Press Release
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DBV Technologies Announces Publication of Detailed Phase III Trial Results Evaluating Viaskin Peanut as a Novel Treatment for Peanut Allergy in *The Journal of the American Medical Association*

Viaskin Peanut is the first epicutaneous immunotherapy (EPIT) in development that leverages the skin to activate the immune system and induce desensitization in peanut-allergic children

Significant difference in responder rates between Viaskin Peanut and placebo ($p<0.001$) suggests that treated patients are less likely to have allergic reactions due to accidental exposures to peanut

According to a post-hoc analysis, 62.6% of patients receiving Viaskin Peanut showed an increase in their eliciting dose at 12 months of treatment

Low discontinuation rates in the Viaskin Peanut arm due to treatment-emergent adverse events (1.7%) were experienced in the trial

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that detailed results from its pivotal Phase III clinical trial evaluating the efficacy and safety of Viaskin Peanut for the treatment of peanut-allergic children 4 to 11 years of age were published in *The Journal of the American Medical Association* (JAMA).

Data from the Phase III PEPITES[1] (**P**eanut **EPIT** **E**fficacy and **S**afety) study show that Viaskin Peanut (250 µg) administered once-daily on the skin as a non-invasive patch demonstrated clinically meaningful desensitization in peanut-allergic children, suggesting patients who were treated with active therapy may be less likely to have an allergic reaction to an accidental exposure to peanut as compared to placebo. Viaskin Peanut was observed to be well-tolerated in the trial, resulting in a low discontinuation rate due to treatment-emergent adverse events (TEAEs).

"My peanut-allergic patients and their families face the daily fear of accidental

peanut exposure resulting in a possible life-threatening reaction, and desperately seek a well-tolerated treatment that does not add even more restrictions to their everyday lives," said Dr. David Fleischer, Director, Allergy and Immunology Center and Associate Section Head, Children's Hospital Colorado, and lead author of the publication. *"The efficacy and safety data published in JAMA support Viaskin Peanut as a convenient and well-tolerated potential therapeutic option that may provide clinically meaningful benefit for these patients and families without imposing a major treatment burden."*

Viaskin Peanut is an investigational treatment that has been studied in over 775 patients worldwide as part of a global registrational program. The PEPITES trial is the largest randomized controlled efficacy and safety study ever completed using epicutaneous immunotherapy (EPIT) to treat peanut allergy, a potentially life-threatening disease with no FDA-approved treatment options. The study randomized 356 children ages 4 to 11 years with a physician-diagnosed peanut allergy who had an eliciting dose (ED) of ≤300 mg peanut protein (about one peanut) during a double-blind, placebo-controlled food challenge (DBPCFC). During the 12-month trial, patients did not have required restrictions from physical activity while wearing Viaskin Peanut or during concomitant illness.

PEPITES Efficacy Results

Data from the PEPITES trial demonstrates that after 12 months of treatment, a statistically significant greater proportion of patients treated with Viaskin Peanut had an increase in the amount of peanut protein required to elicit an allergic reaction during the food challenge compared with placebo (treatment difference = 21.7%; 95% CI = 12.4% - 29.8%; p<0.001):

- An increase in the cumulative reactive dose (CRD), a key secondary endpoint measuring threshold reactivity, was observed between Viaskin Peanut and placebo (nominal p-value<0.001).
- Exploratory analyses showed that changes in peanut-specific biomarkers, including immunoglobulin E (IgE) and immunoglobulin G4 (IgG4), support the immunomodulatory effect with Viaskin Peanut.
- In a post-hoc analysis, the majority of patients on Viaskin Peanut experienced an increased ED compared with the placebo group (62.6% in active vs. 28% in placebo) at 12 months.
- An additional post-hoc analysis showed that 53.1% of patients treated with Viaskin Peanut increased their baseline ED from ≤100 mg to ≥300 mg,

compared to 19% in the placebo group. Based on quantitative risk modeling, we believe this improvement in ED is predicted to reduce the risk of an allergic reaction due to accidental exposure by over 95%.

Although the difference in responder rates between patients receiving Viaskin Peanut versus placebo was statistically significant, the study did not meet a statistical component of its primary endpoint; the pre-specified 15% lower bound of the confidence interval between the treatment groups was not met, as the lower bound of the confidence interval was 12.4%.

PEPITES Safety and Tolerability Results

A favorable safety and tolerability profile was observed with Viaskin Peanut. Treatment adherence was high (98.5%), and similar discontinuation rates between treatment groups were reported, with 89.9% of patients completing the trial. There was a low discontinuation rate due to treatment-emergent adverse events (TEAEs) (1.7%), and the overall rate of TEAEs, regardless of relatedness to the treatment, was comparable between treatment and placebo groups, at 95.4% and 89.0%, respectively. The most commonly reported TEAEs were mild to moderate application-site reactions that decreased after Month 1 in both frequency and severity. No treatment-related gastrointestinal AEs were observed.

There were no cases of severe anaphylaxis in the trial. Serious AEs (SAEs) were balanced between the Viaskin Peanut and placebo group, at 4.2% vs. 5.1%, respectively. Four SAEs reported in three Viaskin Peanut patients (1.3%) were determined by the investigator as possibly or probably related to treatment. A low rate of treatment-related epinephrine use was reported (2.9% treatment group vs. 0.8% placebo group). Ten cases in eight Viaskin Peanut patients (3.4%) of possibly or probably treatment-related anaphylaxis occurred; all were classified as mild or moderate without evidence of cardiovascular, neurologic, or respiratory compromise. Six of these ten cases were treated with epinephrine, and five of the eight patients continued on Viaskin Peanut in the study.

"I would like to thank all of the investigators, patients, caregivers and staff who contributed to this important trial. We are pleased to see PEPITES published by such a prestigious journal," said Dr. Hugh Sampson, Chief Scientific Officer and interim Chief Medical Officer of DBV Technologies and Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai. "*Viaskin Peanut is the first and only epicutaneous immunotherapy in development today for the treatment*

of peanut allergy. It aims to rebalance the immune system of peanut-allergic patients by exposing them once daily to only about one-one thousandth of a peanut kernel via a non-invasive patch. We expect to submit an updated Biologics License Application (*BLA) for Viaskin Peanut in the third quarter of 2019, potentially bringing us one step closer to providing an FDA-approved treatment for peanut-allergic children and their families."*

Effect of Epicutaneous Immunotherapy vs. Placebo on Reaction to Peanut Protein Ingestion Among Children With Peanut Allergy was published online on February 22, 2019. Data from this trial will also be highlighted at the American Academy of Allergy, Asthma & Immunology Annual (AAAAI) Meeting – Food Allergy: Advances in Prevention and Treatment, taking place February 22-25 in San Francisco.

[1]About PEPITES

The Peanut EPIT Efficacy and Safety Study (PEPITES) was a global, double-blind, placebo-controlled Phase III trial designed to evaluate the safety and efficacy of Viaskin Peanut 250 µg in children ages 4 to 11 years. PEPITES was conducted in 31 centers across North America (Canada and the United States), Germany, Ireland and Australia.

Eligible patients were aged 4-11 years at screening with physician-diagnosed peanut allergy, currently following a strict peanut-free diet. Other key inclusion criteria were peanut-specific IgE >0.7 kUA/L, a peanut skin prick test with a largest wheal diameter ≥6 mm (children 4-5 years) or ≥8 mm (children ≥6 years) at screening, and an ED (the single highest dose at which a patient exhibited objective signs/symptoms of an immediate hypersensitivity reaction) of ≤300 mg peanut protein based on a DBPCFC.

PRACTALL, the joint American Academy of Allergy, Asthma & Immunology (AAAAI) and European Academy of Allergy and Clinical Immunology (EAACI) published food challenge methodology that defines strict, 30-minute intervals for peanut protein dosing, was used to evaluate sensitivity to peanut at baseline and exit. Challenges were stopped when patients exhibited clear, objective symptoms based on a pre-specified symptom scoring scale. A Good Manufacturing Practice food challenge matrix was used for all peanut protein and placebo food challenges.

During PEPITES, patients' responses were assessed using DBPCFCs. 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 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, CRD was also evaluated 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.

During the study, investigators relied on the commonly used National Institute of Allergy and Infectious Diseases (NIAID) definition of anaphylaxis, which has been shown to be highly sensitive but only moderately specific in diagnosing anaphylaxis, in an attempt to capture as many potential reactions as possible.

Two hundred thirteen of the 238 patients randomized to the peanut-patch and 107 of the 118 patients randomized to the placebo-patch completed the study. After 12 months of therapy, patients treated with Viaskin Peanut showed a statistically significant improvement in the ED of peanut required to provoke an allergic reaction at food challenge compared with placebo. After 12 months of treatment, 35.3% of patients on Viaskin Peanut 250 µg were responders, compared to 13.6% of patients in the placebo group (treatment difference = 21.7%; 95% CI = 12.4% - 29.8%; $p<0.001$). An increase in the CRD was also observed between the treatment and placebo groups (nominal p-value<0.001) after 12 months. The median CRD of patients in the treatment group increased from 144 mg at baseline to 444 mg at Month 12, compared with no improvement in the placebo group.

There were no cases of severe anaphylaxis, and only four of 238 patients (1.7%) dropped out due to TEAEs.

An open-label, follow-up trial to PEPITES (PEOPLE) is ongoing, evaluating Viaskin Peanut 250 µg for up to 36 months.

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 trial 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 offices in Bagneux, France, Summit, NJ and New York, NY. The Company's ordinary shares are traded on segment B 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 and the Company's regulatory plans regarding Viaskin Peanut, particularly with respect to the Company's expectations regarding its plan to resubmit its BLA to the FDA. 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 related to the Company's ability to address the concerns raised by the FDA with respect to its BLA, as well as those associated generally with research and development, clinical trials and related regulatory reviews and approvals 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