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• Advancing novel skin immunotherapies for patients with food allergies and other immunological diseases
  – Over the last two decades, limited innovation in the food allergy field has left millions of patients significantly underserved today

• We are focused on discovering, developing and commercializing our novel skin immunotherapy product candidates using our proprietary Viaskin Technology Platform
  – Potent activation of the immune system with Epicutaneous patch
  – No active passage of antigen into blood stream
  – Proprietary manufacturing equipment designed, engineered and developed by DBV
### Promising Pipeline of Product Candidates

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>INDICATION</th>
<th>DEVELOPMENT STAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DISCOVERY</td>
<td>PRE-CLINICAL</td>
</tr>
<tr>
<td><strong>Viaskin Peanut</strong></td>
<td>Peanut Allergy</td>
<td>Ages 4-11 (<em>Breakthrough Therapy and Fast Track Designation</em>)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ages 1-3</td>
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<tr>
<td></td>
<td></td>
<td>Adolescents &amp; Adults</td>
</tr>
<tr>
<td><strong>Viaskin Milk</strong></td>
<td>Cow’s Milk Protein Allergy</td>
<td>Ages 2-17 (<em>Fast Track Designation</em>*)</td>
</tr>
<tr>
<td><strong>Viaskin Egg</strong></td>
<td>Hen’s Egg Allergy</td>
<td>Ages 4-17</td>
</tr>
<tr>
<td><strong>Mechanistic Study</strong></td>
<td>Eosinophilic Esophagitis</td>
<td>Ages 4-17</td>
</tr>
<tr>
<td>5 Programs</td>
<td>Undisclosed</td>
<td>Ages 4-17</td>
</tr>
<tr>
<td>Diagnostics with</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nestlé Health Science</strong></td>
<td>Cow’s Milk Protein Allergy</td>
<td>Infants</td>
</tr>
</tbody>
</table>

* US FDA Breakthrough Therapy and Fast Track designation in children
** US FDA Fast Track designation in pediatric patients two and older
Recent Viaskin Peanut Updates: Significant Progress on CMC Readiness

- Scaled-up GMP manufacturing process in place
- Annual production capacity of 30 million Viaskin Peanut patches per GEN4.0 machine
- Plans in place for additional machine post-launch

**Viaskin Electrospay Technology**
- API dry powder: highly purified allergen extract

**Commercial-Scale GEN4.0**

**Fully Integrated Manufacturing Process**
- API
- Electrospay/GEN4.0
- Viaskin Peanut patch
Recent Viaskin Peanut Updates: US Regulatory Filings in 4Q18

Breakthrough and fast track designations potentially allow for expedited review

FDA agreement that the available efficacy and safety data for Viaskin Peanut support submission of BLA for treatment of peanut allergic children ages 4-11
Viaskin Technology: Building a Transformative Immunotherapy Platform

Pioneering a new class of immunotherapy

- Creator of Epicutaneous Immunotherapy (EPIT)
- Biologic compound provides allergenic information to activate the immune system through the skin

Merging science and technology for differentiated drug development

- Viaskin: novel and proprietary technology
- 15 years of R&D resulting in 17 patent families and significant trade secrets
- Viaskin platform targets antigen-p呈现ing cells of the skin

Advancing transformative treatments for large, underserved patient populations

- Food allergies and related allergic diseases
- Immune system disorders
- Autoimmune diseases
- Vaccination
The Skin Has Important Immune Properties

• Immune functions of the skin include
  – Responding to trauma, toxins, and infectious agents
  – Maintaining self-tolerance, preventing allergy, and inhibiting autoimmunity

• Keratinocytes
  – Distinguish pathogens from harmless agents
  – Influence nearby Langerhans cells to generate an appropriate immune response

• Langerhans cells
  – Antigen-presenting cells that can process antigens and migrate to regional lymph nodes

EPIT: Pioneering a New Class of Immunotherapy

Targeting the immune system on **intact skin**

Solubilized antigen is captured by **Langerhans cells** in the epidermis

Transmission of immunogenic information, with no allergen passage to the bloodstream

Image: ©Genoskin
Merging Science & Technology for Differentiated Drug Development

Electrospray: patented manufacturing tool that allows for precise antigen deposits without adjuvants

EPIT Activates the Immune System Through Intact Skin

Patented electrostatic patch with condensation chamber allows the antigen to penetrate upper layer of epidermis

Modular components → technology versatility
- Highly scalable
- Broadly applicable platform

Manufacturing capabilities
- In-house development and engineering of electrospray machines
- Development and engineering expertise at DBV
Core Innovation: Differentiated Electrospray Technology

• **Dose flexibility**
  – Biological API deposit between 20 and 500 µg/cm²

• **API stability**
  – Solid & soluble protein layer, no glue

• **Homogeneous repartition of API**
  – Uniform delivery into skin

• **Replicability**
  – High dosage control in each patch

• **Bioavailability**
  – High solubility from electrostatic forces instead of glue
Robust IP Portfolio: Core Technology, Broad MoAs & Specific Indications

- **Food allergies**
  - Peanut
  - Epicutaneous Vaccination
  - Epicutaneous Desensitization

- **Allergy related diseases**
  - Eosinophilic Esophagitis
  - Immuno Rebalancing
  - Hemophilia A

**CORE TECHNOLOGY**
- Viaskin I
- Viaskin II
- Electrospray

**Epicutaneous vaccination**
- Boost Vaccination

**Epicutaneous Tolerance induction**

**Broad geographic applications**
- USA, Europe, Australia, Canada

**Long patent protection**
- Initial core patents through 2022
- Other key patents through 2030-35

**Innovation-driven patent lifecycle management**
Food Allergies: Addressing an Urgent Unmet Medical Need

~8% of children in the U.S.

or ~2 children in every classroom, have a food allergy^1

Peanut allergy is one of the most common food allergies in children

In the U.S., approximately 1 million children ages 1-11 have a diagnosed peanut allergy^1,^5

- Every 7 minutes a child goes to the emergency room for an allergic reaction to food^2
- Each year, approximately 150 deaths are due to allergic reactions; most deaths occur in patients who are aware of their allergy^3
- 50% of peanut-allergic patients experience accidental allergen ingestion over a median span of 5.6 years^4
- Peanut allergy can cause severe, potentially fatal, allergic reactions, including anaphylaxis
- Eosinophilic esophagitis (EoE), a progressive inflammatory disease, is often caused by ingesting foods, such as peanut, milk and egg^6

In Last Several Decades, No Significant Innovation in Food Allergy Immunotherapy

**There is NO margin for error when exposing patients to a potentially life-threatening allergen**

- **Safety is paramount**: ingesting small quantities of offending allergen can cause life-threatening reactions
- **After several decades, these patients are still underserved**: there are no approved treatments today
- **Current disease management is allergen avoidance**: time-consuming, restrictive, major cause of worry and stress
Our Solution for a Hard-to-Treat Disease

- Contamination leading to peanut consumption is a serious threat\(^1\)
- Estimated detectable peanut residue ranges from 0.025-45mg of peanut protein\(^2\)
- Desensitization therapies could offer significant reduction of the risks associated with accidental exposures \(^1,3,4\)

Yet, even amounts of less than 1 peanut can cause severe reactions

**Viaskin Peanut** utilizes the skin’s immune properties, which amplifies minimal allergen exposure

Balancing risk-benefit drug profiles for these patients has been a difficult task for the field

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PEPITES Pivotal Phase III Trial Results Reported in 4Q17

**Study Population**

**Highly allergic patients ages 4-11**
- > 0.7 kU/L peanut-specific IgE and ≥ 6mm or 8 mm SPT* wheal
- Reactive dose at M0 ≤ 300 mg peanut protein (i.e. approx 1 peanut)

**Efficacy Endpoints**

**Treatment responder definition**
- Assessed using DBPCFC**
- For patients with a M0 ED*** ≤ 10mg: responder if ED ≥ 300 mg at M12
- For patients with a M0 ED > 10mg: responder if ED ≥ 1,000 mg at M12

**Key secondary endpoints**
- CRD****, changes in peanut sIgE and sIgG4

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* SPT: Skin Prick Test (≥ 6mm for children 4 to 5 years ≥ 8 mm children ≥ 6 years
** DBPCFC: Double-Blind Placebo-Controlled Food Challenge
*** ED: Eliciting Dose
**** CRD: Cumulative Reactive Dose at Food Challenge

356 peanut allergic children
31 centers in US, Canada, Australia, Germany, Ireland

PEPITES Open Label Follow Up
PEPITES Baseline Characteristics: Highly Allergic Patient Population

356 Patients Randomized
- Active: 238
- Placebo: 118

Peanut Eliciting Dose (mg)
- Median: 100
- Mean: ~140

Medical History of Patients
- Asthma
  - n: 169, %: 47.5
- Eczema/Atopic Dermatitis
  - n: 218, %: 61.2
- Allergic Rhinitis
  - n: 199, %: 55.9
- Polyallergic
  - n: 305, %: 85.7
Results: Primary Efficacy Endpoint Shows Significant Treatment Benefit with Favorable Safety

Response rate was statistically significant, but 15% lower bound of the 95% CI proposed in the SAP submitted to FDA was not reached.

Favorable tolerability & safety profile reported:

- Most AEs were mild to moderate application site reactions
- No cases of severe anaphylaxis
- No SAE imbalance (4.2% in Viaskin Peanut vs 5.1% in placebo)
- 1.1% discontinuation rate due to treatment-emergent AEs
- >95% compliance during the trial
- No observed treatment-related AEs due to physical activity or concomitant illness

Response Rate (ITT):

<table>
<thead>
<tr>
<th></th>
<th>LCL</th>
<th>UCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>12.4</td>
<td>29.8</td>
</tr>
<tr>
<td>Viaskin Peanut 250 µg</td>
<td>35.3%</td>
<td></td>
</tr>
</tbody>
</table>

\[ \Delta = 21.7\% \]

\[ p = 0.00001 \]
PEPITES Results: Significant Increase in Threshold Reactivity to Peanut Protein Observed

Unique MoA increases protection to peanut without requiring major exposure to offending allergen

- No consumption of peanut during treatment
- Viaskin Peanut 250 μg dose = ~1/1,000 mg of a peanut kernel
- Threshold reactivity measured during exit food challenge showed a significant difference between active and placebo
- Significant immunomodulation confirmed increase in peanut consumption over time

mBOCF = Modified Baseline Observation Carried Forward
PEPITES Results: Robust Immunological Changes Support Treatment Effect

PS-IgE Changes Overtime

<table>
<thead>
<tr>
<th>Month</th>
<th>VP250 μg Patch</th>
<th>Placebo Patch</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>238</td>
<td>232</td>
</tr>
<tr>
<td></td>
<td>117</td>
<td>116</td>
</tr>
<tr>
<td></td>
<td>112</td>
<td>112</td>
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<tr>
<td></td>
<td>109</td>
<td>109</td>
</tr>
</tbody>
</table>

PS-IgG4 Changes Overtime

<table>
<thead>
<tr>
<th>Month</th>
<th>VP250 μg Patch</th>
<th>Placebo Patch</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>238</td>
<td>231</td>
</tr>
<tr>
<td></td>
<td>117</td>
<td>116</td>
</tr>
<tr>
<td></td>
<td>112</td>
<td>111</td>
</tr>
<tr>
<td></td>
<td>109</td>
<td>110</td>
</tr>
</tbody>
</table>

ANCOVA = analysis of covariance; CI = confidence interval; ED = eliciting dose; PS-IgE = peanut-specific immunoglobulin E; PS-IgG4 = peanut-specific immunoglobulin G4.

*Model independent (using observed data).

†Based on T-test associated with the randomized group beta coefficient from a fixed-effects, repeated-measures ANCOVA model for change from baseline with randomized group, timepoint, treatment-by-timepoint interaction, and screening ED subgroup as categorical covariates (using log-transformed PS-IgE and PS-IgG4 observed data).
JAMA Publication 2017: Long-term Extension Data Shows Benefit Increases Over Time in Phase IIb Study

Response Rate at OLFUS: Baseline, Year-1 and Year-2

- OLFUS baseline: 57.1% (12/21)
- OLFUS year 1: 80.0% (16/20)
- OLFUS year 2: 83.3% (15/18)

Cumulative Reactive Dose in OLFUS

- VIPES baseline: Median = 84.5 mg
- median = 22 mg
- OLFUS baseline: Median = 44 mg
- Median = 444 mg
- OLFUS year 1: Median = 1,440 mg
- Median = 1,883.5 mg
- OLFUS year 2: Median = 1,440 mg
- Median = 2,453.9 mg

Results shown for Viaskin Peanut 250 µg
* 1 child discontinued (not related to Viaskin Peanut)
** 2 children discontinued (none related to Viaskin Peanut)

PEPITES Post-Hoc Analysis Using VIPES Responder Definition Suggests Consistent Treatment Effect Observed from Phase II to Phase III

**Actual Reported Response Rate in PEPITES (%)**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>% of Responders</th>
<th>LCL</th>
<th>UCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>13.6%</td>
<td>12.4</td>
<td>29.8</td>
</tr>
<tr>
<td>VP 250</td>
<td>35.3%</td>
<td>18.9</td>
<td>37.4</td>
</tr>
</tbody>
</table>

Δ = 21.7%
p < 0.00001

**PEPITES Response Rate Using the VIPES Response Criteria**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>% of Responders</th>
<th>LCL</th>
<th>UCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>16.9%</td>
<td>18.9</td>
<td>37.4</td>
</tr>
<tr>
<td>VP 250</td>
<td>45.8%</td>
<td>28.8</td>
<td>54.8</td>
</tr>
</tbody>
</table>

Δ = 28.8%
p < 0.0001
Positive Phase III REALISE Results Support Planned Regulatory Filings for Viaskin Peanut

Positive 6-month safety results confirmed the safety and tolerability profile observed in PEPITES, VIPES and CoFAR6

Study Population

Patients 4 to 11 with history of IgE-mediated reactions to peanut
  - Including patients with severe anaphylaxis ≥ 14 kU/L peanut-specific IgE and ≥ 8 mm SPT* wheal

Safety & Exploratory Endpoints

Primary endpoint to assess safety at M6
  - Treatment Emergent Adverse Events

No oral food challenges are required at baseline

Exploratory endpoints
  - Quality of Life Questionnaires (FAQLQ & FAIM)
  - Evolution of peanut-specific serological markers over time (IgE, IgG4, SPT wheal)

* SPT: Skin Prick Test
Viaskin Peanut’s Profile Aligned with Patients and HCPs Treatment Objectives

Most important attribute: low risk of serious reactions caused by the treatment

<table>
<thead>
<tr>
<th>Patient Objectives</th>
<th>Allergist Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Favorable Safety and Tolerability</td>
<td>Manageable Side Effect Profile</td>
</tr>
<tr>
<td>Patient-Friendly At-Home Application</td>
<td>Fits Seamlessly into Current Practice</td>
</tr>
<tr>
<td>Fits Into Daily Life</td>
<td>Can be Offered to Most Peanut-Allergic Patients</td>
</tr>
<tr>
<td>Reduce Risk of Reaction from Accidental Exposure</td>
<td>Risk Reduction for Patients</td>
</tr>
</tbody>
</table>

1. DBV Internal Market Research; survey of allergists (100) in 1Q 2017 and 4Q 2017; survey of physicians (500), caregivers/children (360): 2016-2017, 1Q 2015 survey of 240 caregivers of peanut allergic children, DBV Internal Market Research, 3Q 2017 ethnography research with 24 caregiver families.
Balancing Risk-Benefit to Treat Peanut-Allergic Patients in Real-Life

- Unmet medical need today is to de-risk patients when accidentally exposed to peanut
- Contamination of foods with trace amounts of peanut is a daily threat
- Baseline sensitivity in our clinical trials was less than ~1 peanut
- Viaskin Peanut 250 µg has shown progressive and long-lasting desensitization after 12, 24\textsuperscript{1,2} and 36\textsuperscript{1,2} months of treatment
- High compliance and low-dropout rate observed during Phase III and Phase II trials show long-term treatment with Viaskin Peanut could be achievable
- Differentiated efficacy and safety profile observed
  - Same dose of 250 µg used throughout treatment; µg dosage reduces risk of systemic AEs
  - Over 3 years, patients treated with Viaskin Peanut were only exposed to ~1 peanut via the skin\textsuperscript{1,2}

Novel MoA activates immune system via the skin, potentially maximizing efficacy and minimizing adverse events

Expanding the Franchise: Viaskin Peanut in Children (Ages 1-3) Phase III Trial Initiated in August 2017

Part A: 51 patients randomized
- Placebo (n = ~10)
- 100 µg (n = ~20)
- 250 µg (n = ~20)

Part B: ~281 additional patients
- Highest safe dose
  - n = 187
- Placebo
  - n = 94

If no safety concerns, patients remain on dose from Part A

Study Population
- Children ages 1-3 with peanut allergy
  - > 0.7 kU/L peanut-specific IgE and ≥ 6 mm SPT* wheal
  - Reactive dose at M0 ≤ 300 mg peanut protein

Efficacy Endpoints
- Primary endpoint at M12:
  - Treatment responders (%) in active group compared to placebo at DBPCFC:
    - For patients with a M0 ED** ≤ 10mg: responder if ED ≥ 300 mg at M12
    - For patients with a M0 ED > 10mg: responder if ED ≥ 1,000 mg at M12
- Main secondary endpoints: CRD***, changes in peanut sIgE and sIgG4

* SPT: Skin Prick Test, ** ED: Eliciting Dose, *** CRD: Cumulative Reactive Dose at Food Challenge

Denotes a completed food challenge, Denotes a pending food challenge
Expanding the Franchise: Milk Allergy (CMPA) Phase II Study Identified Safe/Effective Dose for Children

**Pediatric Phase I/II USA & Canada**
Part A: 18 patients
Part B: 180 patients

**Phase I (Part A)**
- Cohort at 500µg dose
  - DSMB
- Cohort at 300µg dose
  - FDA & DSMB
- Cohort at 150µg dose
  - DSMB

**Phase II (Part B)**
- Placebo
- 150 µg
- 300 µg
- 500 µg
- Treatment responder definition at M12:
  - ≥ 10-fold increase in CRD** and at least 144 mg of CMP
  - OR CRD ≥ 1,444 mg

**Key secondary endpoints:**
- Change from baseline in IgE, IgG4

**Study Population**
- Children (2-11) and adolescents (12-17)
- Highly sensitive to milk (≥ 10 kU/L milk-specific IgE and ≥ 6 mm SPT* wheal)
- Reactive dose at baseline (M0) ≤300 mg cow’s milk protein (CMP) (~ ≤ 9.4 mL of cow’s milk)

*S PT: Skin Prick Test
**CRD: Cumulative Reactive Dose at Food Challenge
***Evaluating protocol changes to switch all patients to 300 µg (from 500 µg)
Denotes a completed food challenge; Denotes a pending food challenge
MILES Patient Population at Baseline

198 patients randomized
- 152 Children (2-11)
- 46 Adolescents (12-17)

CRD of Cow’s Milk
- Mean
  - Children: 216.3 mg
  - Adolescents: 222.0 mg
- Median
  - Children: 144 mg
  - Adolescents: 144 mg

Medical history of patients

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>139</td>
<td>70.2</td>
</tr>
<tr>
<td>Atopic Dermatitis</td>
<td>139</td>
<td>70.2</td>
</tr>
<tr>
<td>Allergic Rhinitis</td>
<td>144</td>
<td>72.7</td>
</tr>
<tr>
<td>Polyallergic</td>
<td>178</td>
<td>89.9</td>
</tr>
</tbody>
</table>

Mean Cow’s Milk sIgE
- Children: 135.2 kU/L
- Adolescents: 127.9 kU/L
MILES Results: Support Viaskin Milk 300µg as the Potential First Treatment for CMPA in Children 2-11

Favorable safety, tolerability and compliance

- Overall discontinuation rate of 4.5%
  - 1.5% dropout due to AEs
- Most AEs related to application site (mild to moderate)
- No severe anaphylaxis
- No SAEs or epinephrine related to treatment
- Treatment adherence was high
  - Mean patient compliance > 95%

### Response Rate (ITT*)

<table>
<thead>
<tr>
<th></th>
<th>Placebo n = 40</th>
<th>150 µg n = 38</th>
<th>300 µg n = 38</th>
<th>500 µg n = 36</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of Responders</td>
<td>32.5%</td>
<td>34.2%</td>
<td>57.9%</td>
<td>38.9%</td>
</tr>
</tbody>
</table>

*p = 0.042*  
*p > 0.999*  
*p = 0.733*  

* Missing data: failure imputation (considered as non-responders) in ITT population  
P-values obtained using exact logistic regression  
ITT, Intent-to-Treat
MILES Results: Significant Improvement in Threshold Reactivity with Viaskin Milk 300µg in Children 2-11

**Change of CRD (ITT*)**

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>VM150 µg</th>
<th>VM300 µg</th>
<th>VM500 µg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SE) Change of CRD at M12 vs Baseline, mg*</td>
<td>565.6 (33)</td>
<td>624.6 (33)</td>
<td>1322.4 (33)</td>
<td>839.8 (33)</td>
</tr>
</tbody>
</table>

p-values obtained from ANCOVA model including on CRD at M0 and treatment group as fixed effect, using log-transformed data.

**Change of CRD (PP*)**

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>VM150 µg</th>
<th>VM300 µg</th>
<th>VM500 µg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SE) Change of CRD at M12 vs Baseline, mg*</td>
<td>510.8 (26)</td>
<td>569.6 (26)</td>
<td>1340.3 (26)</td>
<td>848.0 (26)</td>
</tr>
</tbody>
</table>

*Among patients with evaluable CRD assessment at Month 12.
†Note, not all subjects underwent a Month-12 OFC: 1 subject in PBO, 1 subject in VM150 µg, 2 in VM300 µg, and 2 in VM500 µg did not report Month-12 CRD.
Upcoming Milestones

1H 2018

- CHOP to release SMILEE Phase IIa pilot trial results for Viaskin Milk in Eosinophilic Esophagitis (EoE)
- Potential BLA filing for Viaskin Peanut in children ages 4-11
- Expanded Viaskin Peanut Phase III results potentially published and presented at medical meetings
- Initiate Part B of the Phase III Viaskin Peanut trial in children ages 1-3

2H 2018

- Potential MAA filing for Viaskin Peanut in children ages 4-11

2H 2019

- Potential US launch of Viaskin Peanut in children ages 4-11
DBV Technologies: Pioneering a New Class of Immunotherapy

- Topline results from Viaskin Peanut Phase III clinical trials: PEPITES & REALISE
- Planned Viaskin Peanut BLA filing in 4Q18; targeting 2019 U.S. launch
- Fully-scalable, launch-ready manufacturing capabilities in place for Viaskin Peanut
- Key commercial roles recruited and onboarded in Summit, New Jersey office
- Positive preliminary Phase I/II data from second food allergy candidate, Viaskin Milk
- Leveraging the Viaskin Platform in research in unmet medical needs outside of food allergies
- Continuing to build a talented team with global headquarters in France and US
- 1Q18 cash position of €234.5mn (including net proceeds from March 2018 financing)
Measuring Efficacy: Double-Blind Placebo-Controlled Food Challenge

**Baseline**

<table>
<thead>
<tr>
<th>DBPCFC: Efficacy Outcome Scoring with Standardized Challenge Matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td>CATEGORIES</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>I. SKIN</td>
</tr>
<tr>
<td>A. Erythematous rash: % area involved</td>
</tr>
<tr>
<td>B. Pruritus</td>
</tr>
<tr>
<td>C. Urticaria/Angioedema</td>
</tr>
<tr>
<td>D. Rash</td>
</tr>
<tr>
<td>II. UPPER RESPIRATORY</td>
</tr>
<tr>
<td>A. Sneezing/Itching</td>
</tr>
<tr>
<td>B. Nasal congestion</td>
</tr>
<tr>
<td>C. Rhinorrhea</td>
</tr>
<tr>
<td>D. Laryngeal</td>
</tr>
<tr>
<td>III LOWER RESPIRATORY</td>
</tr>
<tr>
<td>A. Wheezing</td>
</tr>
<tr>
<td>IV. GASTROINTESTINAL</td>
</tr>
<tr>
<td>A. Subjective Complaints</td>
</tr>
<tr>
<td>0 1 2 3</td>
</tr>
<tr>
<td>Itchy mouth</td>
</tr>
<tr>
<td>Itchy throat</td>
</tr>
<tr>
<td>Nausea</td>
</tr>
<tr>
<td>Abdominal pain</td>
</tr>
<tr>
<td>V. CARDIOVASCULAR</td>
</tr>
<tr>
<td>Normal heart rate to bradycardia</td>
</tr>
</tbody>
</table>

* DBPCFC in PEPITES and VIPES at month 12, in OLFUS-VIPES DBPCFC included an additional 1,600mg step after the 1,000mg step at month 24 & 36

1. Cochrane et al, Allergy 2012
2. Double-Blind, Placebo-Controlled Food Challenge
3. Sampson et al, JACI 2012

- Standardized GMP challenge matrix¹
- Standardized semi-logarithmic increase of peanut protein doses (DBPCFC² as per PRACTALL³)
- Allergic symptoms are graded from a standardized published protocol⁴
- Challenge stopped by clear objective symptoms
**VIPES: Dose-Finding Phase IIb Efficacy and Safety Trial**

**Study Population**

- **Highly allergic patients**
  - > 0.7 kU/L peanut-specific IgE and ≥ 8 mm SPT* wheal
  - Reactive dose at M0 ≤ 300 mg peanut protein (ie. approx 1 peanut)

**VIPES & OLFUS-VIPES Efficacy**

- **Primary endpoint at M12, M24 and M36**
  - ≥ 1000 mg reactive dose OR
  - ≥ 10-fold of the initial reactive dose

- **Main secondary endpoints:**
  - CRD**, changes in peanut sIgE and sIgG4

---

*SPT: Skin Prick Test  **CRD: Cumulative Reactive Dose at Food Challenge  
Denotes a completed food challenge**
**VIPES: Patient Population Snapshot at Baseline**

- **221 patients randomized**
  - 113 Children (6-11)
  - 73 Adolescents (12-17) & 35 Adults (18+)

- **Highly allergic patients (median)**
  - Children = 30 mg
  - Adolescents & Adults = 100 mg

- **Very high IgE levels: > 100 kU/L**
  - 47% of Children
  - 38% of All Patients

**Medical History of Patients**

<table>
<thead>
<tr>
<th>Condition</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>130</td>
<td>58.8</td>
</tr>
<tr>
<td>Eczema/Atopic Dermatitis</td>
<td>114</td>
<td>51.6</td>
</tr>
<tr>
<td>Allergic Rhinitis</td>
<td>96</td>
<td>43.4</td>
</tr>
<tr>
<td>Polyallergic</td>
<td>183</td>
<td>82.8</td>
</tr>
</tbody>
</table>

**Peanut Protein Eliciting Dose (mg)**

- **Children**
  - 6 mg: 1 patient
  - 11 mg: 11 patients
  - 17 mg: 2 patients
  - 23 mg: 13 patients
  - 30 mg: 13 patients
  - 100 mg: 38 patients
  - 300 mg: 39 patients

- **Adolescents/Adults**
  - 10 mg: 2 patients
  - 100 mg: 18 patients
  - 300 mg: 40 patients
VIPES: Phase IIb Results Published in JAMA in November 2017

- Primary endpoint met with Viaskin Peanut 250 µg
  - Greatest response in children ages 6-11 (53.6% vs. 19.4%, p = 0.008)

- Increase in threshold reactivity of peanut protein showed a clear dose response with greatest benefit in the 250 µg arm
  - In the children subgroup, mean CRD* at month 12 was 1211.9 mg (median 444 mg) in active vs. 239.1 mg (median 144 mg) in placebo (p < 0.001)

- Immunological data supports treatment effect

- Favorable safety and tolerability profile
  - 6.3% discontinuation rate (0.9% related to treatment)
  - Most frequent related AEs: local cutaneous reaction > 90% of patients mainly mild and moderate (50% with a duration < 2 months)
  - Median treatment compliance of 97.6%

*CRD: Cumulative Reactive Dose at Food Challenge
VIPES: Primary Endpoint Met Focus On Children (Ages 6-11)

Response rate in children across doses after 12 months

- Placebo: 19.4% (n = 31)
- 50 µg: 57.1% (n = 28)
- 100 µg: 46.2% (n = 26)
- 250 µg: 53.6% (n = 28)

p = 0.008
VIPES: Peanut Consumption In Children (Ages 6-11)
Clear Dose Response, Clear Magnitude Of Effect
VIPES: Immunological Changes In Children (Ages 6-11) Supports Treatment Effect

**Peanut-specific IgE (kU/L)**

- Viaskin Peanut 250 μg, n=28
- Viaskin Peanut 100 μg, n=26
- Viaskin Peanut 50 μg, n=28
- Placebo, n=31

**Peanut-specific IgG4 (mg/L)**

- Viaskin Peanut 250 μg, n=28
- Viaskin Peanut 100 μg, n=26
- Viaskin Peanut 50 μg, n=28
- Placebo, n=31
VIPES: Primary Efficacy Endpoint Met Identified Viaskin 250 µg As Phase III Dose

Response rate across doses after 12 months

- Placebo: 25.0% (n = 56)
- 50 µg: 45.3% (n = 53)
- 100 µg: 41.1% (n = 56)
- 250 µg: 50.0% (n = 56)

*p = 0.01*
VIPES: Adolescents & Adults High Placebo Response Rate Distorts Analysis

Patients aged 12-55 response rate across doses

- Placebo: 32.0% (n = 25)
- 50 µg: 32.0% (n = 25)
- 100 µg: 36.7% (n = 30)
- 250 µg: 46.4% (n = 28)

p = 0.40
Patients aged 12-55 increase in baseline CRD at 12 months across doses

<table>
<thead>
<tr>
<th>Dose (µg)</th>
<th>CRD Increase (mg)</th>
<th>Median (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>528.4</td>
<td>10.0</td>
</tr>
<tr>
<td>50 µg</td>
<td>619.2</td>
<td>0.0</td>
</tr>
<tr>
<td>100 µg</td>
<td>842.3</td>
<td>30.0</td>
</tr>
<tr>
<td>250 µg</td>
<td>837.4</td>
<td>335.0</td>
</tr>
</tbody>
</table>

**VIPES: Adolescents & Adults Changes From Baseline CRD Indicate Dose Response Trend**
**VIPES: Adolescents & Adults Immunological Changes**

Support Dose Response Trend

**Peanut-specific IgE (kU/L)**

**Peanut-specific IgG4 (mg/L)**
VIPES: Post Hoc Analysis Using PEPITES Responder Definition

VIPES Children (6-11 years) - Viaskin 250 μg at M12

**Reported Response Rate**

- **Placebo**
  - n = 31
  - % of Responders: 19.4%

- **250 μg**
  - n = 28
  - % of Responders: 53.6%

**VIPES Response Rate Using the PEPITES Response Criteria**

- **Placebo**
  - n = 31
  - % of Responders: 6.5%

- **250 μg**
  - n = 28
  - % of Responders: 46.4%

*p = 0.008*  
*p = 0.0007*
OLFUS-VIPES: Open-label Follow-up Trial To VIPES Extension Trial To Support Use Of Viaskin Peanut

221 stratified patients, 22 centers in US, Canada, France, Poland, and Netherlands

VIPES Dose-finding

Placebo

50 µg

100 µg

250 µg

OLFUS-VIPES Open Label Follow-Up Study

M0 M12 M24 M26

250 µg

250 µg

171 patients opted to enroll in OLFUS (overall 83% roll-over rate from VIPES)

- 97 children and 74 adolescents & adults

Assessed long-term safety and efficacy

Double-Blind Placebo-Controlled Food Challenge (DBPCFC) administered at month-12 and month-24

Month-26 DBPCFC to explore “sustained unresponsiveness”

- Patients unresponsive to CRD* > 1,440 mg at month-24 DBPCFC were eligible to continue study
- Two-month period without treatment or consumption of peanut to assess durability of response

*CRD: Cumulative Reactive Dose at Food Challenge

Denotes a completed food challenge
**OLFUS-VIPES**: Long-term Follow-up Data Key

**Conclusions**

**Late Breaking Oral Presentation at AAAAI 2017**

- In children treated for three years with a 250 µg dose there was a trend of progressive response to treatment as measured by increased response rate, higher CRD* and serological changes
  - Treatment benefit was observed to be long-lasting for three years
  - 83.3% response rate after three years, an increase from 57.1% at OLFUS baseline
  - Mean CRD reached 2,453.9 mg at the end of OLFUS, from 1,067.8 mg at OLFUS baseline

- No decreased compliance or increased frequency of AEs in VIPES patients treated for 24 additional months
  - 95.5 % overall compliance rate was observed throughout the study
  - No SAEs or epinephrine use due to treatment was reported in 36 months
  - Most adverse events were related to application site and were mild to moderate, with decreasing severity and frequency over time

Shreffler et al. AAAAI 2017, #L7

*CRD: Cumulative Reactive Dose at Food Challenge*
OLFUS-VIPES: Immunological Changes, Ages 6-11

Median relative change = 100 x (Month xx – Baseline)/Baseline
Viaskin Peanut 250 µg, n = 18
CoFAR6: Efficacy And Safety – NIAID Sponsored Phase II

221 stratified patients, 22 centers in US, Canada, France, Poland, and Netherlands

Enrollment
n = 75

Entry OFC positive to cumulative dose of < 1044 mg peanut protein

Randomization
1:1:1

Placebo

250 mg Viaskin Peanut

100 mg Viaskin Peanut

250 mg Viaskin Peanut

Week 52
5044 mg OFC

[End of study]

Defined Endpoints

Primary endpoint: Proportion with a treatment success following 52 weeks of blinded treatment

- Passing a 5044 mg OFC* to peanut protein at week 52 OR ≥ 10-fold increase in the successfully consumed dose (SCD) of peanut protein at week 52 compared to baseline OFC

Secondary endpoints:

- Comparison of Viaskin Peanut 100 µg vs Viaskin Peanut 250 µg doses at week 52
- Desensitization and sustained unresponsiveness at week 130
- Incidence of all adverse events
- Changes in immune markers


*OFC: Oral Food Challenge

Denotes a completed food challenge. Denotes a pending food challenge
CoFAR6: Primary Endpoint Was Met

- No SAEs or Epinephrine due to drug
- 96% compliance
- Primary endpoint met ($p = 0.003$)
- Significant age by treatment interaction
  - $\approx 1/3$ of children treated with 250 µg were able to tolerate > 1,000 mg protein ($\approx$4 peanuts)
  - Significant increase in IgG4

MILES Results: All Dose Cohorts At Month-12 Response Rate, Overall Population (ITT*)

Response Rate (ITT*)

<table>
<thead>
<tr>
<th>Dose Level</th>
<th>n</th>
<th>% of Responders (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>53</td>
<td>30.2% (25.8, 34.6)</td>
</tr>
<tr>
<td>VM150 µg</td>
<td>49</td>
<td>36.7% (31.6, 41.8)</td>
</tr>
<tr>
<td>VM300 µg</td>
<td>49</td>
<td>49.0% (43.2, 54.9)</td>
</tr>
<tr>
<td>VM500 µg</td>
<td>47</td>
<td>36.2% (30.8, 41.6)</td>
</tr>
</tbody>
</table>

P-values obtained using exact logistic regression:
- Placebo vs VM150 µg: p = 0.641
- VM150 µg vs VM300 µg: p = 0.085
- VM150 µg vs VM500 µg: p = 0.682

Response Rate (PP)

<table>
<thead>
<tr>
<th>Dose Level</th>
<th>n</th>
<th>% of Responders (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>45</td>
<td>28.9% (23.5, 34.3)</td>
</tr>
<tr>
<td>VM150 µg</td>
<td>36</td>
<td>36.1% (30.1, 42.1)</td>
</tr>
<tr>
<td>VM300 µg</td>
<td>40</td>
<td>55.0% (48.2, 61.8)</td>
</tr>
<tr>
<td>VM500 µg</td>
<td>43</td>
<td>37.2% (31.4, 43.0)</td>
</tr>
</tbody>
</table>

P-values obtained using exact logistic regression:
- Placebo vs VM150 µg: p = 0.649
- VM150 µg vs VM300 µg: p = 0.027
- VM150 µg vs VM500 µg: p = 0.522

*Missing data: failure imputation (considered as non-responders) in ITT population
ITT=Intent-to-Treat; PP=Per Protocol
**MILES Results: All Dose Cohorts At Month-12 CRD, Overall Population (ITT)**

<table>
<thead>
<tr>
<th>Dose Cohort</th>
<th>Mean CRD Increase at M12 vs Baseline, mg*</th>
<th>Median CRD Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>555.5</td>
<td>Median 100 mg</td>
</tr>
<tr>
<td>150 µg</td>
<td>745.1</td>
<td>Median 300 mg</td>
</tr>
<tr>
<td>300 µg</td>
<td>1,201.0</td>
<td>Median 400 mg</td>
</tr>
<tr>
<td>500 µg</td>
<td>723.5</td>
<td>Median 93 mg</td>
</tr>
</tbody>
</table>

*Among patients with evaluable CRD assessment at Month 12

*Note, not all subjects underwent a Month-12 OFC: 1 subject in PBO, 1 subject in VM150 µg, 4 in VM300 µg, and 2 in VM500 µg did not report Month-12 CRD

P-values obtained from ANCOVA model including on CRD at M0 and treatment group as fixed effect, using log-transformed data

ITT=Intent-to-Treat; PP=Per Protocol; SE=Standard Error
MILES Immunologic Data in Children 2-11 (ITT): Significant Immunomodulation with Viaskin Milk

- For sIgE levels in children, there is a trend towards reduction with VM doses
- No changes observed in SPT responses

P-values obtained from repeated-measures ANCOVA model including treatment group, timepoint, treatment-by-timepoint interaction and M0 value as fixed effect, using log-transformed data; ITT=Intent-to-Treat
**MILES Immunologic Data in Children 2-11 (ITT): Significant Immunomodulation with Viaskin Milk**

- **sIgE casein, kUA/L**
- **sIgE α-lactalbumin, kUA/L**
- **sIgE β-lactoglobulin, kUA/L**

P-values obtained from repeated-measures ANCOVA model including treatment group, timepoint, treatment-by-timepoint interaction and M0 value as fixed effect, using log-transformed data; ITT=Intent-to-Treat

- There is a trend towards reduction of sIgE levels in VM doses