



Press Release

Montrouge, France, November 20, 2018

DBV Technologies Presents Data at ACAAI 2018 on Investigational Viaskin Peanut for the Treatment of Peanut-Allergic Children

Three oral presentations highlighted analyses from the PEPITES Phase III study

New data show that with Viaskin Peanut a majority of patients experience an increase in peanut threshold reactivity after the first 12 months of treatment (#A303)

DBV Technologies (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that three oral abstracts supporting the therapeutic potential of Viaskin Peanut were presented at the American College of Allergy, Asthma and Immunology (ACAAI) 2018 Annual Scientific Meeting in Seattle, Washington, November 15-19, 2018. The presentations included additional analyses from PEPITES, a pivotal Phase III efficacy and safety study of Viaskin Peanut in children ages four to 11. All abstracts are available online on the ACAAI Meeting website.

Dr. Hugh Sampson, Chief Scientific Officer of DBV Technologies and Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai said, *"The breadth of data we shared with the scientific and medical community at ACAAI further illustrate the therapeutic benefit children may receive from treatment with Viaskin Peanut. From an analysis showing a robust overall patient desensitization to a quantitative model suggesting that patients treated with Viaskin Peanut in PEPITES may experience a meaningful reduction of the risks associated with accidental exposure, we are continuing to see important evidence supporting the potential use of Viaskin Peanut in the treatment of peanut allergy."*

In an oral presentation entitled, **"Increased Reactivity Threshold in Peanut-Allergic Subjects Treated With 12 Months of Epicutaneous Viaskin Peanut" (#A303)**, Dr. Carla Davis, Texas Children's Hospital, Houston, TX, presented findings showing that 62.6% of patients who were treated with Viaskin Peanut for 12 months in the PEPITES trial increased their peanut Eliciting Dose (ED), compared to 28.0% of patients in the placebo group. An odds ratio (OR) analysis indicated that patients treated with



active therapy were 4.3 times more likely to improve their peanut threshold reactivity level versus placebo (OR = 4.3 (95% CI 2.7- 7.0), $p < 0.001$). In the PEPITES study, Viaskin Peanut 250 μg was observed to demonstrate a statistically significant higher rate of responders over placebo after 12 months of treatment (difference in response rates = 21.7%; $p = 0.00001$; 95% CI = 12.4% - 29.8%).

"Peanut allergy is a life-long, potentially life-threatening disease, which is currently affecting roughly two children in every US classroom. This significant unmet medical need impacts families daily, as the potential for accidental exposure to peanuts is pervasive: accidents can happen in restaurants, at school or even at home," said **Dr. Davis**. *"These new results from the PEPITES study, which investigated a potential first-in-class peanut desensitization therapy with the epicutaneous patch system, show that most patients treated with Viaskin Peanut are seeing an improvement in peanut reactivity after just the first year of treatment. This is an exciting time for the peanut allergy community as Viaskin Peanut continues to move toward a potential approval."*

Two additional oral presentations also highlighted analyses from the PEPITES study providing further understanding on the potential reduction of risks associated with accidental exposure to peanut, as well as data illustrating immunomodulatory changes that may be relevant when monitoring patients treated with Viaskin Peanut.

#A302: Quantitative Risk Reduction Through Epicutaneous Immunotherapy (EPIT): Results from the PEPITES Phase III Trial

Dr. Benjamin C. Remington, TNO, Ziest, The Netherlands, presented results from a quantitative risk analysis model showing that in this study, children treated with Viaskin Peanut for 12 months could potentially experience up to a 96.6% reduction of risk in developing an allergic reaction during accidental exposure to peanuts in various packaged food products. Children in the trial who were randomized to the placebo arm experienced a reduction of risk of only 2.5% to 2.9%. The main clinical implications from the study are that the risks of unexpected allergic reactions are drastically reduced for the treatment group after one year of EPIT with 250 μg of peanut protein.

#A305: Serum Biomarkers of Immunomodulation During Peanut Epicutaneous Immunotherapy (EPIT) in Peanut-allergic Subjects



Dr. Matthew Greenhawt, Children's Hospital Colorado, Aurora, CO, presented additional analyses from the PEPITES Phase III trial further expanding on the immunomodulatory profile of Viaskin Peanut that exists to date. Significant changes in peanut-specific and peanut-component IgG4 levels were observed as early as in the first 3 months of treatment with Viaskin Peanut 250 µg ($p < 0.001$). At month 6 and 12, significantly higher levels of peanut-specific IgG4 were observed with Viaskin Peanut 250 µg compared to placebo ($p < 0.001$). These findings suggest that immunomodulatory effects start early during the treatment course and change in IgG4 levels may be important to monitor treatment progression with Viaskin Peanut.

About PEPITES

The Peanut EPIT Efficacy and Safety Study (PEPITES) was 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. PEPITES was conducted in 31 centers across North America (Canada and the United States), Germany, Ireland and Australia. Topline results from PEPITES were announced in October 2017.

During PEPITES, patients' response has been assessed using a double-blind, placebo controlled food challenge (DBPCFC). Patients were randomized 2:1 to receive either Viaskin Peanut 250 µg or placebo for 12 months. The primary endpoint was 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 was 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 patients with a baseline ED greater than 10 mg, a responder was 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), has also been 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 were also measured at baseline, 3, 6, and 12 months in order to characterize the immunological changes in patients.

About VIPES

The VIPES 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 responded 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 serious adverse events or epinephrine injection related to treatment.

About DBV Technologies

DBV Technologies is developing Viaskin®, a proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT®, 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. The Company's ordinary shares are traded on segment A of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and the Company's ADSs (each representing one-half of one ordinary share) are traded on the Nasdaq Global Select Market (Ticker: DBVT).

Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding the potential of Viaskin Peanut as a treatment for peanut allergic children. 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 results of historical clinical trials will not be replicated in future clinical trials and the risk that historical clinical results in one patient population may not be predictive of future clinical trial results in different patient populations. 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, 2017 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.

DBV Investor Relations Contact

Sara Blum Sherman
Senior Director, Investor Relations & Strategy
+1 212-271-0740



sara.sherman@dbv-technologies.com

DBV Media Contact

Joe Becker

VP, Global Corporate Communications

+1 646-650-3912

joseph.becker@dbv-technologies.com