

Press Release

Montrouge, France, November 20, 2017

## DBV Technologies Announces Positive Topline Safety Results from REALISE Phase III Trial of Viaskin Peanut for the Treatment of Peanut-Allergic Patients

Blinded period evaluated the safety of Viaskin Peanut versus placebo in children four to 11 years of age, including patients with a history of severe anaphylaxis

A favorable safety and tolerability profile was observed, which was comparable to data from other trials with Viaskin Peanut

These results, which are part of a global Phase III program, will support planned regulatory discussions for Viaskin Peanut

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced positive topline results from the Phase III REALISE (REAL Life Use and Safety of EPIT) trial. The REALISE double-blinded period compared the safety of treatment with Viaskin Peanut 250 µg versus placebo for six months. Patients who completed the blinded portion of the study will continue to receive active treatment for up to 36 months during an open-label extension, further studying the long-term safety and use of Viaskin Peanut in routine clinical practice.

The REALISE trial met its primary objective, demonstrating that Viaskin Peanut was well-tolerated with no new or unexpected adverse events. Based on preliminary analysis, a similar safety profile was observed in all patients included in the trial, regardless of history of severe anaphylaxis. The safety data reported today complete the Food and Drug Administration (FDA) safety database requirement for the Viaskin Peanut program in children four to 11 years of age. Results from this study, in addition to data from the PEPITES Phase III efficacy and safety trial, will form the basis for planned regulatory discussions in the United States, Europe and other countries for use of Viaskin Peanut in this patient population.

**Dr. Jacqueline Pongracic**, Head, Allergy and Immunology, Ann & Robert H. Lurie Children's Hospital of Chicago, Professor of Pediatrics and Medicine, Northwestern University Feinberg School of Medicine, and Principal Investigator of REALISE, said: *"As more patients are treated with Viaskin Peanut in clinical trials, our understanding of this novel immunotherapy has deepened. In REALISE, we have observed that using the skin to activate the immune system of these patients resulted in a favorable safety and tolerability profile, likely contributing to the high compliance rate maintained throughout the blinded portion of the trial. The medical community has been eagerly anticipating a*

*treatment that could be effective in real-life, and I am excited to have been part of this groundbreaking clinical program, which may bring us one step closer to meeting patients' needs."*

Results from this trial were comparable with outcomes from previous studies of Viaskin Peanut 250 µg. The most commonly reported adverse events were local application site reactions, that were mostly mild and moderate in nature. No imbalance in serious adverse events (SAEs) was observed in the trial, with 3 cases in 3 subjects in the active arm (1.0%), and 2 cases in 2 subjects in the placebo arm (2.0%); 1 case in 1 subject in the active arm was qualified by the investigator as moderate anaphylaxis probably related to treatment. The patient responded to standard outpatient therapy. In the six-month blinded period, the discontinuation rate was 2.5%, with a 1.0% dropout related to adverse events. Mean patient compliance was above 95%.

*"For the millions of patients and their caregivers who cope with the tremendous burden of this disease daily, offering not only an effective medicine, but one that is safe is so essential," said **Dr. Jim Baker**, Chief Executive Officer and Chief Medical Officer, Food Allergy Research & Education (FARE). "The data from the six-month period of this trial underscores the favorable safety profile of Viaskin Peanut, which has also been observed in previous clinical studies. We look forward to seeing the long-term results from the rest of this trial and understanding the benefit of this potential treatment for patients."*

To date, over 700 patients have been studied in the Company's ongoing Phase III program in children ages four to 11, which includes both the PEPITES and REALISE trials. A Phase III trial is also ongoing in children one to three years of age.

*"We remain steadfast in our commitment to bringing a treatment to peanut-allergic patients as soon as possible," said **Dr. Pierre-Henri Benhamou**, Chairman & Chief Executive Officer of DBV Technologies. "This trial, which was the first Phase III trial to study peanut-allergic patients in the absence of food challenges, is an important consideration in understanding the use of Viaskin Peanut in a real-life setting. We are hopeful that data generated from REALISE will continue to strengthen the profile of Viaskin Peanut in routine clinical use."*

Detailed results from this study are expected to be submitted for presentation at a future medical meeting.

#### **About REALISE**

REALISE is a multicenter, randomized, double-blinded, placebo-controlled Phase III study designed to generate safety data after six months of blinded treatment in 393 patients four to 11 years of age and assess the use of Viaskin Peanut 250 µg in routine medical practice. At the six-month time point, 383 patients in both the placebo and active arms continued in the open-label portion of the study, which will monitor patients for a total of 36 months of active treatment. Exploratory criteria also include scores from patients' Food Allergy Quality of Life Questionnaire (FAQLQ) and the Food Allergy Independent Measure (FAIM), as well as the evolution of peanut-specific serological markers over time. The study is conducted in 32 centers in North America. No oral food challenges are required in REALISE. Patients in the study were selected based on a well-documented medical history of IgE-mediated reactions to peanut, including children with a history of severe anaphylaxis, as well as analyses of baseline peanut-specific immunological markers. During the first six months of trial, patients were randomized 3:1 active versus placebo. Key assessments of safety parameters include treatment-emergent adverse events observed in both the placebo and active treatment groups during the initial six months, which continue to be monitored during the open-label portion of the study.

### 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.

### 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. 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 of Viaskin Peanut and the Company's regulatory strategy related to Viaskin Peanut. 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 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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