

## Topline Results from Two-Year Follow-Up Study of Viaskin Peanut Show Long-Lasting and High Levels of Desensitization to Peanut

Favorable safety and high compliance were reported in OLFUS, consistent with prior results

A vast majority of children continue to respond to treatment and tolerate larger doses of peanut, including patients treated with Viaskin Peanut 250 µg for up to 36 months

Peanut-specific biomarkers reflect strong immunomodulation in patients

After two months of treatment discontinuation, sustained responses were observed in all children who qualified for and completed a food challenge at month-26

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), today announced topline results from the two-year OLFUS-VIPES study supporting the durable effect and favorable safety profile of Viaskin Peanut for the treatment of peanut-allergic children. OLFUS-VIPES, or OLFUS, is an open-label, follow-up study to VIPES, the Company's Phase IIb clinical trial of Viaskin Peanut. Previously, the Company reported positive results from VIPES in September 2014 and provided an interim analysis from the first 12 months of OLFUS in October 2015.

Investigators in OLFUS followed patients who completed the VIPES study for an additional 24 months in order to assess the long-term safety and efficacy of Viaskin Peanut beyond the VIPES primary endpoint at 12 months. As in VIPES, participants' response to treatment<sup>1</sup> was evaluated by a double-blind, placebo-controlled food challenge (DBPCFC), which was administered at month-12 and month-24 during the OLFUS study.

Consistent with prior observations in OLFUS, the favorable safety, tolerability and compliance profile of Viaskin Peanut was maintained from year-1 to year-2, with no treatment-related epinephrine use or serious adverse events (SAEs) reported in any of the subgroups. Patient compliance, which measures adherence to treatment dosing, was maintained at a median rate of 95.5%.

### Highlights from the two-year follow-up results in children:

Children treated with Viaskin Peanut 250 µg throughout the duration of VIPES and OLFUS were

observed to maintain long-lasting desensitization to peanut for a total of 36 months. Observations in these patients include the following:

- Treatment benefit was observed to be long-lasting, with 83% (15/18) of children continuing to respond to treatment during the second year of OLFUS.
- By month-24, a significant proportion of children were tolerating larger doses of peanut compared to the OLFUS baseline.
- Mean and median cumulative reactive dose (CRD) of peanut protein, which measures threshold reactivity during the DBPCFC, progressed to 2,454 mg and 1,440 mg, respectively, at the completion of OLFUS; from 1,884 mg and 1,440 mg, respectively, during the month-12 interim assessment; and from 1,068 mg and 444 mg, respectively, at the OLFUS baseline.
- Several children reached a CRD of at least 5,040 mg of peanut protein at the completion of the study (7/18 patients).
- Peanut-specific immunoglobulin E (IgE) levels were maintained below baseline from year-1 to year-2, and immunoglobulin G4 (IgG4) levels remained high.
- After two years, 14% (3/21) of patients in this cohort discontinued treatment, none reportedly related to Viaskin Peanut.

*“Peanut allergy is a debilitating disease affecting millions of patients worldwide, but despite its rapidly increasing prevalence there are still no FDA approved treatments. These results help validate the potential of Viaskin Peanut to generate meaningful and long-lasting desensitization to peanuts in children ages four to 11. If the product is approved after the ongoing Phase III trial, we will be one step closer to providing peanut allergic children with protection against the life-threatening risks associated with accidental allergen exposure,”* said **Dr. Stephen A. Tilles**, Executive Director, ASTHMA Inc. Clinical Research Center, Physician Partner at Northwest Allergy & Asthma Center (NAAC), and Site Principal Investigator for the OLFUS study in Seattle. *“One of Viaskin Peanut’s most important attributes has been its safety and tolerability profile. This is likely the reason for the high degree of treatment adherence during this several year study, and may be an important determinant of its success in clinical practice.”*

Despite treatment with suboptimal dose regimens, children treated with Viaskin Peanut 50 µg or 100 µg in VIPES, who later received the 250 µg dose during OLFUS, showed increased levels of desensitization at month-24. Additional exploratory observations include the following:

- A majority of children receiving suboptimal dose regimens responded to treatment by the completion of OLFUS.
- Patients generally increased oral peanut intake over time in a dose-dependent manner.
- Patients initially treated with the lowest dose were more likely to discontinue therapy and were also less likely to achieve the highest CRD levels at month-24.

### Preliminary analysis on sustained benefit following treatment discontinuation:

All subjects who were unresponsive to a cumulative reactive dose of above 1,440 mg of peanut protein at the month-24 DBPCFC in OLFUS were eligible to continue the study for two additional months. During this period, patients did not receive treatment and were required to maintain a peanut-free diet. In an exploratory analysis, all of the 19 children who completed the DBPCFC at

month-26 reached a CRD of at least 1,440 mg, showing a meaningful durability of response in the absence of treatment.

Complete results from the OLFUS study will be submitted for presentation at a future medical meeting.

*“We would like to thank the patients, caregivers, and clinicians who devoted their time to complete this long trial,”* said **Dr. Hugh Sampson**, Chief Scientific Officer of DBV Technologies, Director of the Jaffe Food Allergy Institute at Mount Sinai, and Co-Principal Investigator of the OLFUS-VIPES study. *“These three years of epicutaneous immunotherapy data seem to support DBV’s innovative and proprietary approach of desensitizing food allergic-patients through the skin in order to minimize safety concerns associated with allergen exposure. We are also excited to see durable responses in the absence of treatment and no peanut consumption, although additional analyses will need to be performed to better understand these findings. These results suggest that the immunomodulatory changes observed in patients treated with Viaskin may be more sustained.”*

#### About OLFUS-VIPES

OLFUS-VIPES (**O**pen-**L**abel **F**ollow-**U**p **S**tudy-**V**iaskin **P**eanut’s **E**fficacy and **S**afety), or OLFUS, enrolled 171 subjects who had previously received either placebo or one of three 12-month dose regimens administered during VIPES. During the first year of OLFUS, patients were to receive a daily application of Viaskin Peanut 50 µg or Viaskin Peanut 100 µg or Viaskin Peanut 250 µg for 12 months. According to a study protocol change implemented in March 2014, all patients were switched to receive Viaskin Peanut 250 µg during OLFUS. All patients in OLFUS maintained a peanut-free diet during the study. Baseline response levels in OLFUS were based on the results of the last double-blind, placebo controlled food challenge (DBPCFC) in VIPES, and adjusted by the number of patients enrolling in OLFUS. Responders in the OLFUS trial were defined as subjects with a peanut protein eliciting dose equal to or greater than 1,000 mg peanut protein or with a greater than 10-fold increase of the eliciting dose compared to their baseline eliciting dose observed in the VIPES study. Patients enrolled in OLFUS who received placebo in VIPES were analyzed separately from subjects who initially received Viaskin Peanut. At month-24 in OLFUS, patients who were unresponsive to a cumulative dose above 1,044 mg were eligible to discontinue study drug for two months while maintaining a peanut-free diet. Patients who opted to enter into this additional period performed a DBPCFC at month-26 to assess durability of response.

#### About VIPES

The VIPES (**V**iaskin **P**eanut’s **E**fficacy and **S**afety) trial was a double-blind, placebo-controlled, multi-center clinical trial conducted at 22 sites in North America and Europe. 221 peanut-allergic subjects were randomized 1:1:1:1 into four treatment arms to evaluate three doses of Viaskin Peanut, 50 µg, 100 µg and 250 µg, compared to placebo. Each patient underwent two DBPCFCs: one at screening and one after 12 months of treatment. The challenge was halted once the subject exhibited an objective allergic symptom. Patients in VIPES received a daily application of the Viaskin Peanut patch over 12 months. Each patch was applied for 24 hours on the upper arm for adults (age 18-55) and adolescents (age 12-17) or on the back of children (age 6-11). The primary efficacy endpoint was the percentage of treatment responders for each active treatment group compared to placebo. With Viaskin Peanut 250 µg, 53.6% of children were observed to respond to treatment compared to a 19.4% response rate in the placebo group (p=0.008). The compliance rate was more than 97% across all cohorts, the dropout for related adverse events was less than 1%, and there were no reported serious adverse events or epinephrine injection related to treatment.



### About DBV Technologies

DBV Technologies is developing Viaskin<sup>®</sup>, a proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT<sup>®</sup>, DBV's method of delivering biologically active compounds to the immune system through intact skin. With this new class of self-administered and non-invasive product candidates, the company is dedicated to safely transforming the care of food allergic patients, for whom there are no approved treatments. DBV's food allergies programs include ongoing clinical trials of Viaskin Peanut and Viaskin Milk, and preclinical development of Viaskin Egg. DBV is also pursuing a human proof-of-concept clinical study of Viaskin Milk for the treatment of Eosinophilic Esophagitis, and exploring potential applications of its platform in vaccines and other immune diseases.

DBV Technologies has global headquarters in Montrouge, France and New York, NY as well as New Jersey, CT. Company shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and traded on the Nasdaq Global Select Market in the form of American Depositary Shares (each representing one-half of one ordinary share) (Ticker: DBVT). For more information on DBV Technologies, please visit our website: [www.dbv-technologies.com](http://www.dbv-technologies.com)

### Forward Looking Statements

This press release contains forward-looking statements, including statements reflecting management's expectations regarding the clinical development of Viaskin Peanut, the safety, efficacy and durability of Viaskin Peanut for the treatment of peanut allergy, and the commercial potential of Viaskin Peanut. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, the risk that historical clinical trial results may not be predictive of future trial results and the risk that Viaskin Peanut may not receive regulatory approval notwithstanding the results of clinical trials. A further list and description of these risks, uncertainties and other risks can be found in the Company's regulatory filings with the French Autorité des Marchés Financiers, the Company's Securities and Exchange Commission filings and reports, including in the Company's Annual Report on Form 20-F for the year ended December 31, 2015 and future filings and reports by the Company. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release, whether as a result of new information, future events or circumstances or otherwise.

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<sup>i</sup> Responders in the OLFUS trial were defined as subjects with a peanut protein eliciting dose equal to or greater than 1,000 mg peanut protein or with a greater than 10-fold increase of the OLFUS eliciting dose compared to the baseline eliciting dose observed in the VIPES study.