

## **DBV Technologies Shows Commitment to the Development of Treatments for Food Allergies at EAACI 2018**

**Therapeutic potential of the Viaskin platform featured in seven abstracts**

**Additional data presented further showcases comprehensive Viaskin Peanut development program in peanut-allergic patients**

**Late breaking oral abstract session highlighted Viaskin Milk 300 µg as a potential treatment for milk allergy**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that new data from clinical trials evaluating the therapeutic potential of the Company's Viaskin technology platform for the treatment of two food allergy indications were presented at the 2018 European Academy of Allergy and Clinical Immunology (EAACI) Annual Meeting in Munich, Germany, May 26-30, 2018. Data presentations included new analyses from Viaskin Peanut Phase II and Phase III programs in peanut-allergic patients, as well as results from a Phase II study of Viaskin Milk.

*“We are excited to have had the opportunity to share findings from several epicutaneous immunotherapy trials with the medical and scientific communities at EAACI. The data presented highlight the progress we have made in advancing the Viaskin platform for the potential treatment of food allergies”* said **Dr. Hugh Sampson**, Chief Scientific Officer of DBV Technologies and Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai. *“At the same time, we are actively preparing to file a Biologics License Application for Viaskin Peanut in the fourth quarter of this year, and look forward to making this investigational therapy available for patients as soon as possible, if approved.”*

### **Viaskin Peanut Highlights**

**Abstract #0111:** In an oral abstract session, Dr. Benjamin Remington, Scientific Consultant, Food Allergy, TNO, presented results from a quantitative risk analysis model assessing the reduction of risk in developing an allergic reaction from accidental exposure to peanuts in various packaged food products. Dr. Remington's model studied a population of children (ages 6-11) who received treatment with Viaskin Peanut 250 µg during a Phase IIb study, and concluded that these patients



could benefit from more than a 95% reduction of risk after one year of treatment, compared to less than 15% reduction of risk in the placebo arm. After three years of treatment, the risk reduction in developing an allergic reaction due to accidental exposure to peanuts increased to more than 99% in treated patients.

**Abstract # 0457:** Dr. Terri Brown-Whitehorn, Associate Professor of Clinical Pediatrics, Perelman School of Medicine, University of Pennsylvania, Children's Hospital of Philadelphia (CHOP), presented a new analysis from the Phase IIb OLFUS-VIPES trial showing that a subset of eligible patients treated with Viaskin Peanut 250 µg for 24 to 36 months were observed to sustain a therapeutic effect after a two-month treatment interruption period. In the study, patients exhibiting sustained unresponsiveness (SU) were defined as those who did not react to a cumulative dose of  $\geq 1440$  mg of peanut protein during a double-blind-placebo-controlled food challenge (DBPCFC) after two months without receiving treatment and maintaining a peanut free diet. Analysis of the data showed that 80% (n=20/25) of patients achieved SU, and all patients (n=25/25) reached a cumulative reactive dose (CRD) of  $\geq 1440$  mg of peanut protein at the exit DBPCFC. Immunomodulatory changes observed after long-term treatment with Viaskin Peanut 250 µg were also sustained during the two-month treatment interruption part of the trial.

**Abstract # 0456:** Additional data from the PEPITES Phase III safety and efficacy trial of Viaskin Peanut 250 µg was presented by Dr. Matthew Greenhawt, Associate Professor of Pediatrics, Director, Food Challenge and Research Unit, Children's Hospital Colorado. This poster presentation highlighted biomarker data showing that significant immunologic changes were observed in patients who were treated with Viaskin Peanut 250 µg for 12 months. Patients on the placebo arm did not show meaningful changes in biomarkers compared to baseline.

### Viaskin Milk Highlights

**Abstract # 1643:** In a late breaking oral abstract session, Dr. Robert Wood, Chief, Eudowood Division of Allergy and Immunology, Johns Hopkins Children's Center, presented detailed results from MILES, a dose-finding Phase II trial of Viaskin Milk in children and adolescents with IgE-mediated CMPA. The primary endpoint of the study assessed the percentage of patients who responded to Viaskin Milk or placebo after 12 months of treatment. Responders were defined as patients who achieved a  $\geq 10$ -fold increase in CRD and at least 144 mg of cow's milk protein and/or a CRD  $\geq 1,444$  mg. The Company previously reported topline results from the MILES study in February 2018.



In MILES, Viaskin Milk 300 µg was identified as the most safe and effective dose tested, with the greatest benefit observed in the pre-specified children (ages 2-11) population (p=0.042, Intent-to-Treat (ITT), p=0.021, Per-Protocol (PP)). After 12 months, children treated with Viaskin Milk 300 µg increased their threshold reactivity, as measured by change in CRD, by a median of 1,000 mg (mean = 1322.4 mg, ITT, 1340.3 mg, PP) from baseline. Patients in the placebo arm had a median increase in CRD of ~100 mg (mean=565.6 mg, ITT, 510.8 mg, PP) from baseline. The CRD increase in the Viaskin Milk 300 µg arm was statistically significant compared to placebo (p=0.045, ITT, p=0.043, PP). Children treated with Viaskin Milk also showed significant immunomodulatory changes over time.

Viaskin Milk was observed to be well-tolerated across all doses, with no treatment-related serious adverse events (SAEs) reported. Most commonly reported adverse events (AEs) were mild and moderate application site skin reactions, with a 1.5% dropout rate due to AEs. The overall discontinuation rate in the study was 4.5%. Median patient compliance was greater than 99%.

*“Food allergies remain a significant unmet need for patients, and it is encouraging to see additional data on the therapeutic potential of epicutaneous immunotherapy,”* said **Dr. Wood**. *“In particular, patients suffering from milk allergy face significant risk of accidental allergen exposure in their daily lives, and Viaskin Milk may offer a potential new treatment option for this underserved population. I look forward to seeing future progress.”*

A complete listing of abstracts can be found on the EAACI website: [www.EAACI.org](http://www.EAACI.org)

### About the PEPITES Study

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 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 MILES Study

The Viaskin Milk Efficacy and Safety (MILES) trial is a multi-center, double-blind, placebo-controlled, randomized Phase I/II trial to study the safety and efficacy of Viaskin Milk conducted at 17 sites in North America. The study was divided into two consecutive parts. Part A of the MILES trial was completed with no safety concerns. Part B was designed to determine a safe and effective dose in two age groups: children ages two to 11 and adolescents ages 12 to 17 with IgE-mediated cow's milk protein allergy, or CMPA. 198 patients (18 patients from Part A and 180 patients from Part B) were randomized 1:1:1:1 into four treatment arms to evaluate three doses of Viaskin Milk, 150 µg, 300 µg and 500 µg, compared to placebo. Each patient underwent a DBPCFC at screening and after 12 months of treatment. The challenge was halted once the patient exhibited an objective allergic symptom. Patients in MILES received a daily application of the Viaskin Milk patch over 12 months. Each patch was applied for 24 hours on the back of children (age 2- 11) or on the upper arm for adolescents (age 12-17). The primary efficacy endpoint was the percentage of treatment responders for each active treatment group compared to placebo. Responders at month-12 were defined as patients with either 1) a cow's milk protein CRD equal to or greater than 1,444 mg (approximately 45 mL of milk) or 2) a 10-fold or greater increase in CRD compared to baseline and at least 144 mg cow's milk protein (approximately 4.5 mL of milk).

### 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



ADs (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 and Viaskin Milk and of the Company's and clinical development and regulatory plans regarding Viaskin Peanut and Viaskin Milk. 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, 2016 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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