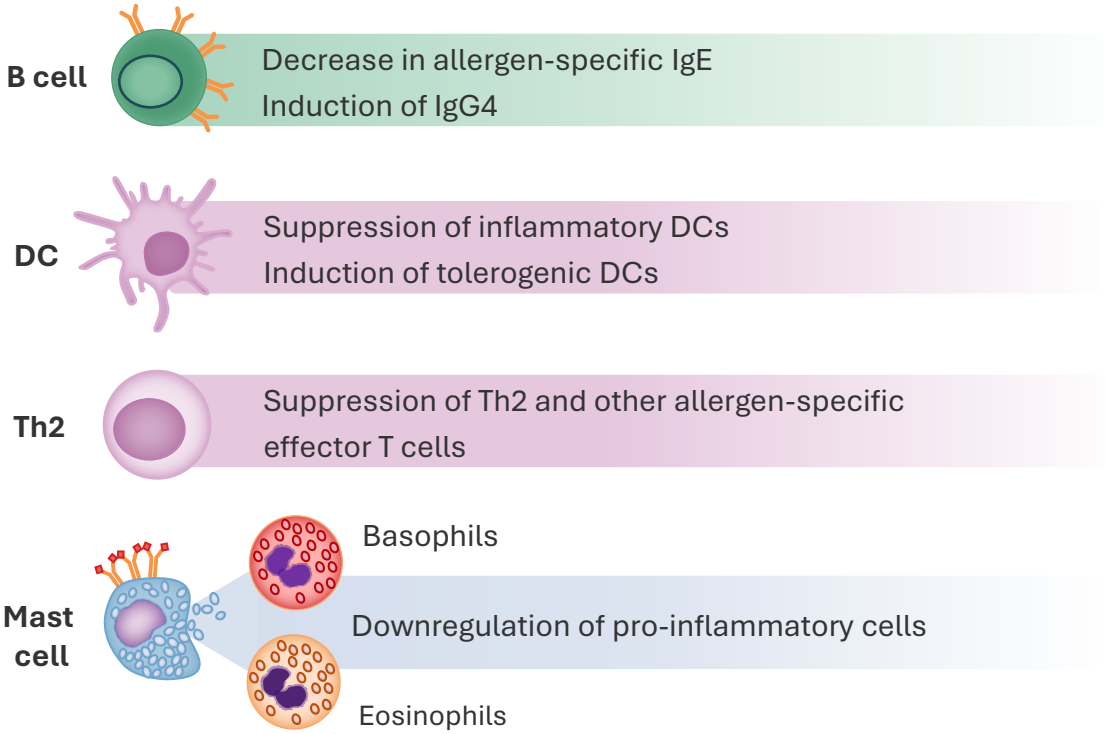
EPIT delivers allergen to the skin



Antigen Presenting Cells capture allergen and induce unique Regulatory T Cells



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

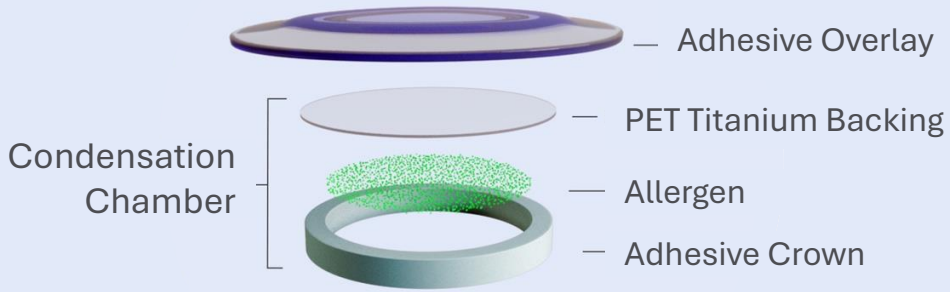


DC=dendritic cell; IgE=immunoglobulin E; IgG4=immunoglobulin G4; Th2=T-helper 2 cell.

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

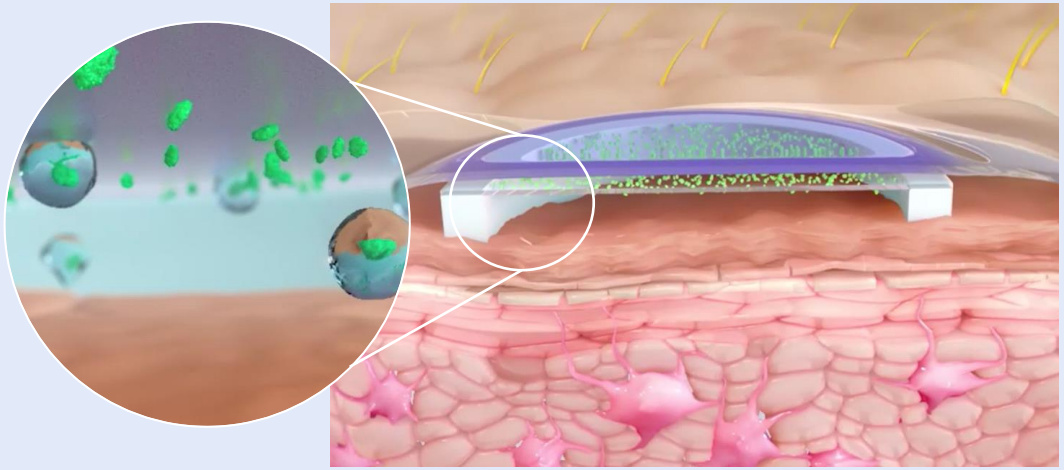
VIASKIN® Patch: Our Innovative Approach to Epicutaneous Immunotherapy[1-3]

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.

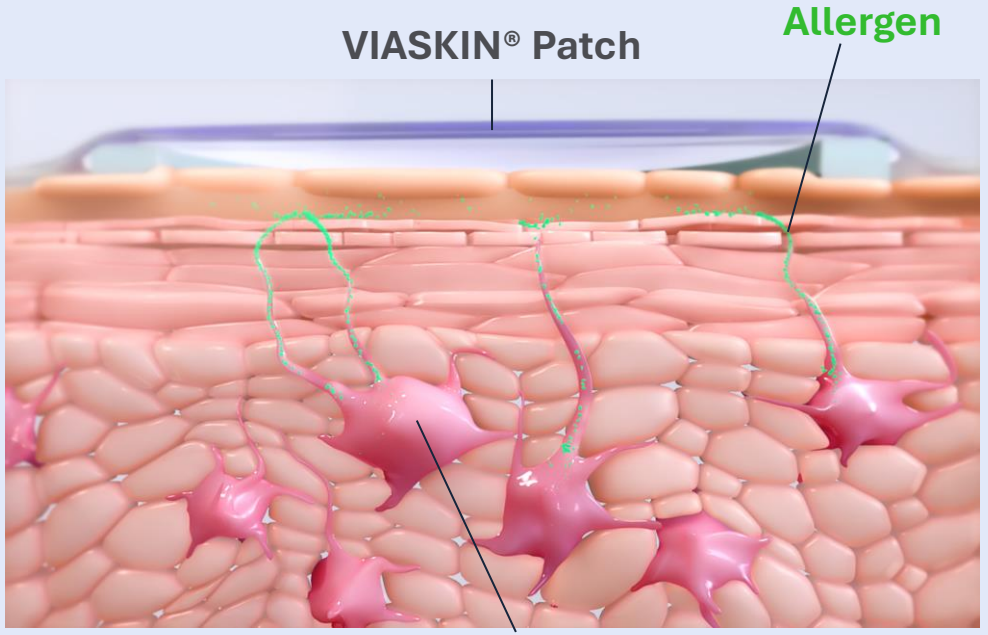
VIASKIN® Patch Uses Minimal Amounts of Allergen to Induce Desensitization[1-3]

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 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

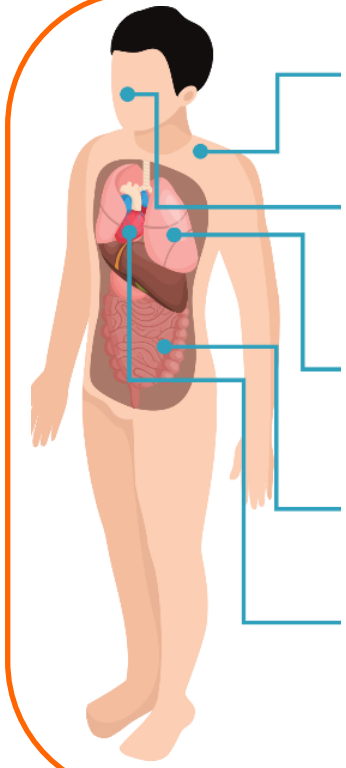


Langerhans Cell
(capturing allergen in the outer layer of the epidermis)

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.

Desensitization is Measured by Increases in Eliciting Dose (ED)

ED = the amount of allergen that induces allergic symptoms[1]:



SKIN: erythematous rash, scratching, hives, lip or face swelling

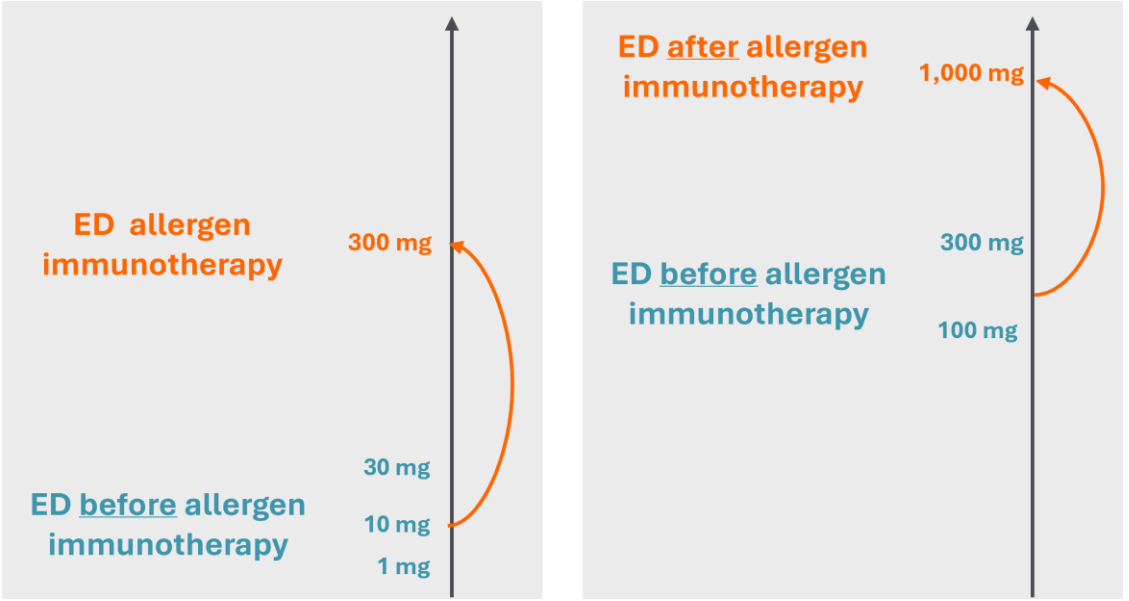
UPPER RESPIRATORY: sneezing/itching, frequent sniffing, periocular swelling, rubbing of nose and/or eyes

LOWER RESPIRATORY: wheezing, cough, hoarseness throat tightness/pain

GASTROINTESTINAL: nausea, abdominal pain, itchy moth/throat, vomiting, diarrhea

CARDIOVASCULAR/NEUROLOGIC: weakness, dizziness, tachycardia, drop in blood pressure, change in mental status

Decrease in Reaction Risk with Increased ED Following Allergen Immunotherapy



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

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

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

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

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

VITESSE

VITESSE Study Design
Targeting a Younger, More Sensitive Patient Population[1]

- **Fully enrolled since end of Q3 2024[2] → 654 subjects ages 4-7 YO (vs target enrollment of 600[3])**
- **Largest immunotherapy clinical trial for this patient population[2]**

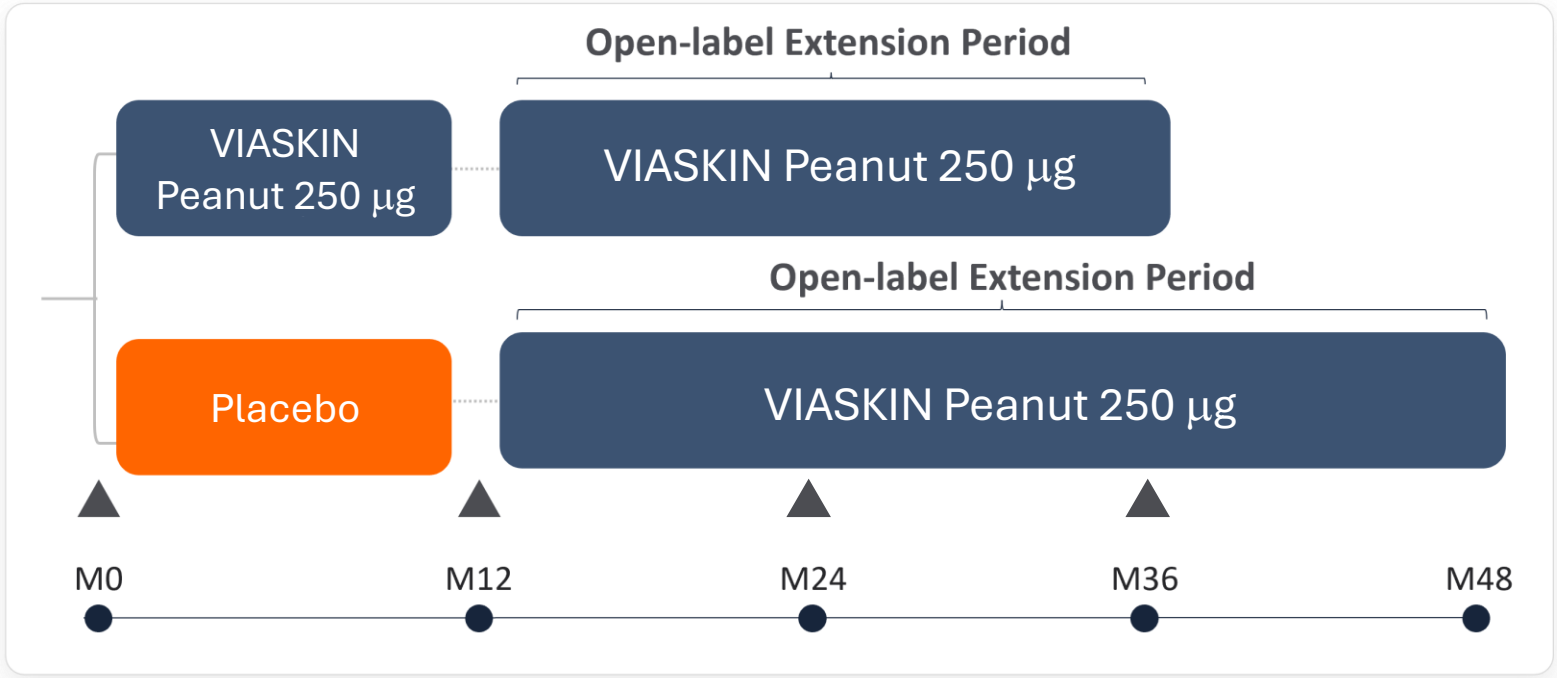
Global Phase 3 Trial

Randomized, double-blind, placebo-controlled

- **654 subjects** 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.

Key Design Elements of the VITESSE Study

Targeted a younger, more sensitive population relative to previous 4-11 YO indication[1] as assessed in Phase 3 pivotal trial, PEPITES

→ **More malleable immune systems that can be more easily re-educated with immunotherapy[2,3]**

+

Lowered baseline entry OFC to 100 mg (Prior DBV Phase 3 studies used 300 mg)

→ **More sensitive subjects (lower ED) tend to have a higher responder rate[4,5]**

+

Other inclusion criteria remain largely unchanged[1] (e.g., SPT, sIgE)

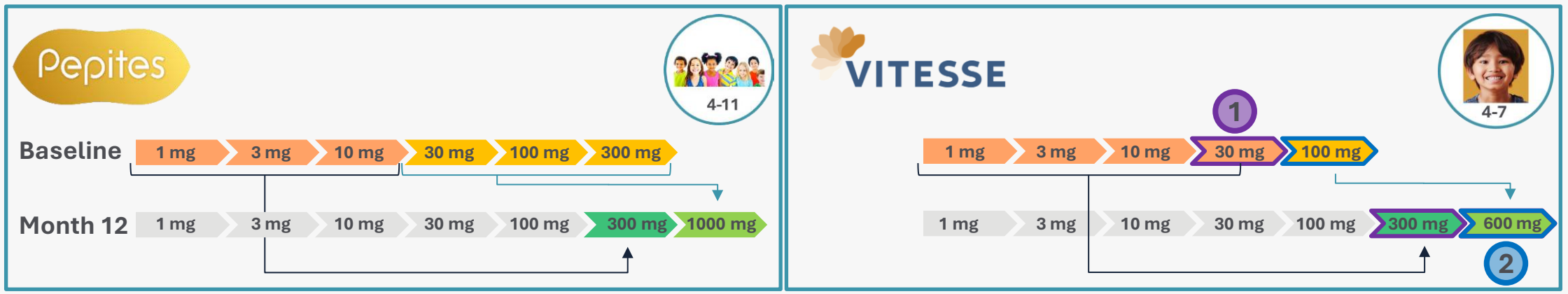
VITESSE specifically targets younger and more sensitive patients who are also some of the highest risk patients

1. Presented by Dr. David Fleischer at Western Society of Allergy, Asthma & Immunology, February 2025. VITESSE Phase 3 Study of Epicutaneous Immunotherapy for the Treatment of Peanut Allergy in Children; 2. Presented by Dr. David Fleischer at Canadian Society for Allergy and Clinical Immunology Annual Meeting, September 2022. Efficacy of Epicutaneous Immunotherapy with VIASKIN® Peanut for 4–7-Year-Old Peanut-Allergic Children in a Phase 3 Clinical Trial (PEPITES); 3. Loke et al. Food Allergen Immunotherapy in Preschool Children: Do we have the Evidence? *JACI In Practice*. 2023; 11(4):1028-1035; 4. Greenhawt M, et al. Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy. *N Engl J Med*. 2023;388:1755-1766; 5. 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.

PEPITES=Peanut EPIT Efficacy and Safety Study; OFC=Oral Food Challenge; SPT=Skin Prick Test; ED=Eliciting Dose.

Statistical Definition of a Responder Reflects a More Sensitive Population Enrolled in VITESSE

Responder Criteria Changed to Reflect a Younger, More Sensitive Population



PEPITES=Prior Phase 3 Pivotal Study in Children Ages 4-11 Years Old (Appendix I: Pages 46-50)

Two Key Differences in VITESSE Responder Criteria

1 **Subjects with baseline ED of 30 mg will be considered as responders if Month12 ED ≥300 mg**
→ DBV's prior Phase 3 studies required the **30 mg baseline ED group** to reach a Month 12 **ED of ≥1000 mg**

2 **600 mg ED criterion added**
→ **Subjects with a baseline ED of 100 mg must reach an ED of ≥600 mg to be considered as a responder**
→ DBV's prior Phase 3 studies required the **100 mg baseline ED** group to reach a Month 12 **ED of ≥1000 mg**

PEPITES=Peanut EPIT Efficacy and Safety Study.

VITESSE

VITESSE Study Fully Enrolled as of August, 2024[1]

DBV's original statistical calculations had at least 90% power with 600 randomized subjects

→ 654 subjects enrolled: power >90%

+

57% of enrolled subjects are aged 4-5 YO[2] (43% of cohort = 6-7 YO)

→ Younger patients tend to respond better[2]

+

Overall randomized population has lower than expected specific IgE (39.2 kU_A/L)[2]

→ Patients with lower IgE tend to respond better[3]

Both factors, younger age and lower sIgE are associated with more robust treatment effects with VIASKIN Peanut patch[3,4]

1. DBV Technologies Press Release. September 23, 2024; 2. Presented by Dr. David Fleischer at Western Society of Allergy, Asthma & Immunology (WSAAI), February 2025. VITESSE Phase 3 Study of Epicutaneous Immunotherapy for the Treatment of Peanut Allergy in Children; 3. 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; 4. Fleischer DM, et al. Allergy Asthma Pro. 2025;41:326-335.

epitope COMFORT toddlers

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

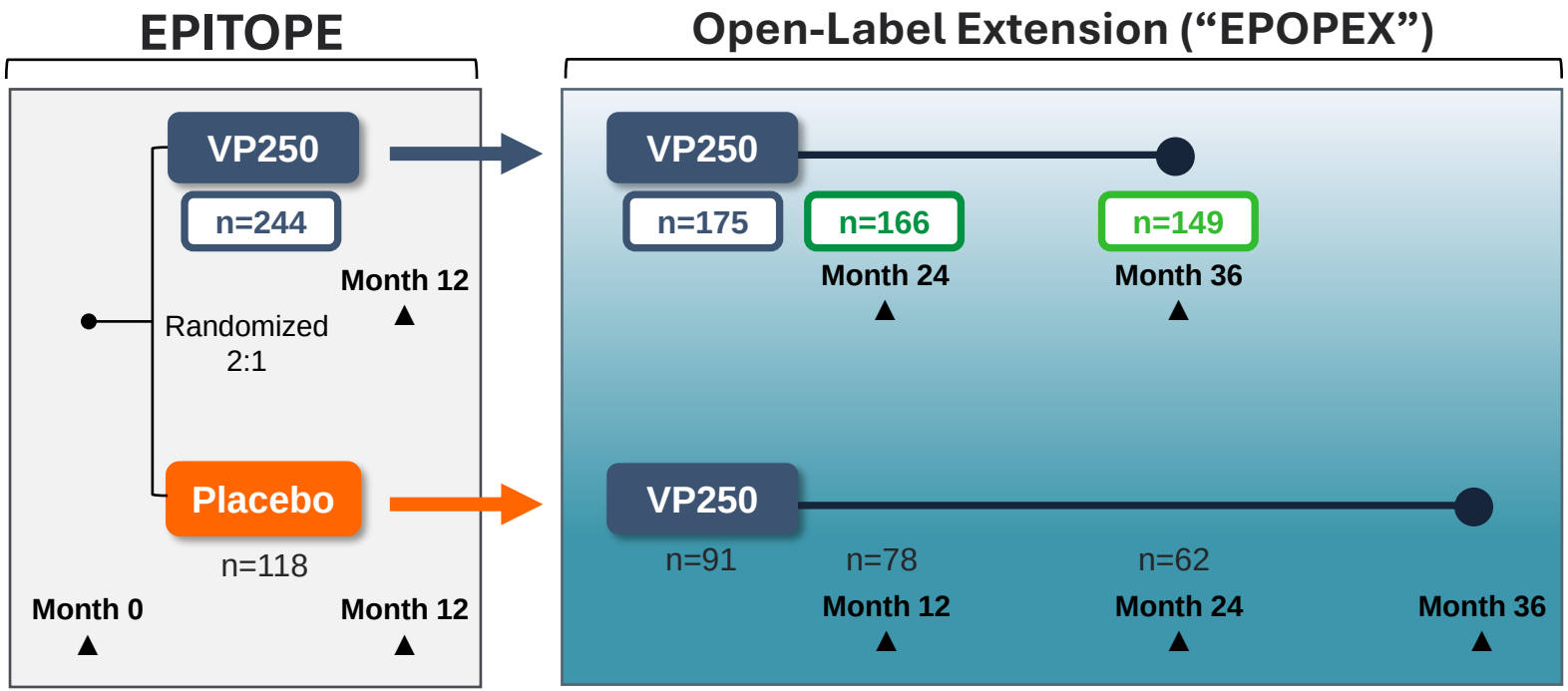
Treatment-related anaphylaxis occurred in 1.6% in the VP250 group and none in the placebo group

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 Technologies 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]



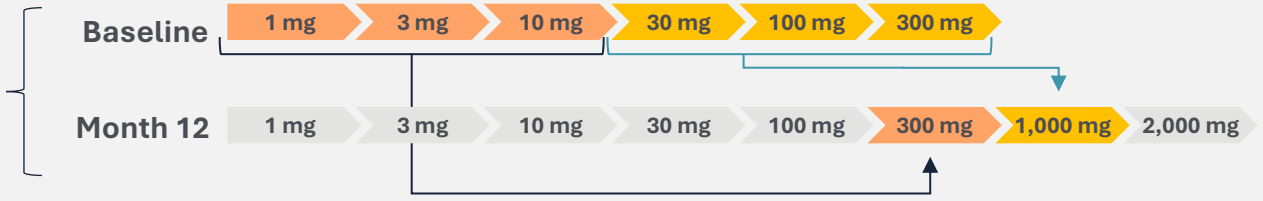
High % of subjects opted to stay on VP250 after Year 1 EPITOPE through 36 Months[3,4]

- **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

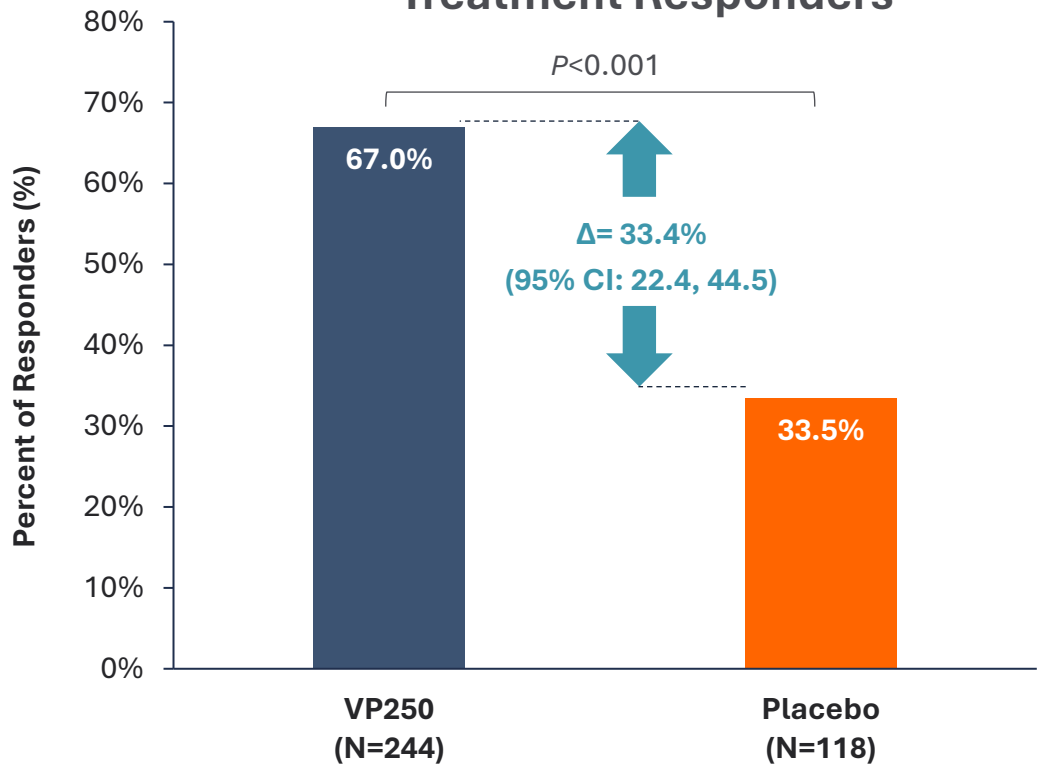


VP250=VIASKIN® Peanut patch 250 µg; ED=eliciting dose.

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.

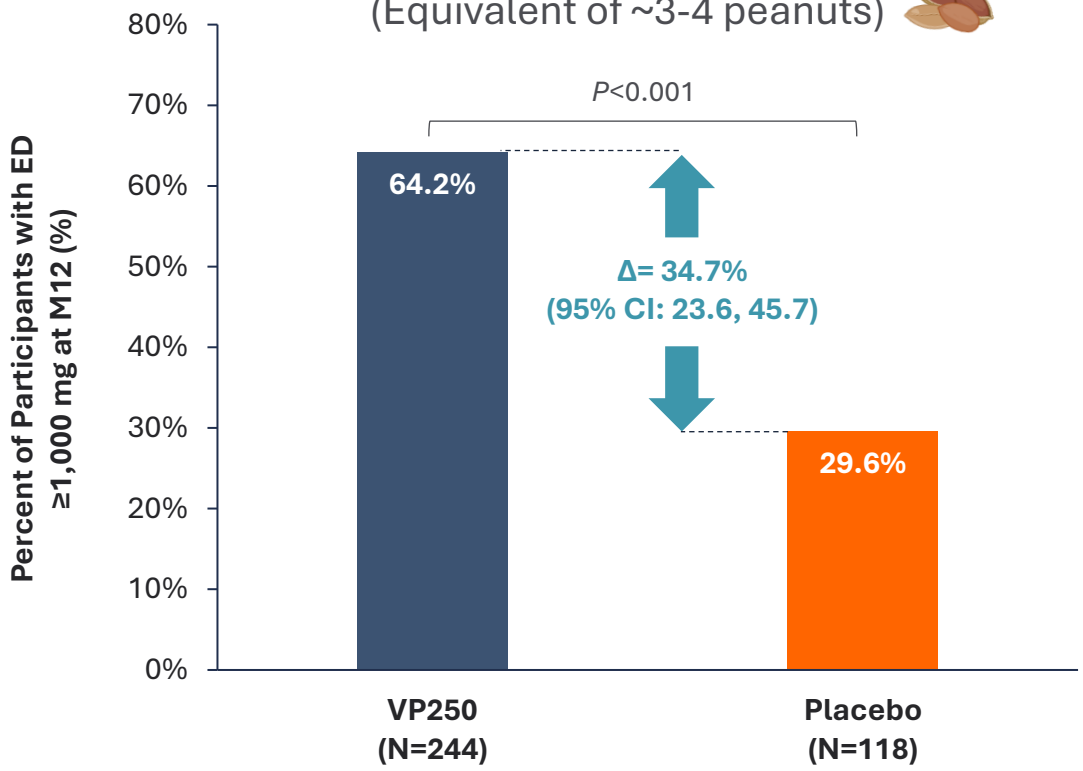
VIASKIN® Peanut Patch Demonstrated a Statistically Significant Treatment Effect in Toddlers After 12 Months[1,2]

† Treatment Responders



†† ED ≥ 1000 mg

(Equivalent of ~3-4 peanuts)



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]

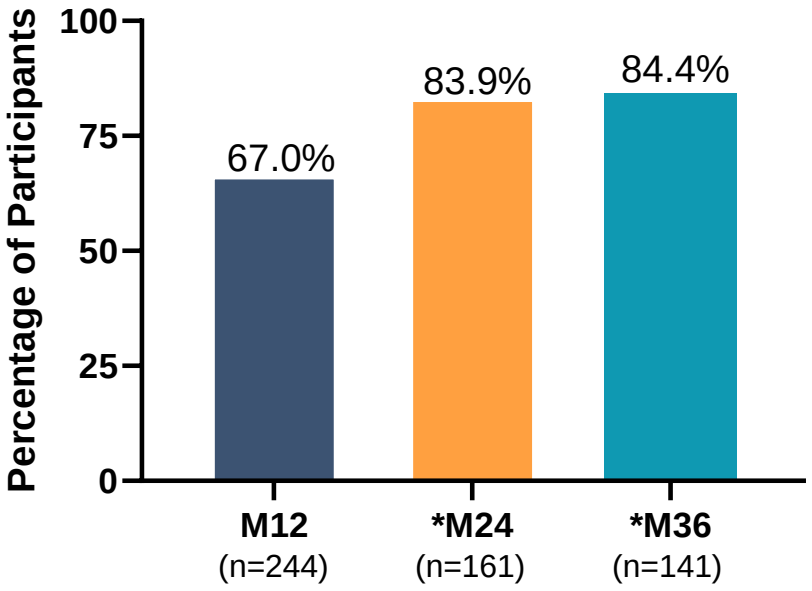
†If ED ≤10 mg at baseline, responder if ED ≥300 mg at M12; If ED >10 mg at baseline, responder if ED ≥1000 mg at M12.
VP250=VIASKIN® Peanut patch 250 µg; CI=Confidence Interval; ED=Eliciting Dose.

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.

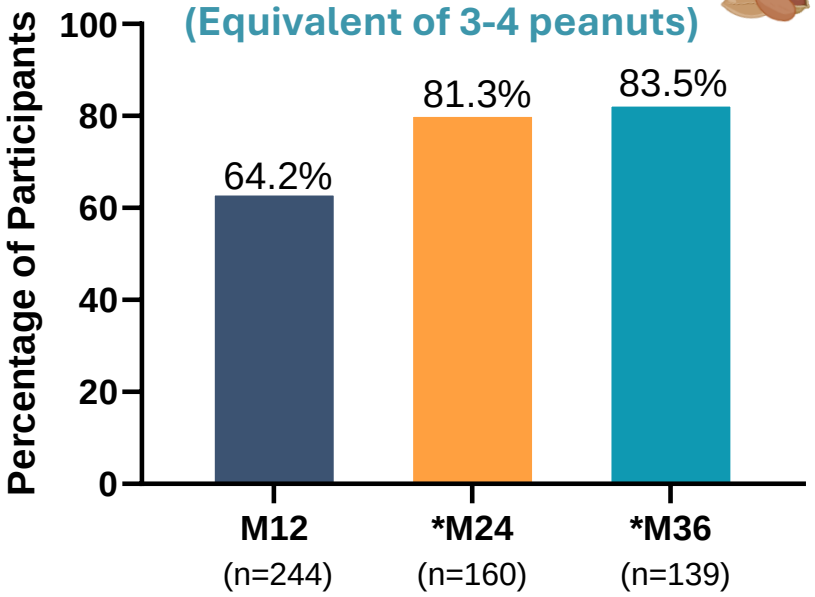
Data from EPITOPE Open-Label Extension Show Continued Improvement in Treatment Response in Toddlers Through 36 MO[1-4]

- 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)



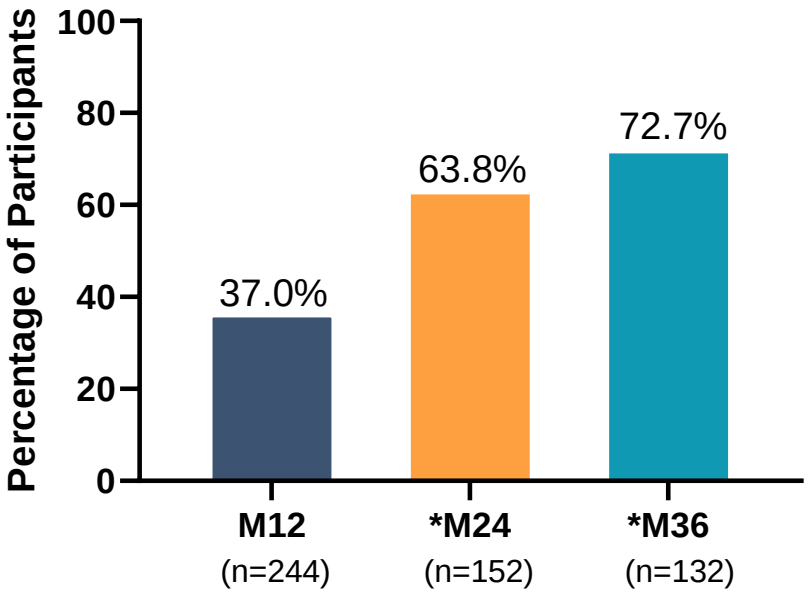
In EPITOPE placebo participants who received treatment with VP250 in the OLE study (2-4 YO), efficacy was consistent with results seen after 12 and 24 months of VP250 treatment in EPITOPE[2]

†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 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 EPITOPE. *J Allergy Clin Immunol Pract*. 2025;13:1176-1187; 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.

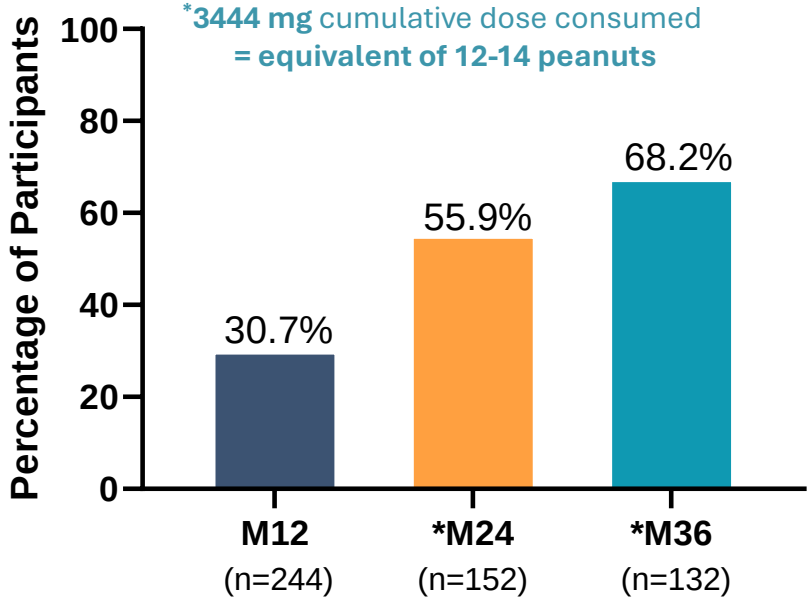
Data from EPITOPE Open-Label Extension Show Continued Improvement in Treatment Response in Toddlers Through 36 MO[1-3]

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



Completed Food Challenge* Without Meeting Stopping Criteria

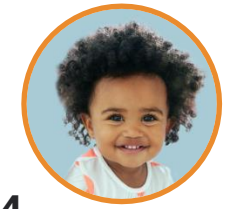
*3444 mg cumulative dose consumed
= equivalent of 12-14 peanuts



In EPITOPE placebo participants 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[2]

†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 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 EPITOPE. *J Allergy Clin Immunol Pract*. 2025;13:1176-1187; 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.



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. 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. 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 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:

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 Data in Peanut Allergic Toddlers, Ages 1-3 YO

- 6-month study with an optional 18-month open-label extension
- Anticipate enrolling 480 subjects, randomized 3:1 (active: placebo)
- 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]
- Adhesion and average daily application time are exploratory assessments only[1]
- **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.

Proposed Labeling Approach to FDA Based on Early Wear-Time Experience in 1–3-Year-Old Subjects in EPITOPE

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]

↓

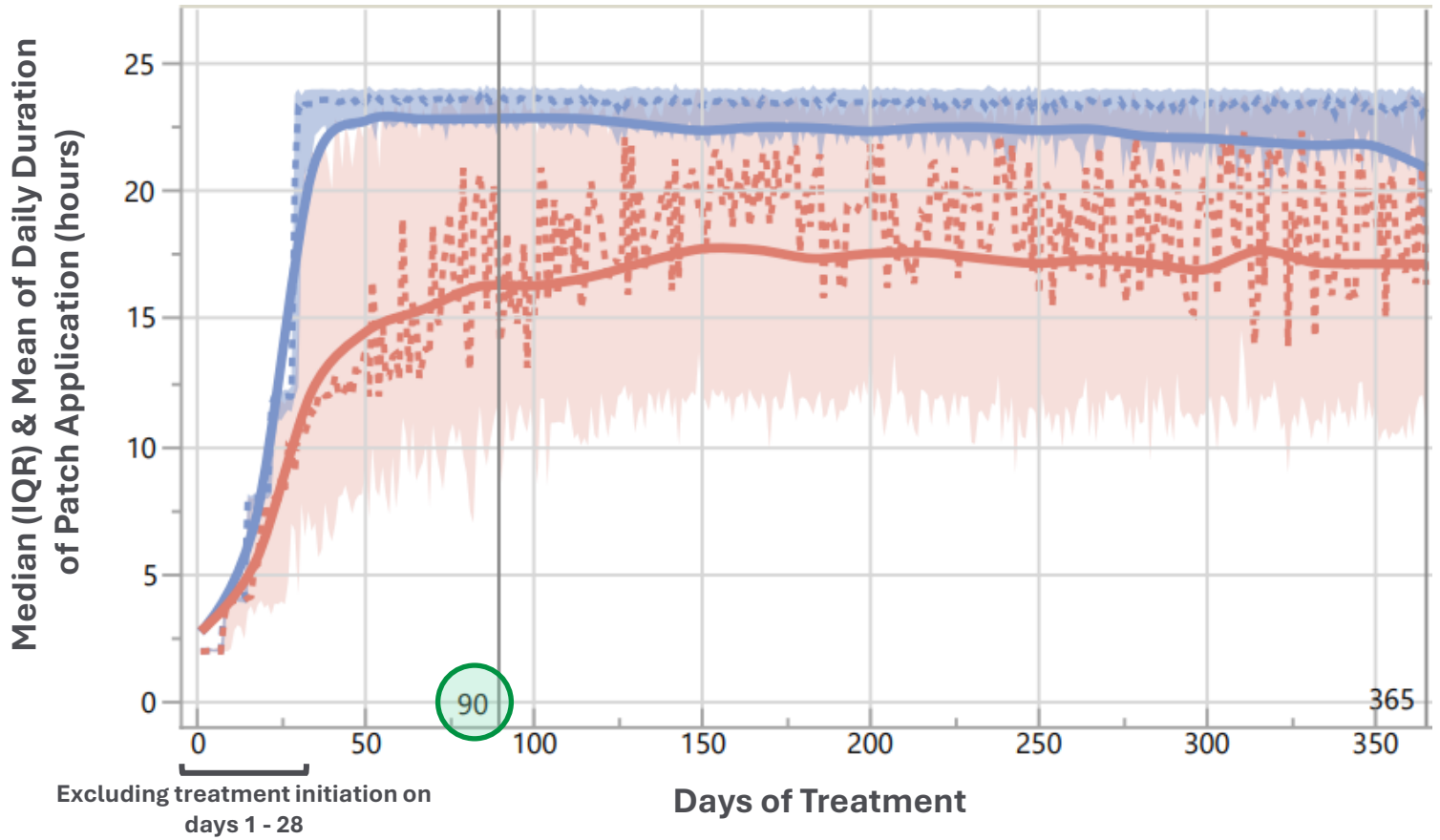
Identifies patients who would have the highest potential clinical benefit at Month 12 based on wear-time experience in the first 90 days of treatment

→ 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 Are Distinguished by This Labeling Approach

~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)[1,2]



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)

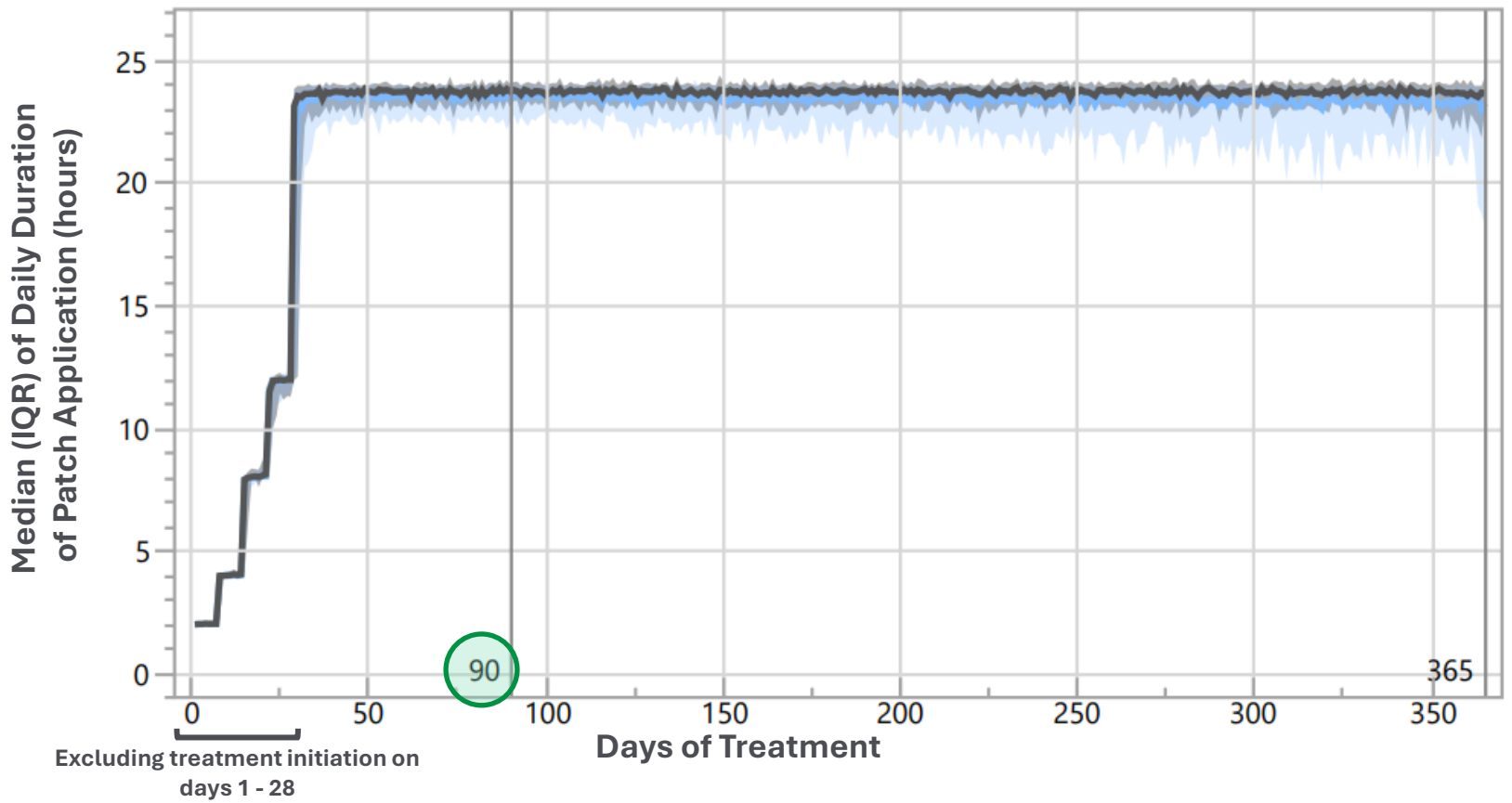
Solid lines = Mean

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]

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



=IQR Band (VP250 ≥20h ADWT)

=IQR Band (Placebo)

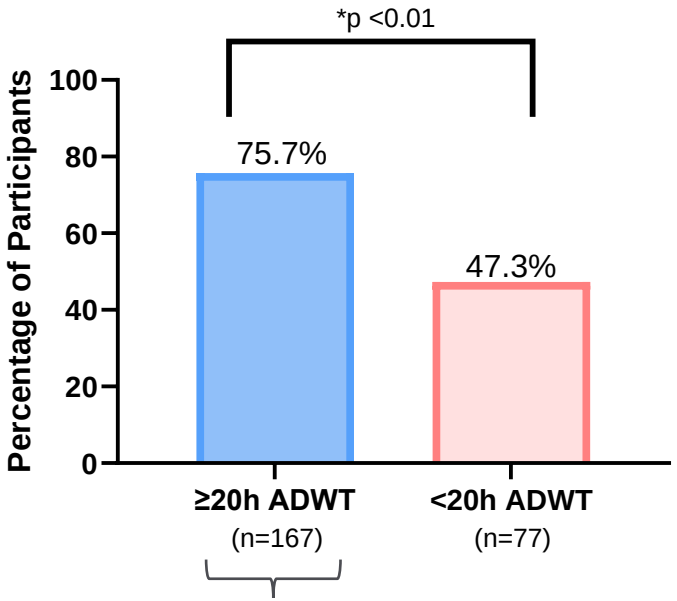
VP250 ≥20h ADWT	22.9 hours Median ADWT
Placebo	23.7 hours Median ADWT

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 Higher Average Daily Wear-Time (ADWT ≥20 Hours) Are Better Responders at Month 12 [1,2]

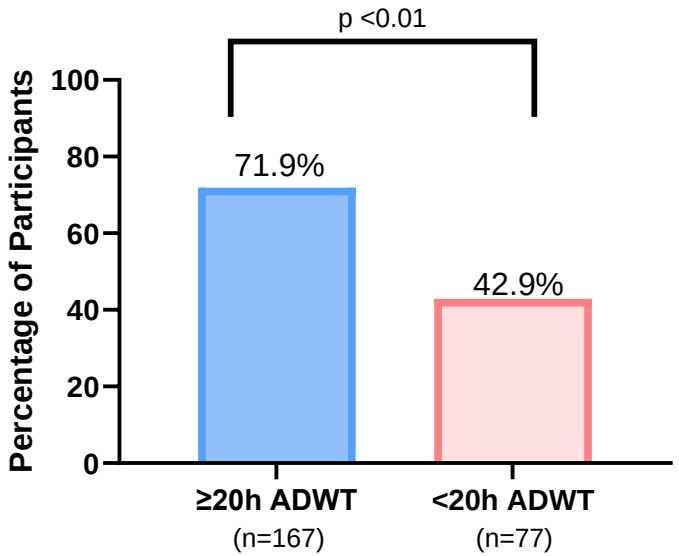
Responder Primary Analysis



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

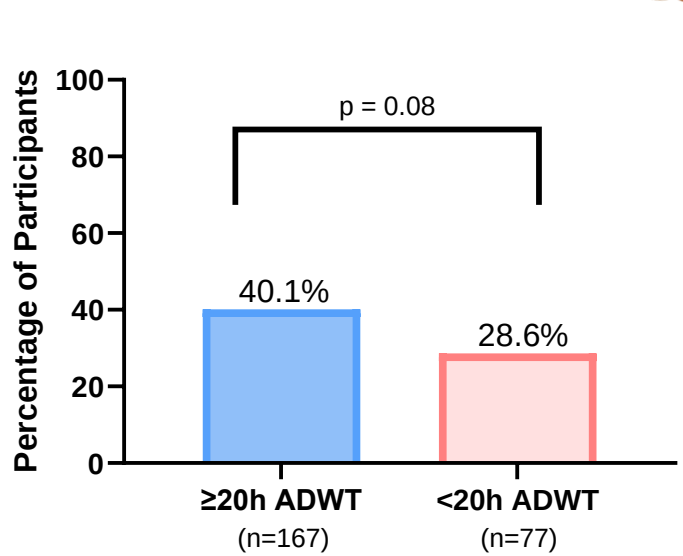
Eliciting Dose ≥1000 mg

(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.

Similar Baseline Characteristics Between the Two Groups of Subjects at Treatment Initiation Regardless of ADWT

Lower Tolerability to Peanut Allergen ("More Itchiness") Observed 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.

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.

SUMMARY – Optimizing Patch User Experience Based on Patch Wear-time in Toddlers, Ages 1-3 YO

Post-hoc analyses showed that in EPITOPE, participants could be readily distinguished based on Average Daily Wear Time (ADWT)[1,2]

- **HIGH ADWT ≥20 hours**
- **LOWER ADWT <20 hours**

→

Despite this, 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[1,2]

Reported more scratching leading to patch detachment *– suggesting these toddlers experience lower tolerability (more "itchiness") to peanut-induced local skin immune response*

→

Subjects with LOW day-to-day ADWT variability (~70% of subjects in Year One) have a very similar wear time experience to placebo patients[1,2]

- **Median ADWT = 22.9 hours**
- **Median ADWT =23.7 hours** Placebo

- **ADWT within the first 90 days of treatment is highly predictive of clinical efficacy at month 12:**
  - **75.7% of subjects with an ADWT ≥20h were treatment responders (vs 67.0% of all EPITOPE subjects)[3]**
  - **47.3% of subjects with an ADWT <20h were treatment responders vs 33.5% of placebo subjects**
- **ADWT within the first 90 days is also highly predictive of ADWT over a 12-month treatment period**

ADWT is a practical approach that could be adopted to guide shared decision-making & optimal use of VIASKIN® Peanut patch, if approved

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.

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

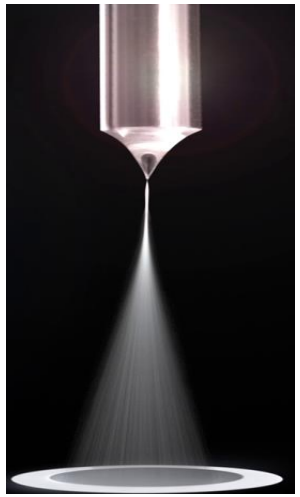
Integrated End-to-End Patch Manufacturing in Place

Source Material

Active Pharmaceutical Ingredient (API)

Final Product Process

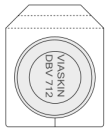
Proprietary electrospray technology
deposits a precise antigen dose without any adjuvant on a PET titanium backing film



APPENDIX I:
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

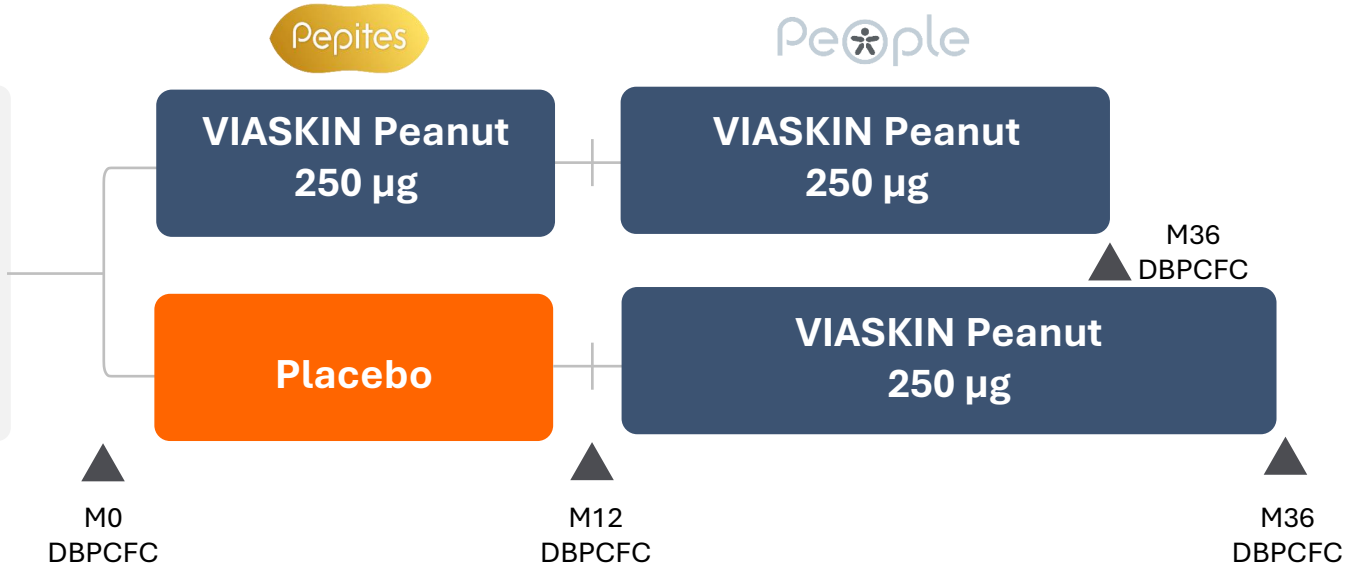
Results Published in JAMA (PEPITES)[1] & Journal of Allergy & Clinical Immunology (PEOPLE)[2]

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

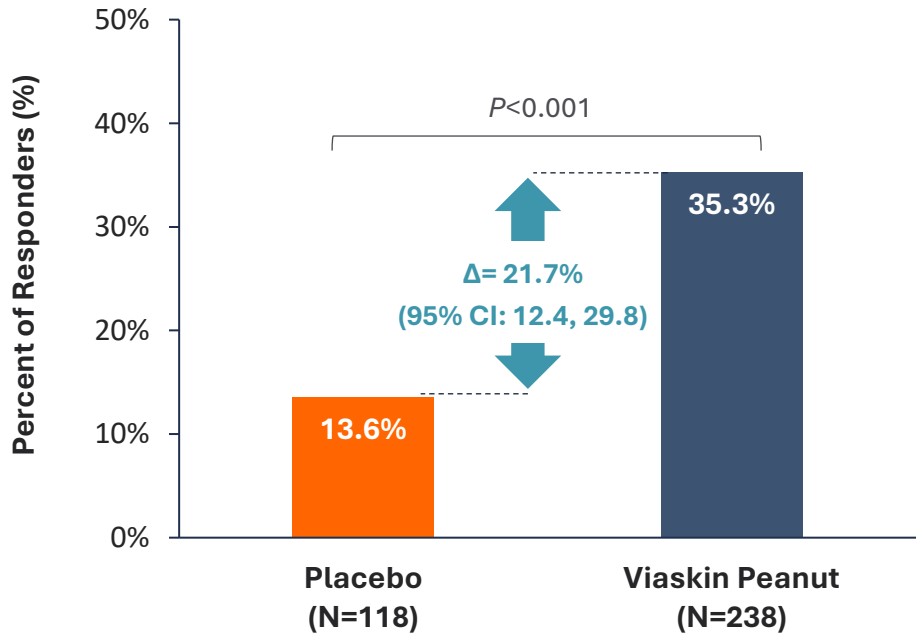
*Confirmed peanut allergy by SPT ≥6 mm for 4- to 5-year-olds or ≥8 mm for 6- to-11-year-olds and sIgE levels (>0.7 kUA/L).
DBPCFC=Double-Blind Placebo-Controlled Food Challenge; ED=Eliciting Dose.

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

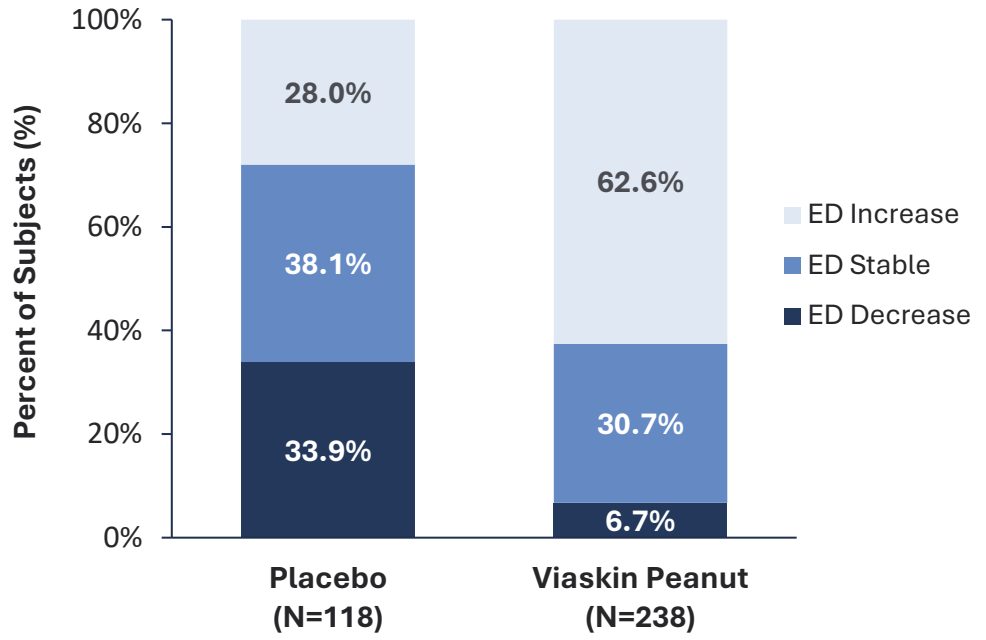
Primary Efficacy Outcome Showed Statistically Significant Treatment Benefit

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*



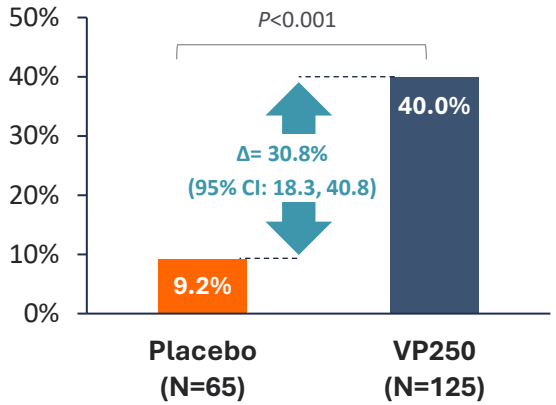
An increase in ED was >4 times more likely to occur in the VIASKIN® Peanut patch group compared with placebo

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

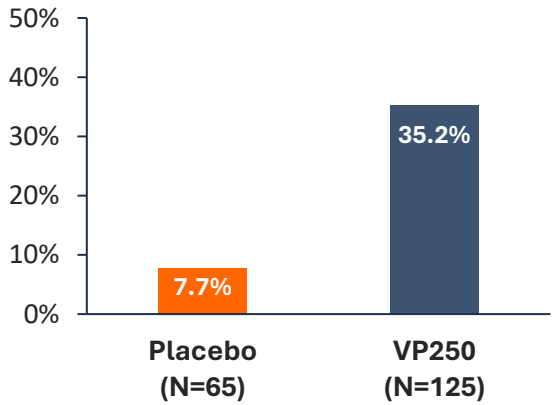
1. Fleischer DM, et al. Effect of Epicutaneous Immunotherapy vs Placebo on Reaction to Peanut Protein Ingestion Among Children With Peanut Allergy: The PEPITES Randomized Clinical Trial. *JAMA*. 2019;321:946-955.

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

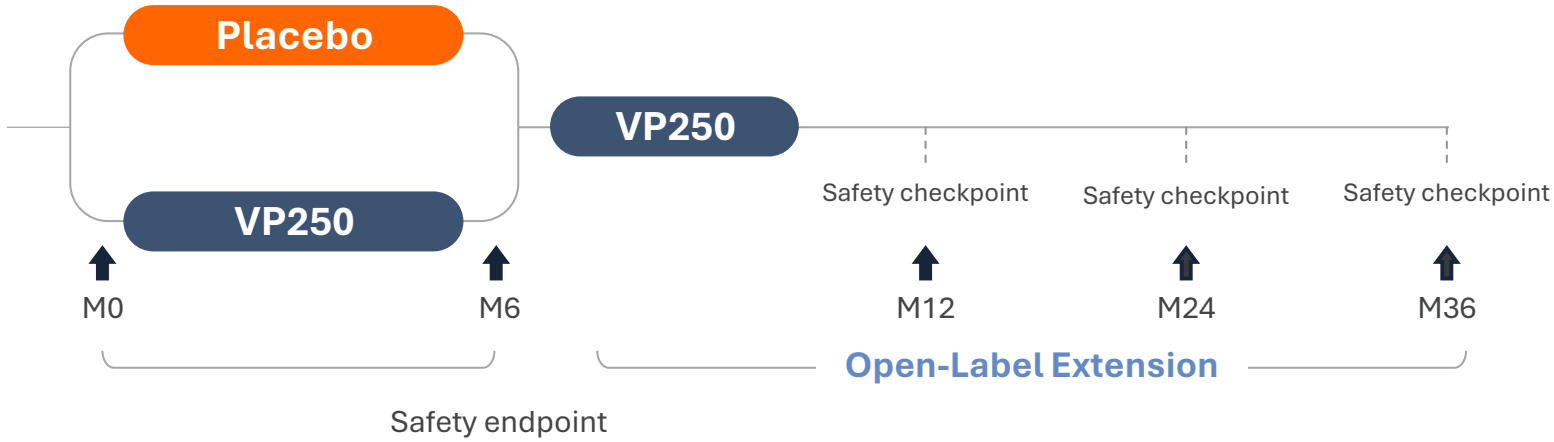
Children 4–11 Years Old

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.

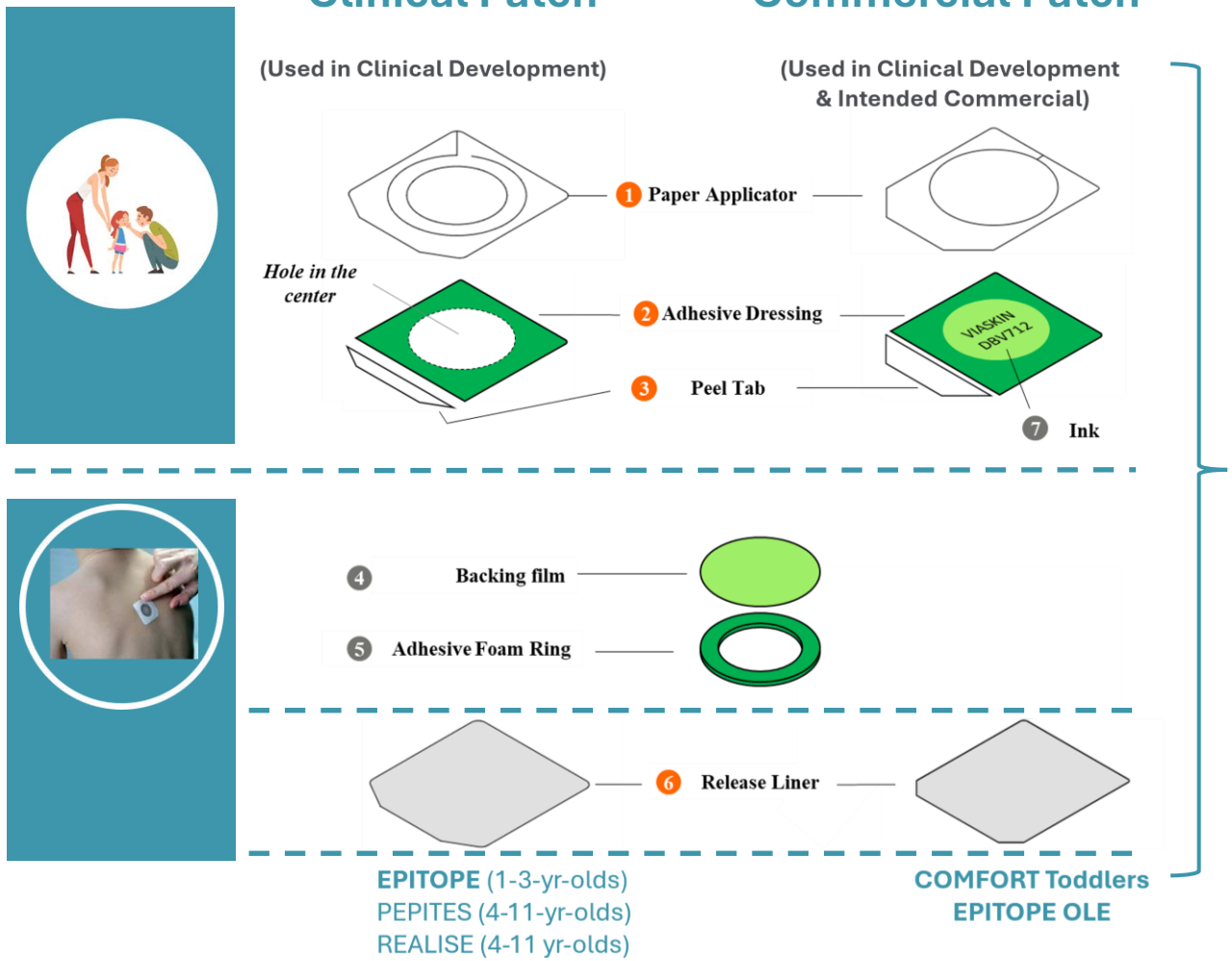
1. Pongracic JA, et al. *J Allergy Clin Immunol Pract*. 2022 Jul;10(7):1864-1873.e10. 2. Pongracic JA, et al. Presented at the American Academy of Allergy Asthma and Immunology, 2020.

epitope COMFORT toddlers

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

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

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