

Press Release

Montrouge, France, March 5, 2017

## Data at AAAAI 2017 Show Lasting Response and Favorable Safety Profile of Investigational Agent, Viaskin Peanut, Throughout Three Years of Treatment of Peanut Allergic Children

During a Late Breaking Oral Abstract Session, Dr. Shreffler reported that 83.3% of pediatric patients responded to Viaskin Peanut 250 µg after three years with a favorable safety profile and no SAE's related to treatment

An additional oral abstract, presented by FARRP, used a robust risk analysis model to show the significant benefit associated with increasing an individual's peanut protein threshold with immunotherapy

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced that detailed results from OLFUS-VIPES, a long-term extension study to the VIPES Phase IIb trial, were presented at the 2017 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in Atlanta, Georgia, at a Late Breaking Oral Abstract Session. The Company previously reported topline results from the OLFUS-VIPES study in October 2016.

*“It is encouraging to see that with continued treatment, the effect of Viaskin Peanut for children was sustained or increased throughout three years, while also maintaining a favorable and easily manageable safety profile,”* said **Dr. Wayne Shreffler**, Division of Allergy and Immunology, Department of Pediatrics, Massachusetts General Hospital, Harvard Medical School and Investigator of the OLFUS-VIPES Study. *“Peanut allergy is one of the leading life-threatening food allergies among children. Even with conscientious avoidance, accidental ingestions are common and can be life-threatening.”*

### Viaskin Peanut Highlights

Viaskin Peanut is the company's lead product candidate, based on its proprietary EPIT platform, which aims to deliver biologically active compounds to the immune system through the skin, and is currently being evaluated in a global, pivotal Phase III program in peanut-allergic children four to 11 years of age. The company also expects to initiate a Phase III trial of Viaskin Peanut in children one to three years of age in the first half of 2017.

#### Late Breaking Abstract #L7

The 36-month data from the OLFUS-VIPES study, presented by Dr. Wayne Shreffler, support the lasting response and favorable safety and tolerability profile of Viaskin Peanut 250 µg in peanut-allergic children six to 11 years of age. The study was also selected to be highlighted at the “Research in Food Allergy Immunotherapy Press Event” hosted by AAAAI.

The detailed results presented today show that progressive response to treatment was observed in children who received Viaskin Peanut 250 µg from the onset of therapy in VIPES. After completion of three years of treatment with the 250 µg dose, 83.3% of children in this subgroup responded to therapy compared to 53.6% at the completion of VIPES. At the end of OLFUS, cumulative reactive doses (CRDs) reaching 1,000 mg or more of peanut protein during the oral food challenge were observed in 61% of children receiving Viaskin Peanut 250 µg, which was double the number of patients reaching that CRD at the completion of VIPES. Furthermore, 39% of children reached CRD rates of 5,040 mg or more during the oral food challenge at the end of OLFUS. For reference, one peanut contains approximately 250 mg of peanut protein.

Over the 36-month study period, no treatment-related serious adverse events (SAEs) or epinephrine use was reported. In the overall population, the majority of adverse events reported were mild and moderate application-site skin reactions, for which severity and frequency were observed to decrease over time. Additionally, treatment compliance, which measures adherence to treatment dosing, remained high throughout the study at a median rate of 95.5%, and was not impacted by the dose of Viaskin Peanut administered or the age of patients enrolled in the study. At the end of OLFUS, the overall dropout rate due to adverse events remained low at 2.3%.

#### Abstract #561

Another oral presentation featured results from a study exploring peanut contamination cases in frequently consumed packaged foods, while assessing the potential clinical benefit of increasing an individual’s degree of desensitization following treatment with immunotherapy. Presented by Dr. Joe Baumert, University of Nebraska, Food Allergy Research & Resource Program (FARRP), the study results suggested that peanut-allergic patients who can increase their peanut sensitivity thresholds following immunotherapy are at a much lower risk of having an allergic reaction from common packaged food items that may contain unknown traces of peanut.

Dr. Baumert’s presentation showed that increasing an individual’s peanut protein threshold, or eliciting dose, following immunotherapy would provide a significant relative risk reduction. A greater than 99% relative risk reduction was associated with reaching a post-therapy threshold of 300 mg if the individual’s initial eliciting dose was less than or equal to 10 mg, or reaching a post-therapy threshold of 1,000 mg, if the individual’s initial eliciting dose was less than or equal to 300 mg.

The study was conducted using a Quantitative Risk Assessment (QRA) model developed independently by FARRP, a leading institution focused on providing expertise on allergenic foods and food safety. The robust QRA model used common packaged food items such as cookies, ice cream, doughnuts/snack cakes and snack chip mixes as references for this risk assessment. DBV provided funding for the study and formulated the research question as related to the VIPES Phase IIb clinical trial of Viaskin Peanut.

*"This meeting at AAAAI has been filled with exciting data that highlights Viaskin and its potential in food allergies. Our presence at AAAAI involves six poster presentations and two oral presentations, including long-term results from OLFUS-VIPES and important findings from FARRP, which emphasize our commitment to developing a patient-centric, safe and effective treatment for peanut allergy," said Dr. Pierre-Henri Benhamou, Chairman & Chief Executive Officer of DBV Technologies. "We are very proud of these clinical and research accomplishments, and I would like to thank all of our patients and investigators for their support and continued efforts in moving the Viaskin Peanut development program forward. The results we have shown over the past couple of days highlight our dedication to bringing a treatment to peanut-allergic patients as quickly as possible."*

#### **About the OLFUS-VIPES Study**

OLFUS-VIPES (Open-Label Follow-Up Study-Viaskin Peanut's Efficacy and Safety), 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 1,440 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 the VIPES Study**

The VIPES (Viaskin Peanut's Efficacy and Safety) 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 the PEPITES Study**

The Peanut EPIT Efficacy and Safety Study (PEPITES) is a global, pivotal, double-blinded, placebo-controlled Phase III trial designed to evaluate the safety and efficacy of Viaskin Peanut 250 µg in children ages four to 11 years. During PEPITES, patients' response will be assessed using a double-blind, placebo controlled food challenge (DBPCFC). Patients are randomized 2:1 to receive either Viaskin Peanut 250 µg or placebo for 12 months. The primary endpoint is based on a responder analysis after 12 months of treatment with Viaskin Peanut 250 µg. For patients with a baseline peanut protein eliciting dose (ED) equal to or less than 10 mg, a responder is defined as a patient with a peanut protein ED equal to or greater than 300 mg of peanut protein after 12 months of treatment. For subjects with a baseline ED greater than 10 mg, a responder is defined as a patient with a peanut protein ED equal to or greater than 1,000 mg of peanut protein after 12 months of treatment. As a secondary efficacy endpoint, Cumulative Reactive Dose (CRD), will also be used in PEPITES to



establish the total quantity of peanut protein that triggers patient reactions at month 12 of active treatment versus placebo. Serological markers will also be measured at baseline, 3, 6, and 12 months in order to characterize the immunological changes in patients.

Following the completion of PEPITES, all patients are eligible to rollover into PEOPLE, a long-term, open-label extension study of Viaskin Peanut 250 µg. In the PEOPLE study, patients who were randomized to active treatment during PEPITES will receive Viaskin Peanut 250 µg for two additional years; patients who were previously receiving placebo during PEPITES will be treated with Viaskin Peanut 250 µg for three years. Patients enrolling in the PEOPLE study will remain blinded to their respective treatment group in PEPITES until the PEPITES study results become publicly available.

### 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. Company shares are traded on segment A 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 may contain forward-looking statements and estimates, including statements regarding the potential safety and efficacy of Viaskin Peanut and statements reflecting management's expectations for clinical development of our product candidates and the commercial potential of our product candidates. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties. At this stage, the products of the Company have not been authorized for sale in any country. 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 preclinical results may not be predictive of future clinical trial results, and the risk that historical clinical trial results may not be predictive of future trial results. 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 and estimates, which speak only as of the date hereof. Other than as required by applicable law, DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release.

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