



DBV TECHNOLOGIES

Corporate Presentation | January 2023



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Investment Highlights

Late-stage Clinical Programs

Comprehensive late-stage clinical programs in food allergy indications

Novel Viaskin™ Technology


Novel Viaskin™ technology based on Epicutaneous Immunotherapy (EPIT™)

Science-Driven Leadership Team

Science-driven leadership team with deep regulatory and commercial experience

Well Financed

Well financed with \$212.7 million of cash and equivalents as of September 30, 2022

A young girl with dark hair, wearing a yellow t-shirt and brown shorts, is running happily in a park. She is holding a large, colorful rainbow kite that is flying in the air. The background shows green trees and a clear sky.

We are dedicated to improving the lives of patients with food allergies and other immunological diseases

Committed to Generating Long-term Viaskin™ Data to Inform Real-Life Use

Completed and Currently Ongoing Clinical Trials*

Program and Indication	Trial	Phase 2	Phase 3
Viaskin Peanut (DBV712) - Peanut Allergy	PEPITES: Ages 4-11 years		●
	PEOPLE: Ages 4-11 years		●
	REALISE: Ages 4-11 years		●
	VITESSE: Ages 4-7 years		◐
	Safety study: Ages 4-7 years		○
	EPITOPE: Ages 1-3 years		●
	EPOPEX: Ages 1-3 years		◐
Viaskin Milk (DBV135) – Cow's Milk Allergy	MILES: Ages 2-17 years	◐	
Viaskin Milk (DBV135) – Eosinophilic Esophagitis	SMILEE: Ages 4-17 years	◐	
Non-IgE Mediated Cow's Milk Allergy Diagnostic Tool (DBV1605) with Nestle Health Science	APTITUDE: Ages 6 months to 5 years	◑	

* Phase I and Phase IIb trials of Viaskin Peanut are not included here.

EPIT=epicutaneous immunotherapy; PEPITES=Peanut EPIT Efficacy and Safety Study; PEOPLE=PEPITES Open Label Extension Study; REALISE=Real Life Use and Safety of EPIT; VITESSE=Viaskin Peanut Immunotherapy Trial to Evaluate Safety, Simplicity and Efficacy; EPITOPE=EPIT in Toddlers with Peanut Allergy; EPOPEX=EPITOPE Open Label Extension Study

● Complete ◐ Ongoing ○ Planned

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

Approximately ~75% will not outgrow their allergy¹



1-3 years old

280,000 Toddlers^{2,3}



4-7 years old

390,000 Children^{2,3}



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 efforts¹
- In a follow-up, prospective study, approximately 41% of peanut-allergic children reported an accidental exposure within 3 years of diagnosis²

Reactions Are Unpredictable

- Reactions to peanut are more likely to be severe than in other food allergies³
- Many factors — such as exercise, infection, asthma, hormones and stress — contribute to reaction severity, making it unpredictable⁴

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 life⁷
- Nearly 80% of peanut-allergic children report that fear of accidental exposure impacts their emotional well-being⁷

1. Capucilli P, et al. *Ann Allergy Asthma Immunol.* 2020;124:459-465. 2. Kansen HM, et al. *J Allergy Clin Immunol.* 2020;145:705-707.e7. 3. Gupta RS, et al. *Pediatrics.* 2018;142:e20181235 4. Turner PJ, et al. *Allergy.* 2016;71:1241-1255. 5. Shaker MS, et al. *Curr Opin Pediatr.* 2017;29:497-502. 6. Blaiss MS, et al. *J Manag Care Spec Pharm.* 2021;27:516-527. 7. Nowak-Wegrzyn A, et al. *World Allergy Organ J.* 2021 Feb 15;14(2):100512

Caregivers and physicians are seeking a treatment that^{1,2}:

- Reduces the likelihood of an allergic reaction in case of accidental exposure
- Has a low risk of a serious reaction caused by the treatment and low risk of side effects
- Is accepted by the caregiver and child

The goals of peanut allergy treatment aim to maximize effectiveness by balancing efficacy, safety, and practicality^{1,3}

Multiple treatment options are desired so families and allergists can together choose the best approach considering³:

- Patient preference
- Family lifestyle
- Medical evidence



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



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

Families and Allergists Want Additional Therapy Options for Peanut Allergy^{1,2}

Oral immunotherapy is often not an ideal option for many patients and their families¹



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



Avoidance of certain activities (sports, other strenuous physical activities and hot showers/baths) within 3 hours of dose



Increased risk of an allergic reaction to OIT dose if patient is having an illness such as a viral infection, very tired or missing sleep, stressed, having a menstrual period, or exercising



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



90% of allergists see the need for additional options in the treatment of pediatric peanut allergy²

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

Viaskin Peanut:

No treatment escalation requiring frequent doctor's appointments



No increased risk of side effects due to illness, missed sleep, stress or menstrual cycles



No restriction on activities such as sports, exercise or hot bath/shower



No oral peanut ingestion required

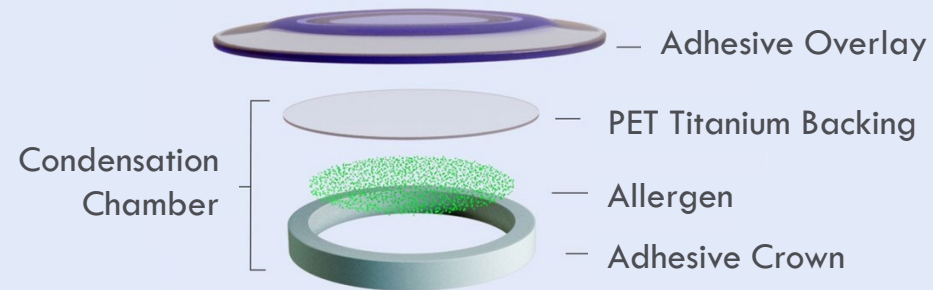


Applied at home, once a day



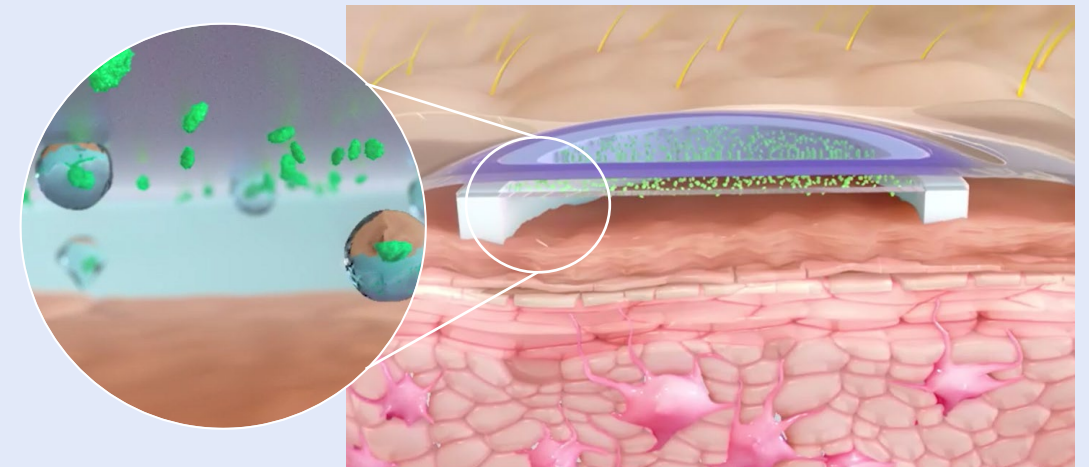
The Viaskin™ Patch: Our Innovative Approach to Epicutaneous Immunotherapy

A Novel Drug-Device Combination For Delivering Allergen Immunotherapy



Condensation Chamber

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

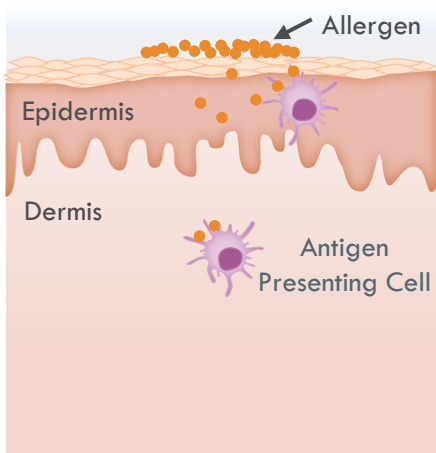


Allergen Solubilization

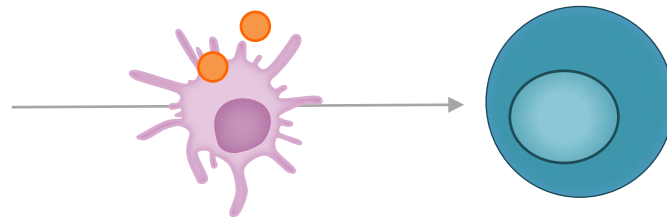
Occurs within condensation chamber when natural epidermal
water loss solubilizes dry antigen on titanium backing

Epicutaneous Immunotherapy (EPIT™) Aims To Re-educate the Immune System by Inducing Specific Regulatory T Cells¹⁻⁶

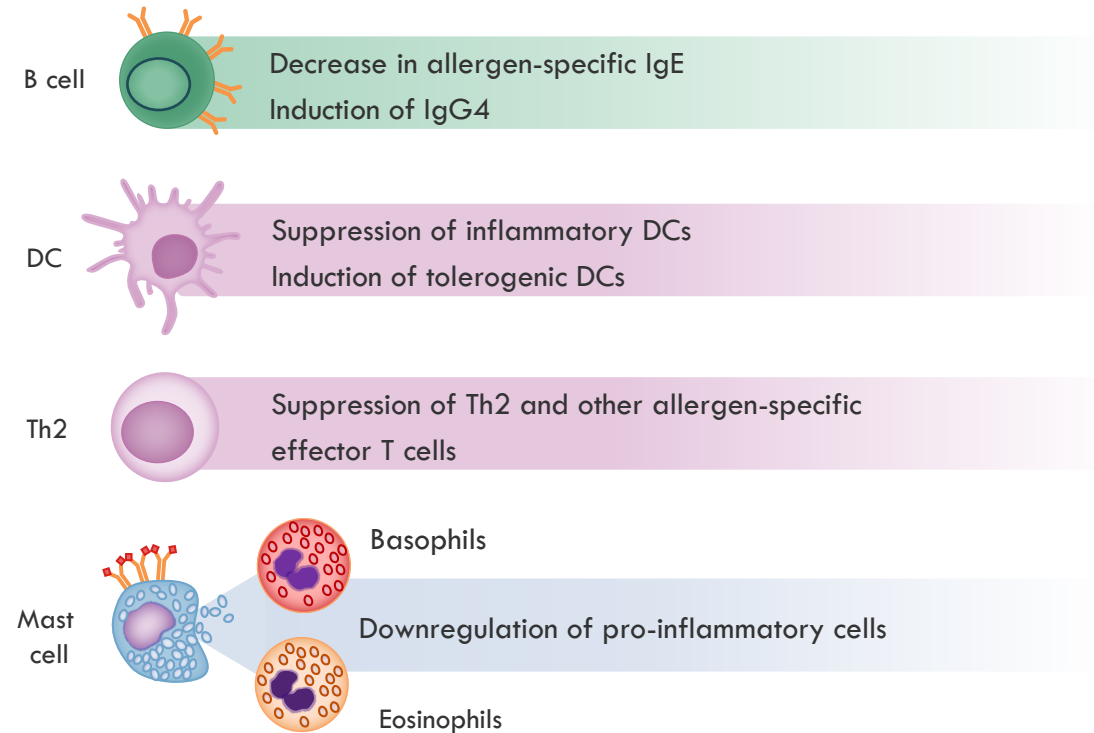
EPIT delivers allergen to intact skin



Antigen Presenting Cells capture allergen and induce unique Regulatory T Cells



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

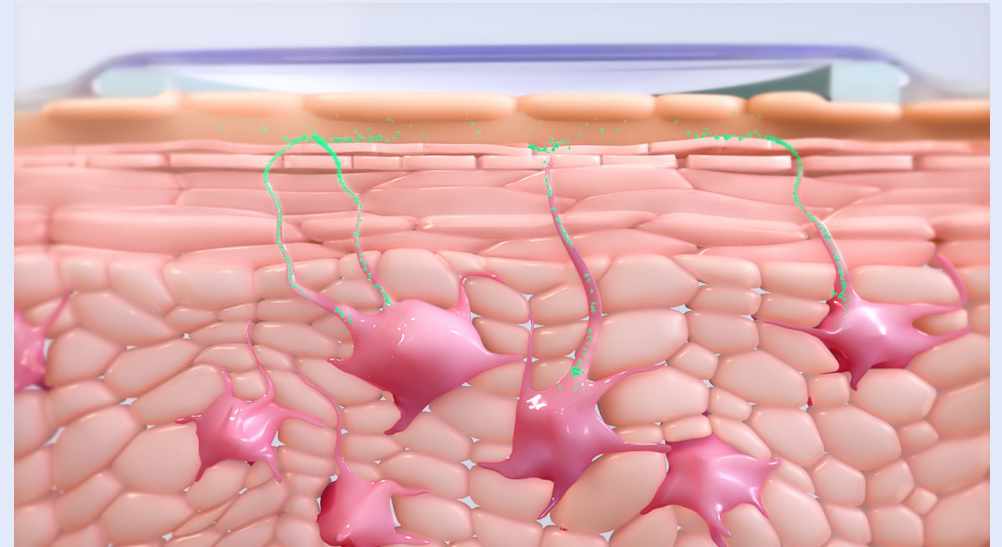


Viaskin™ Uses Minimal Amounts of Allergen to Induce an Immune Response¹⁻³

Solubilized allergen is captured by skin dendritic cells (eg, Langerhans cells) in the epidermis

Langerhans cells process the allergen, migrate to the lymph nodes and present its epitopes to the lymphocytes, leading to a specific immune response

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





Pepites

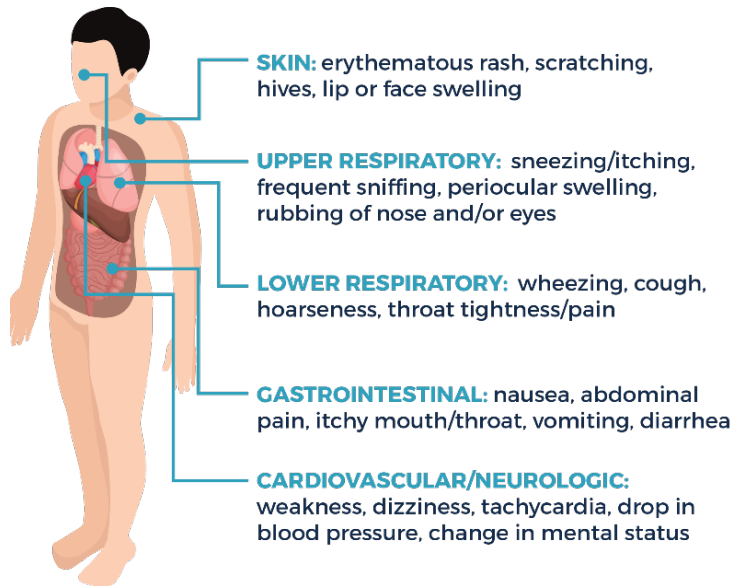
PeoPle

Realise

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

Eliciting Dose

The amount of allergen that induces unmistakable allergic symptoms¹:



Exposure Dose

The amount of allergen accidentally ingested, determined by two factors²:

How much food was consumed?

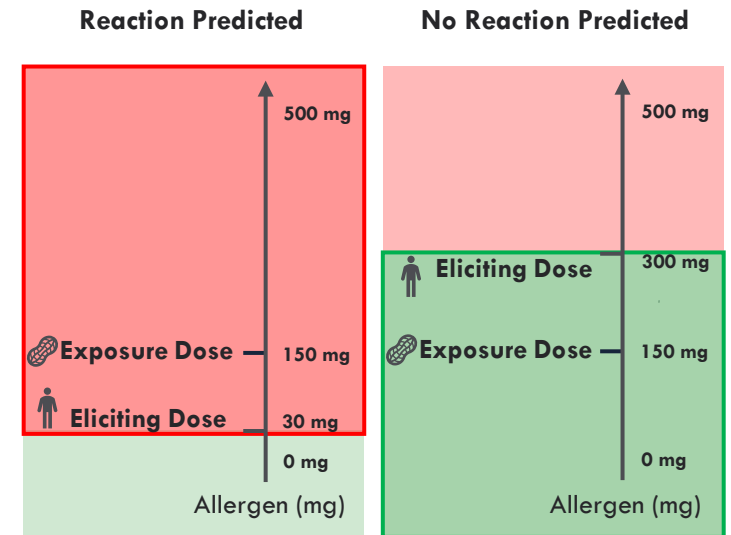


How much allergen was present in the food?



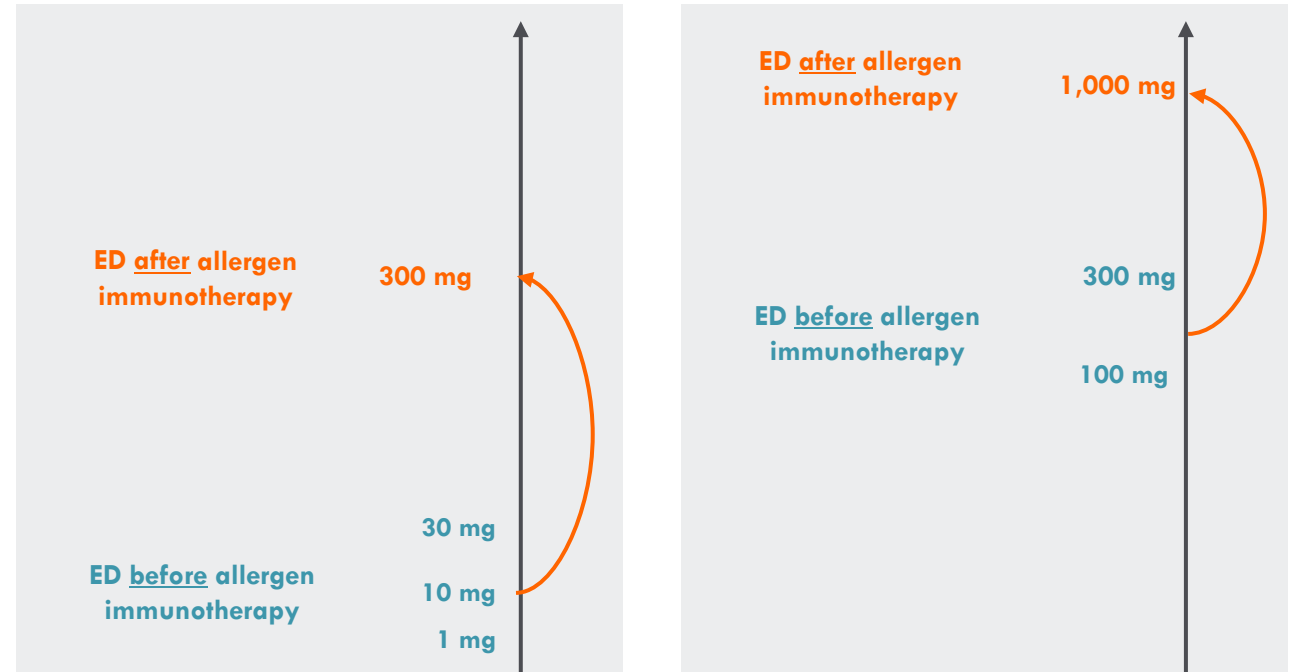
Reaction Prediction

An allergic reaction is predicted to occur when a patient's eliciting dose is less than an exposure dose³



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

Decrease in Reaction Risk Following Allergen Immunotherapy



Increasing a patient's eliciting dose from

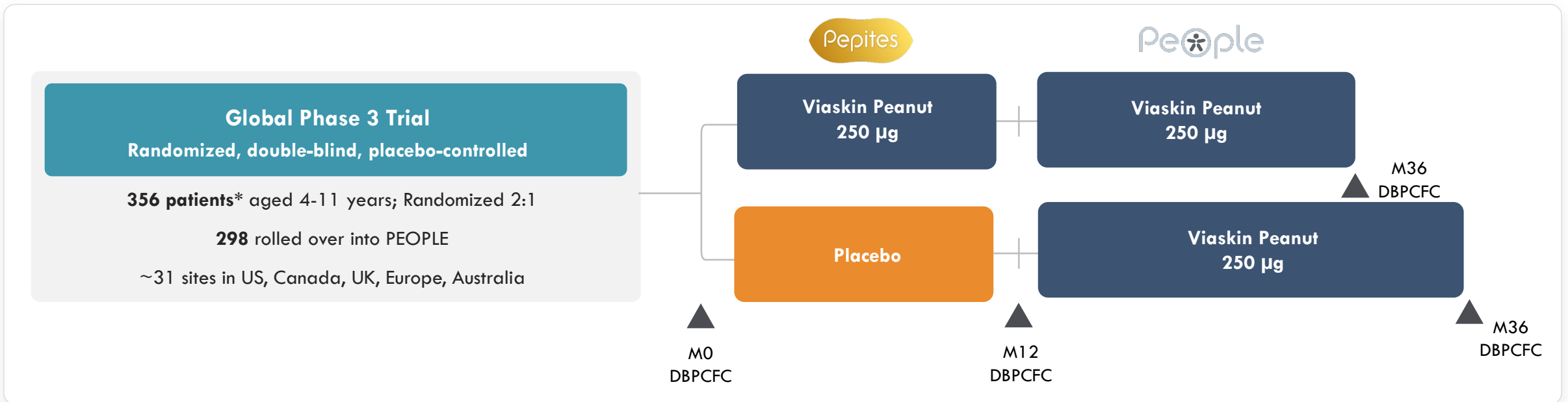
1, 10, or 30 mg to 300 mg or 100 or 300 mg to 1,000 mg

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.

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

Full results published in peer-reviewed publications *JAMA* (PEPITES)¹, *Journal of Allergy & Clinical Immunology* (PEOPLE)²



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

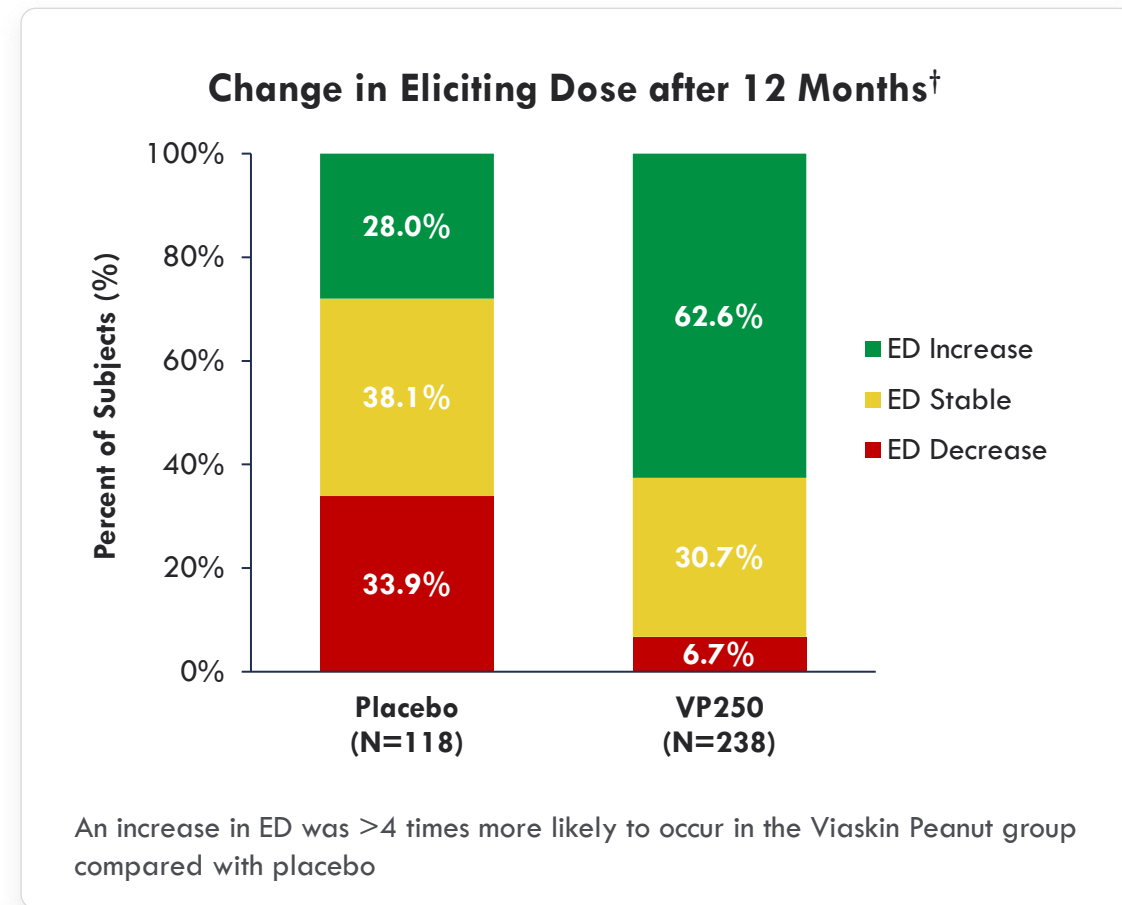
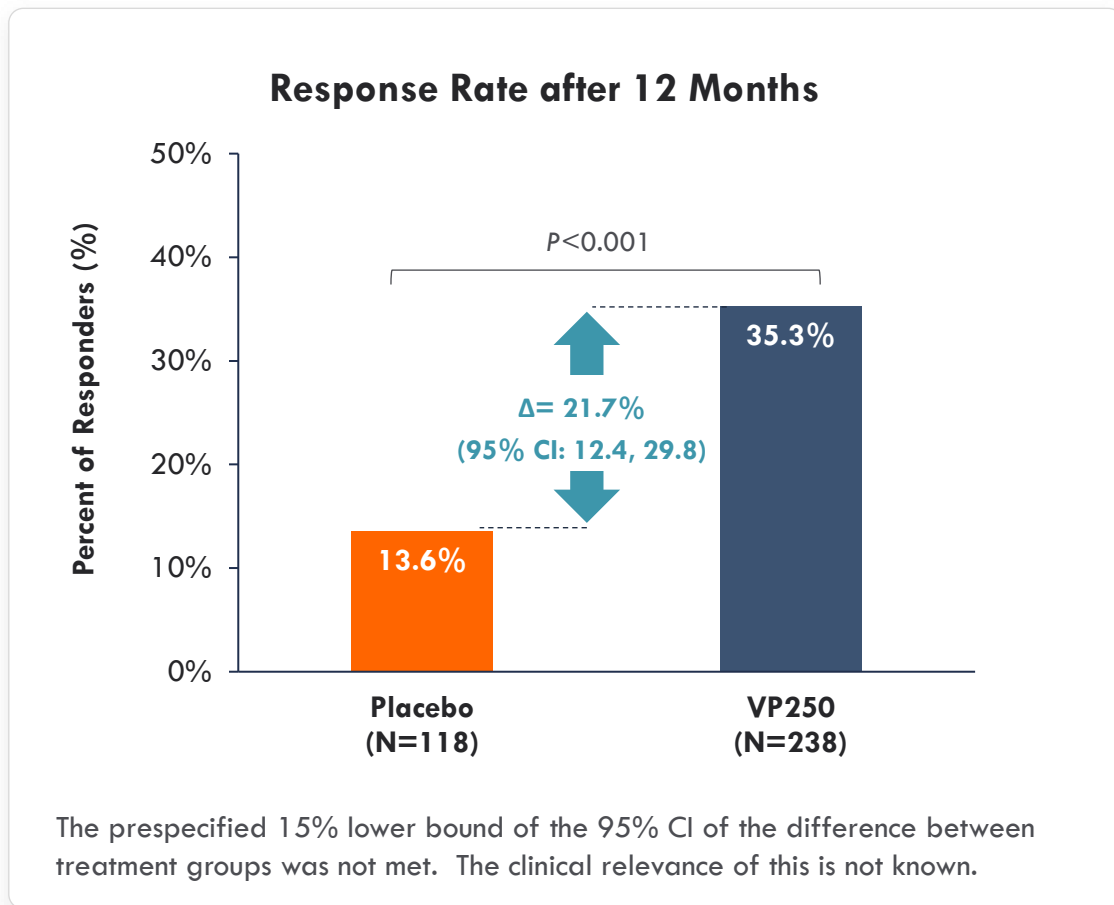
PEOPLE Primary outcome measures: % of subjects originating from the active arm of PEPITES reaching an Eliciting Dose (ED) \geq 1,000 mg after 24 months of additional treatment in PEOPLE

Treatment responder (assessed by DBPCFC) defined as:

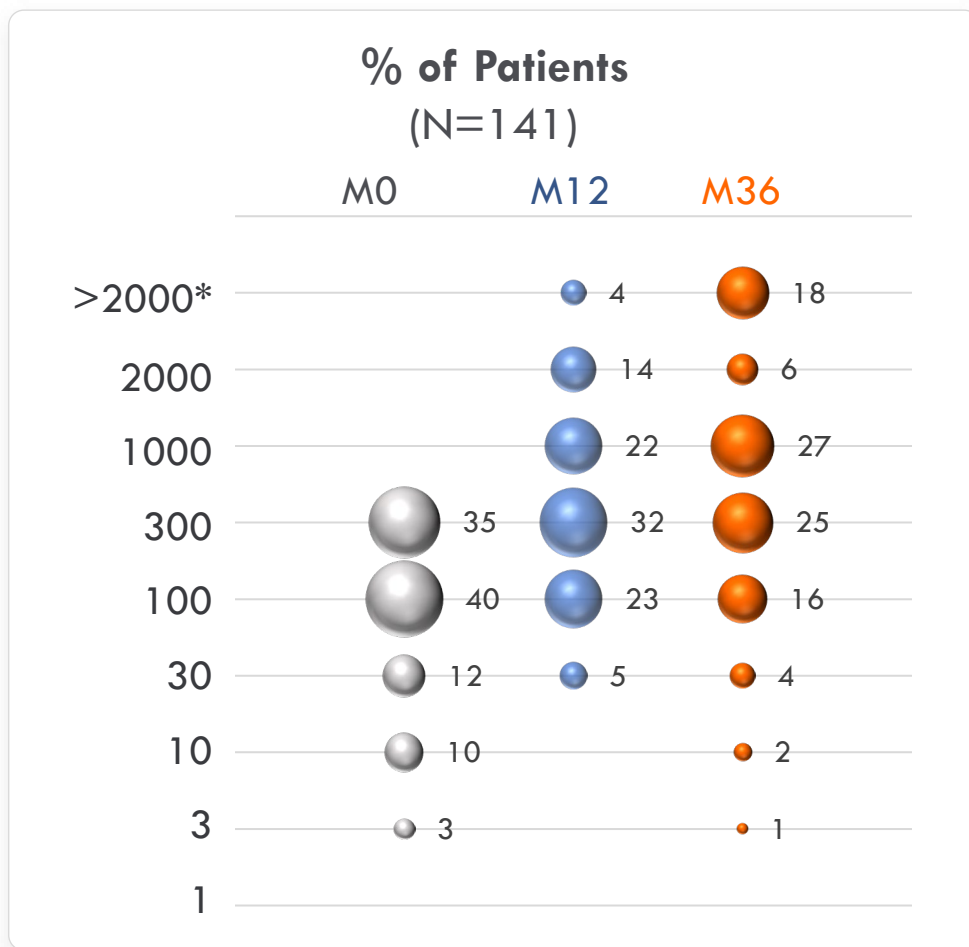
- If ED \leq 10 mg at baseline, responder if ED \geq 300 mg at M12
- If ED $>$ 10 mg at baseline, responder if ED \geq 1,000 mg at M12

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

Primary efficacy outcome showed statistically significant treatment benefit



Changes in ED Maintained or Improved Over 3 Years in the Majority of Subjects in the Open-Label Extension Study¹



- 51.8% of subjects reached an ED of $\geq 1,000$ mg at Month 36, compared to 40.4% at Month 12
- 75.9% of subjects demonstrated an increase in ED from baseline to Month 36
- 13.5% of subjects were able to tolerate the full DBPCFC of 5,444 mg (~18 peanuts) at Month 36
- 77.8% (14/18) of subjects who completed the oral food challenge at Month 38 maintained desensitization with an ED $\geq 1,000$ mg*.

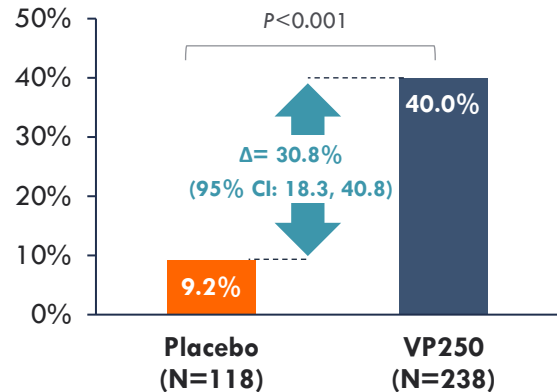
Food Allergy Quality of Life (QoL) Assessment in PEPITES, PEOPLE³

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

Post-Hoc Analysis of PEPITES Data Supports Concept That Greater Gains in Desensitization May be Achieved in Younger vs Older Children¹

Treatment Responders

Children Ages 4-7 Years

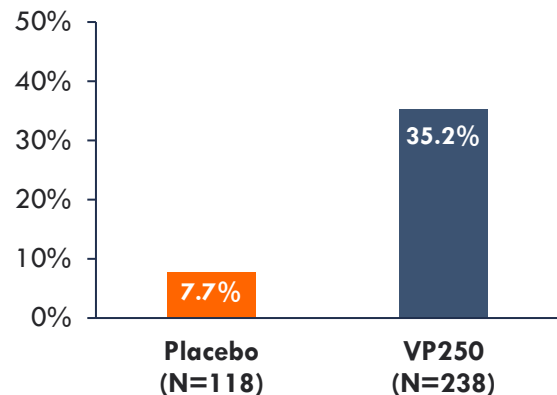


By post hoc analysis, a larger treatment effect in subjects aged 4–7 years who received Viaskin Peanut 250 µg versus placebo was demonstrated

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

ED ≥1,000 mg at Month 12

Children Ages 4-7 Years



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

Pooled Safety Data from Phase III Studies of Viaskin™ Peanut¹

749 subjects included in the overall pooled safety analyses, including 630 subjects treated with Viaskin Peanut 250 µg for up to 36 months

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

- Serious Treatment-Emergent AEs (TEAEs) were experienced by 1.1% of Viaskin Peanut 250 µg subjects and 1.8% of placebo subjects
- TEAEs leading to permanent discontinuation occurred in 1.1% of patients treated for 6 months with Viaskin™ Peanut vs 0% with placebo

630 Subjects Treated with Viaskin Peanut for Up to 36 Months

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

Conclusion

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

Viaskin™ Peanut Regulatory Background



- FDA issued a Complete Response Letter (CRL) in August 2020 regarding the Biologics License Application for Viaskin Peanut in children ages 4 to 11 years¹
- FDA identified four concerns in the CRL, including¹
 - Impact of patch-site adhesion on efficacy
 - Need for patch modifications and supplementary clinical data to support a modified patch
 - Need for Human Factors study with modified patch
 - Additional Chemistry, Manufacturing and Controls (CMC) data requested
- DBV selected the modified Viaskin Peanut patch based on adhesion data from a Phase I trial of five modified patches in healthy adult volunteers²
- DBV determined the most efficient approach to demonstrate effectiveness, safety, and improved adhesion of the modified Viaskin Peanut patch is a new, Phase 3 placebo-controlled efficacy trial³



VITESSE



VITESSE Partial Clinical Hold Lifted on December 23

On September 7

DBV initiated its Phase 3 clinical trial, VITESSE, evaluating VIASKIN PEANUT in children ages 4-7 years old.

On September 21

The company announced that the FDA had placed a partial clinical hold on the trial, specifying changes to elements of the VITESSE protocol with the intent for the trial to support a future Biologics License Application (BLA) submission.

On December 23

DBV announced that the FDA lifted the partial clinical hold on VITESSE and confirmed DBV satisfactorily addressed all clinical hold issues



Importantly, DBV had not screened or recruited any patients into the trial at the time of the partial clinical hold.



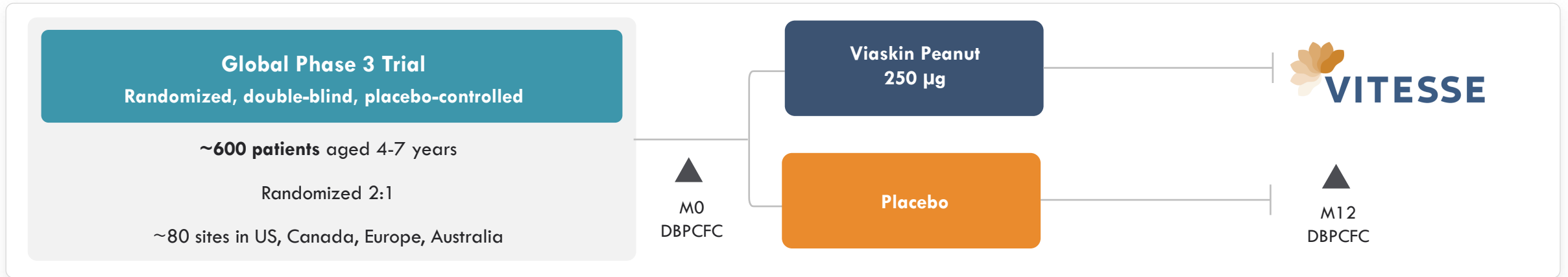
DBV continued internal preparations and start-up activities for VITESSE such as conducting certain site assessments to support prompt study launch once the partial clinical hold lifted.

FDA Stated VITESSE May Proceed with Protocol Revisions That Addressed Agency's Requested Modifications

FDA Modification	DBV Response
Redefinition of Minimum Daily Wear Time	The updated VITESSE IFU now outlines that Viaskin Peanut 250 µg is to be worn for as close to a full day as possible (i.e., 24 hours) with a minimum daily wear time of 20 hours each day.
Statistical Test for Patch Adhesion Assessment	DBV and the FDA agreed a statistical test of adhesion will be included in the VITESSE statistical analysis plan and further considered patch adhesion data collection and interpretation in the context of the novel nature of the Viaskin patch platform.
Reclassification of Adverse Events of Special Interest	Four adverse events will be classified as adverse events of special interest. These AEs were collected and assessed in all previous Viaskin Peanut trials and included in the previous VITESSE protocol. Only the classification of these AEs has changed.
Increase in Number of Trial Participants on Active Treatment	DBV plans to initiate a separate safety study in approximately 275 additional subjects, randomized 3:1 active versus placebo. The additional safety data generated by this six-month study will supplement the safety data generated by the VITESSE trial, resulting in a safety database comprised of approximately 600 children ages 4 – 7 years treated with Viaskin Peanut.

VITESSE is Designed for Younger, More Allergen-Sensitive Patients

Inclusion criteria, primary efficacy endpoint, responder criteria, efficacy assessment methodology and safety endpoints were not impacted by the Partial Clinical Hold letter and remain unchanged from initial VITESSE protocol

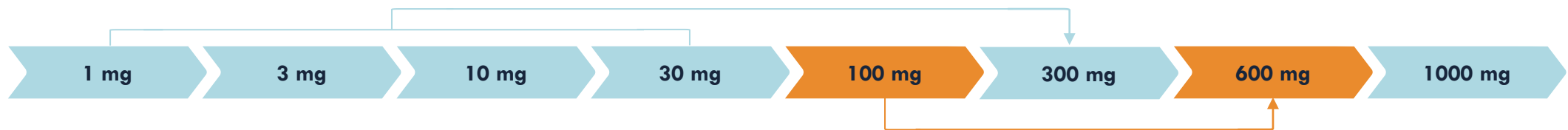


Primary endpoint:



difference between the percentage of treatment responders in the active vs. placebo group after 12 months

Treatment responder (assessed by DBPCFC) defined as:

- If ED \leq 30 mg at baseline, responder if ED \geq 300 mg at M12
- If ED = 100 mg at baseline, responder if ED \geq 600 mg at M12



Summary

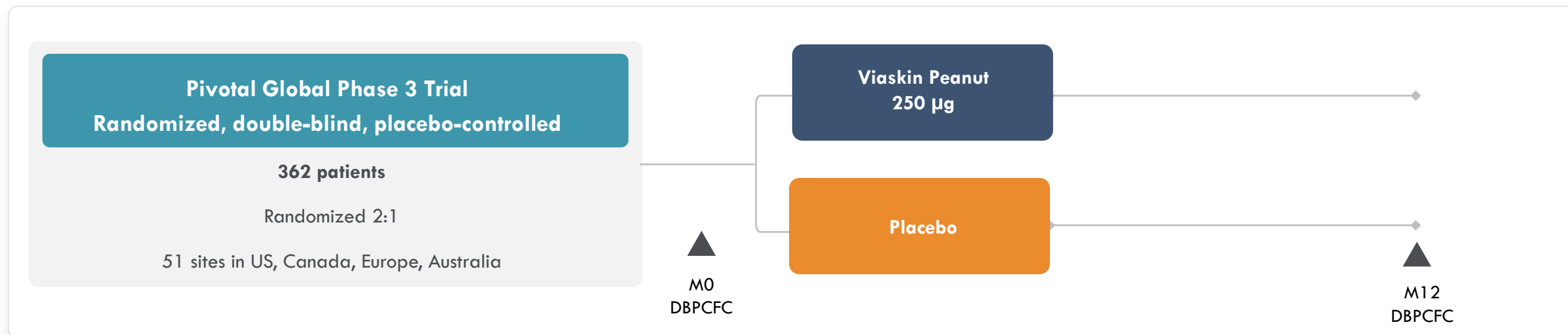
		
Patch overlay*	Modified (circular, larger)	Square
Age	4-7 years	4-11 years
Inclusion Criterion Baseline ED	≤ 100 mg	≤ 300 mg
Responder Definition	<u>Baseline ED</u> <u>Month 12 ED</u>	<u>Baseline ED</u> <u>Month 12 ED</u>
	≤ 30 mg → ≥300 mg	≤ 10 mg → ≥300 mg
	100 mg → ≥600 mg	>10 mg → ≥ 1,000 mg
Instructions for Use (IFU)	Viaskin Peanut 250 µg is to be worn for as close to a full day as possible (i.e., 24 hours) with a minimum daily wear time of 20 hours each day	Viaskin Peanut 250 µg is to be worn 24 +/- 4 hours each day
Adhesion	Statistical test of adhesion will be included in the statistical analysis plan; NOT an approval criterion	Referenced in August 2020 CRL
Efficacy endpoint success criterion	Lower bound of 95% confidence interval ≥ 15%	Lower bound of 95% confidence interval ≥ 15%
Size	600 subjects, randomized 2:1	356 subjects, randomized 2:1
Supplementary Safety Study	275 additional subjects, randomized 3:1	REALISE (393 patients)

epitope



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

Results Presented at American College of Allergy, Asthma and Immunology in November 2022¹



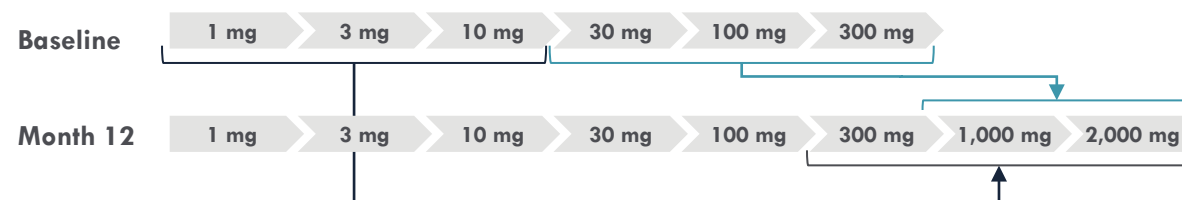
Primary endpoint:

difference between the percentage of treatment responders in the active compared to the placebo group after 12 months

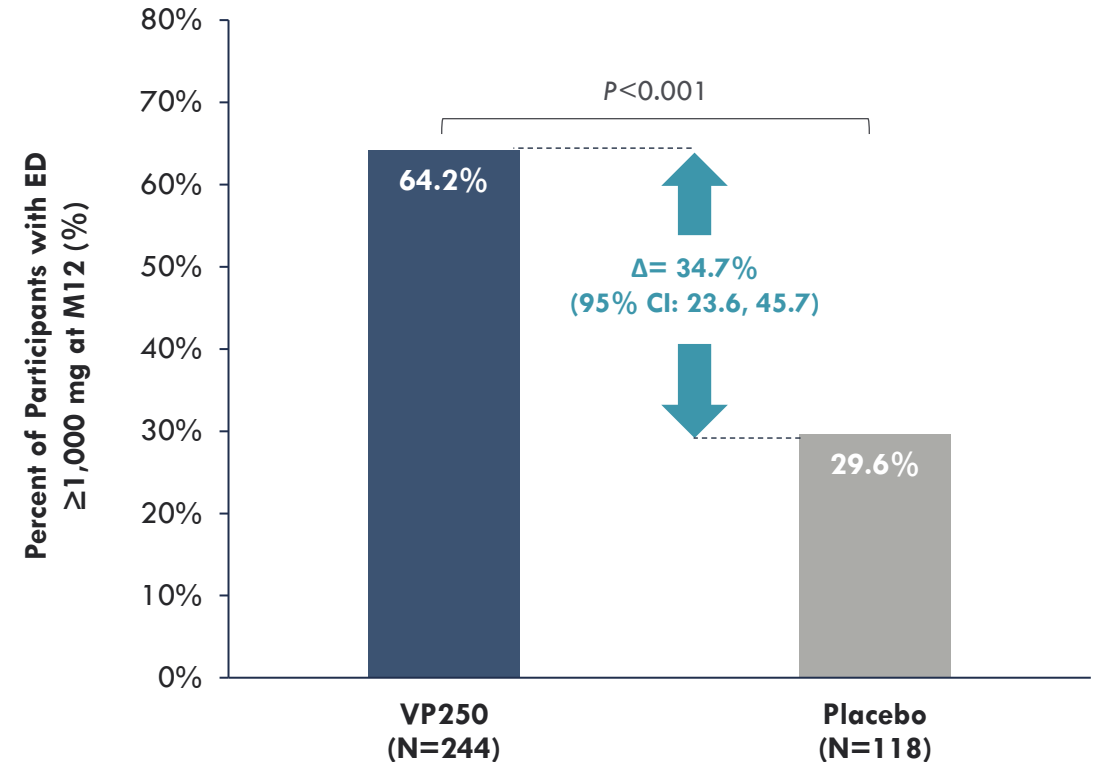
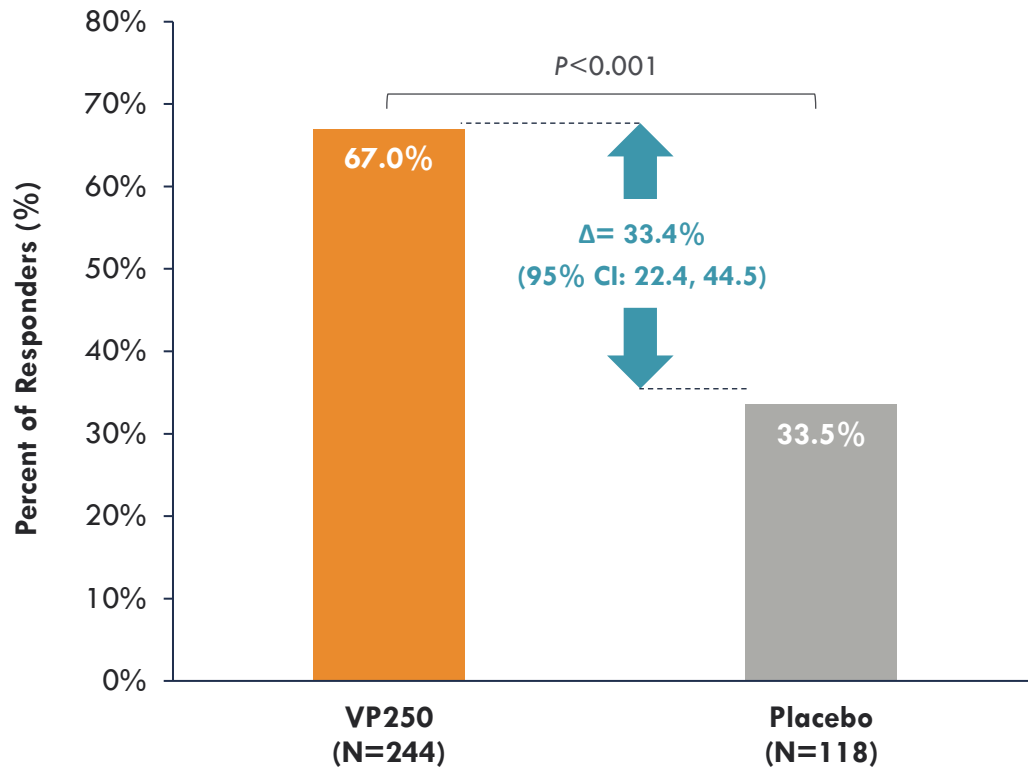
Treatment responder (assessed by DBPCFC) defined as:

If ED ≤ 10 mg at baseline, responder if ED ≥ 300 mg at M12

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



Viaskin Peanut Demonstrated a Statistically Significant Treatment Effect¹



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

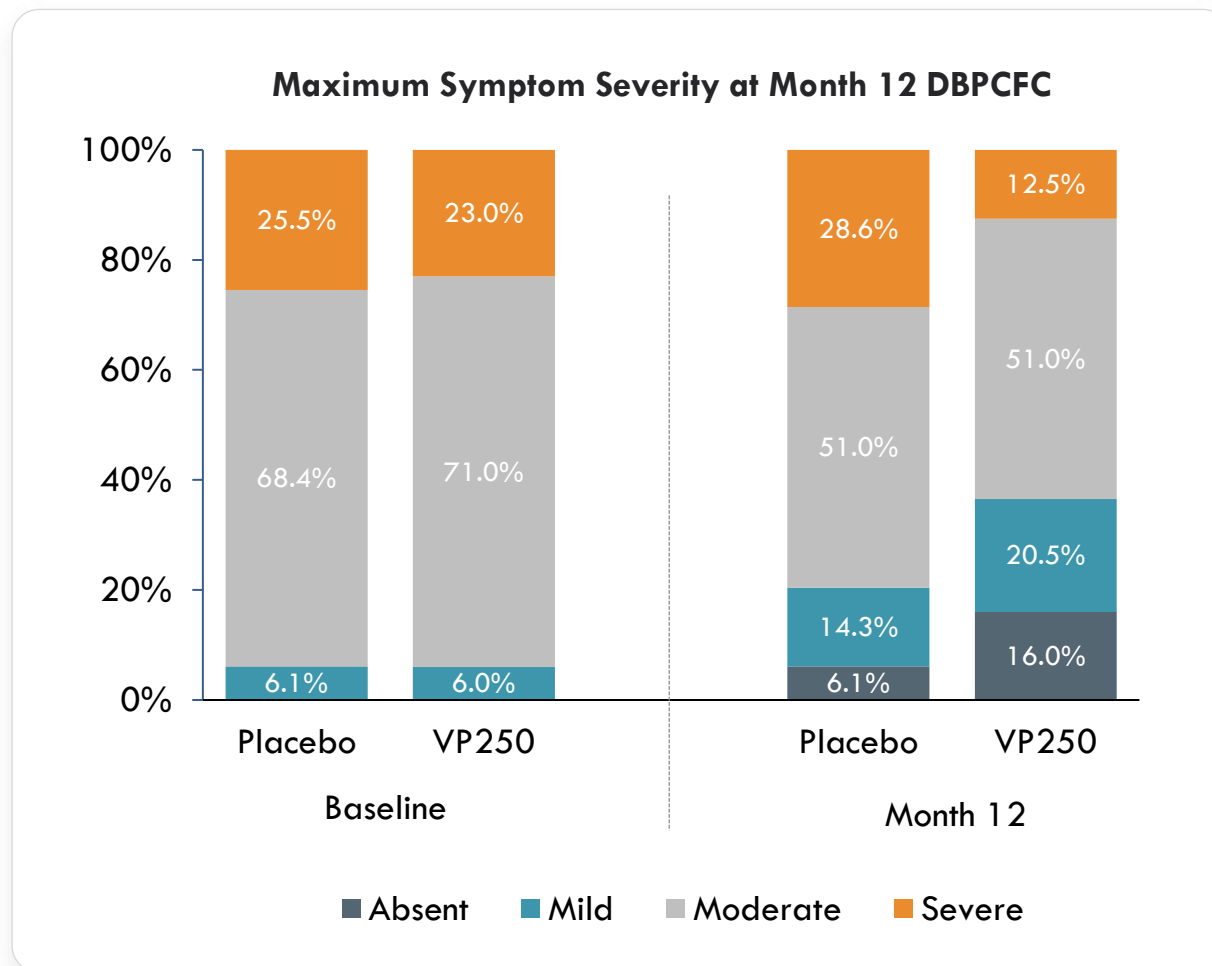
Regardless of baseline ED, a statistically significantly larger percentage
 of participants on VP250 achieved an ED $\geq 1,000$ mg

Shift Toward Reduction in Reaction Severity Following 12 Months of Viaskin Peanut Treatment¹

At baseline Double-Blind, Placebo-Controlled Food Challenge (DBPCFC), the proportions of maximum reaction severity were balanced between groups.

At Month 12, the distribution of maximum symptom severity was significantly shifted toward less severe symptoms in the Viaskin Peanut 250 µg (VP250) group relative to placebo (P<0.001).

This shift toward a reduction in reaction severity coincided with an increase in eliciting dose (ED) and a greater proportion of responders in the Viaskin Peanut 250 µg group versus the placebo group.



EPITOPE Safety Summary¹

Safety Profile Consistent with Prior Viaskin Peanut Studies

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

Two Potential Regulatory Pathways for Viaskin™ Peanut

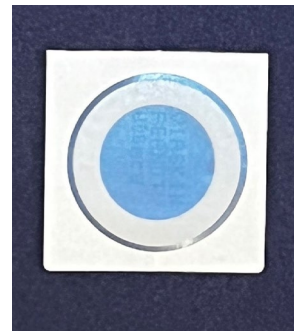
Flexibility of Viaskin manufacturing process supports potential for two in-market patches

Target Age

Patch*

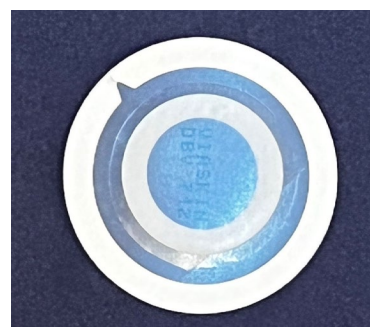
Phase III Efficacy Data

Next Steps



epitope

- FDA guidance on potential regulatory pathway

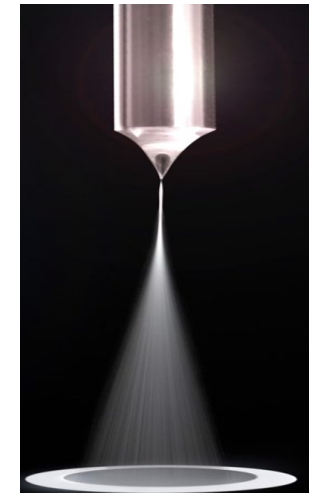


VITESSE

- VITESSE enrollment
- Safety study protocol design submission

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

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



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

Program	Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3
Viaskin Milk (DBV135) – Milk Allergy	[Progress bar spanning Discovery, Pre-clinical, and Phase 1]				
Viaskin Milk (DBV135) – Eosinophilic Esophagitis	[Progress bar spanning Discovery, Pre-clinical, and Phase 1]				
Viaskin – Autoimmune and Inflammatory Disorders	[Progress bar spanning Discovery and Pre-clinical]				
Viaskin – Vaccines	[Progress bar spanning Discovery and Pre-clinical]				



September 30, 2022 YTD Financial Results

\$212.7M in cash and cash equivalents as of September 30, 2022

\$14.1M¹ raised through ATM in May

\$181.2M¹ raised in PIPE in June

\$27.1M reimbursement of the French Research Tax Credit²

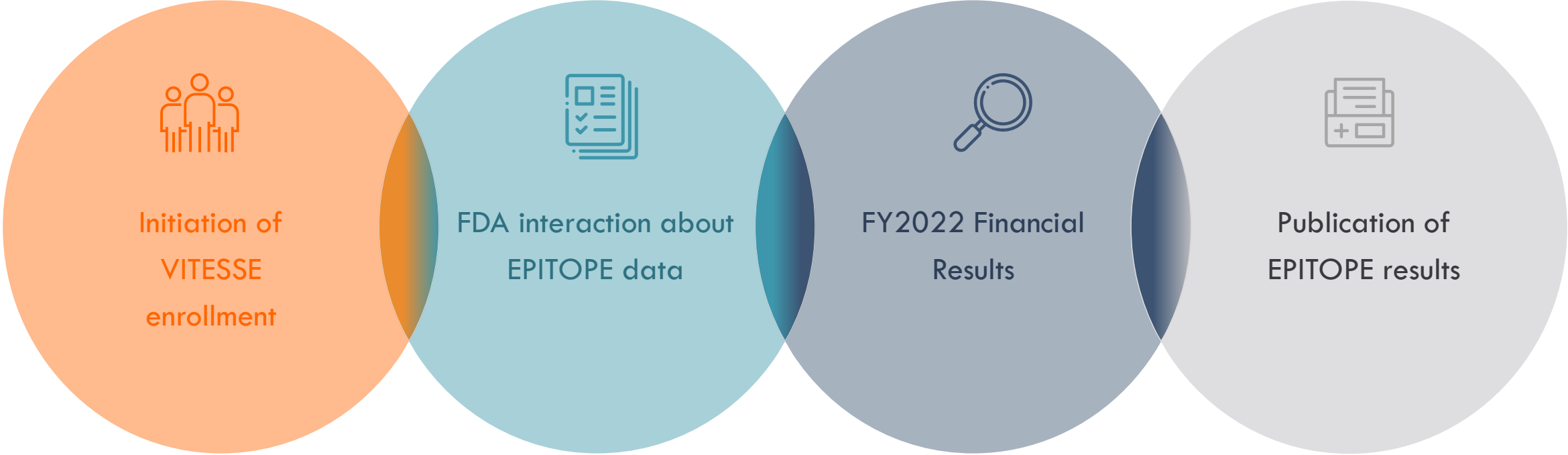
Cash used in operations

Decreased by ~65%³ for nine months ended September 30, 2022, versus comparable period in 2021

Cash runway

Expected to support operations through VITESSE topline data⁴

Near-Term Milestones



Investment Highlights

Late-stage Clinical Programs

Comprehensive late-stage clinical programs in food allergy indications

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Novel Viaskin™ technology based on Epicutaneous Immunotherapy (EPIT™)

Science-Driven Leadership Team

Science-driven leadership team with deep regulatory and commercial experience

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Well financed with \$212.7 million of cash and equivalents as of September 30, 2022

A young girl with dark hair, wearing a yellow t-shirt and brown shorts, is running happily in a park. She is holding a large, colorful rainbow kite that is flying in the air. The background shows green trees and a clear sky.

We are dedicated to improving the lives of patients with food allergies and other immunological diseases



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EPIT and Viaskin are trademarks of DBV Technologies.



Patented Patch Manufacturing Capabilities

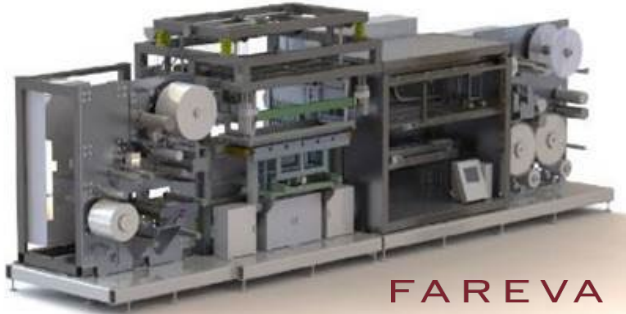
Integrated end-to-end patch manufacturing in place



Source Material



Active Pharmaceutical Ingredient (API)



Final Product Process

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



Robust Intellectual Property Portfolio

IP Covers:

Core patch technology	Condensation chamber
Mechanism of action	Epicutaneous immunotherapy (EPIT) activates the immune system by allowing the antigen to penetrate the upper layer of the epidermis (intact skin)
Manufacturing	Electrospray patch manufacturing allows for precise antigen deposits without adjuvants
Specific indications	EPIT peanut, EoE, vaccines, etc.
Regulatory exclusivity	Up to 12 years of biologic exclusivity, if approved
Broad Geographic Coverage	Including US, Europe, Australia and Canada
Key patent expiries	Through 2035
Patent	Innovation-driven patent lifecycle management

REALISE: study Design and Preliminary Results of the 6-Month Blinded Portion¹

Children 4–11 years

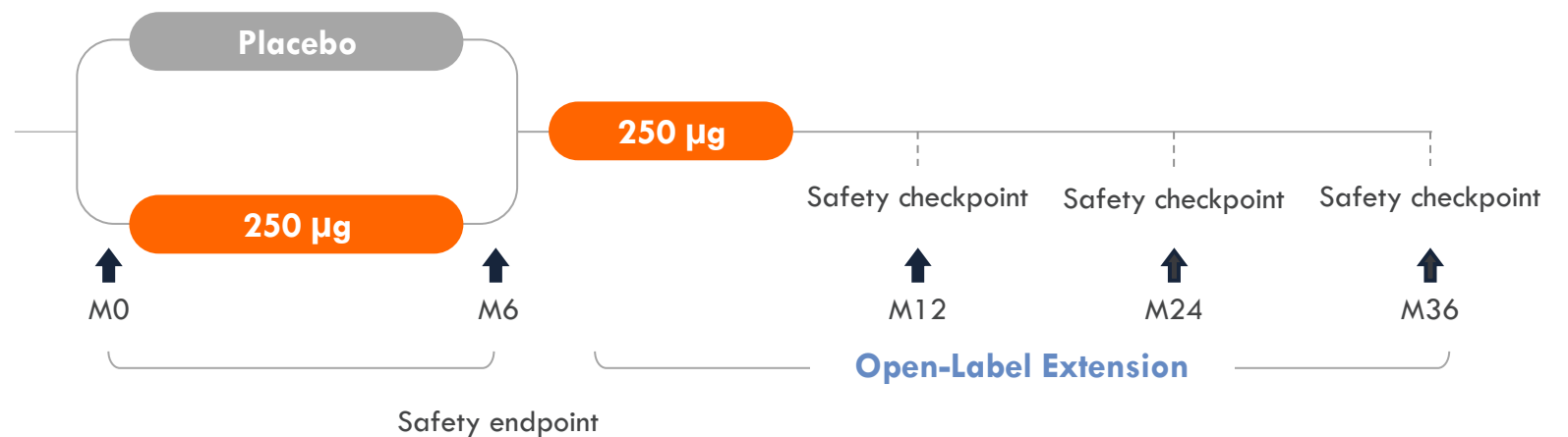
REALISE Phase 3

Randomized, double-blind, placebo-controlled

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

32 centers in the US and Canada

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



- REALISE met its primary endpoint in the 6-month blinded portion of the study, demonstrating that Viaskin Peanut was tolerated with no new or unexpected AEs
- Preliminary results indicated that all study participants had a similar safety profile