

Press Release

Montrouge, France, October 20, 2017

DBV Technologies Announces Topline Results of Phase III Clinical Trial in Peanut-Allergic Patients Four to 11 Years of Age

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced topline results from the PEPITES (Peanut EPIT Efficacy and Safety) Phase III trial evaluating the safety and efficacy of Viaskin Peanut in children four to 11 years of age. Topline results show a statistically significant response with a favorable tolerability profile, with 35.3% of patients responding to Viaskin Peanut 250 µg after 12 months of treatment as compared to 13.6% of patients in the placebo arm (difference in response rates = 21.7%; $p=0.00001$; 95% CI = 12.4% - 29.8%). However, the primary endpoint, which evaluates the 95% confidence interval (CI) in the difference in response rates between the active and placebo arms, did not reach the 15% lower bound of the CI that was proposed in the study's Statistical Analysis Plan (SAP) submitted to the U.S Food and Drug Administration (FDA). Following initial conversations with the FDA on these topline efficacy and safety results, DBV will continue ongoing discussions with the agency, and plans to proceed with the BLA preparation process.

“We believe that this preliminary analysis shows significant therapeutic promise in the peanut-allergic population, where there is a high unmet medical need and no approved treatments,” said **Dr. Pierre-Henri Benhamou**, Chairman & Chief Executive Officer of DBV Technologies. *“Viaskin Peanut has been granted both Breakthrough Therapy and Fast Track designations by the FDA for the treatment of peanut allergy. We are committed to working together with the regulatory agencies to bring forward a safe and effective treatment option for these patients.”*

Preliminary analysis of the Cumulative Reactive Dose (CRD) – a key secondary endpoint measuring threshold reactivity during the double-blind, placebo-controlled food challenge (DBPCFC) – showed that at month 12, patients treated with Viaskin Peanut 250 µg and placebo reached a mean CRD of approximately 900 mg (median 444 mg) and 360 mg (median 144 mg) of peanut protein, respectively. Mean CRD at baseline was approximately 210 mg (median 144 mg) in both groups. This increase from baseline was statistically significant compared to placebo ($p<0.001$), and these findings are consistent with the data observed in the Company's Phase IIb study of Viaskin Peanut. For reference, one peanut contains approximately 250 mg peanut protein.

Safety and tolerability data were generally in-line with prior Phase IIb results. No imbalance in serious adverse events (SAEs) was observed in the trial, with 12 cases in 10 subjects in the active arm (4.2%), and 6 cases in 6 subjects in the placebo arm (5.1%); 4 of these cases were in 3 subjects in the active arm (1.3%), and were qualified by the investigator as possibly related to treatment. None of these cases were qualified as severe anaphylaxis, and all patients responded to standard outpatient

therapy. The most commonly reported adverse events were application site reactions, that were mostly mild and moderate in nature. In the 12-month treatment period, the discontinuation rate was 10.1%, which was evenly-balanced between the active and placebo arms, with a 1.1% dropout due to treatment emergent adverse events (TEAEs). Mean patient compliance was above 95% in the trial.

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 findings in this study underscore the potential of epicutaneous immunotherapy, and we continue to be encouraged by the response rate and clinically meaningful improvements in cumulative reactive dose that we observed. We believe the strength of all clinical data we have seen to date in over 650 patients supports the safety and efficacy profile of Viaskin Peanut, and look forward to seeing the full results from this trial.”* Dr. Sampson continued, *“We are very grateful to all the investigators and their support staff, patients and caregivers for their participation in this important trial.”*

A full assessment of the data is ongoing, with detailed results expected to be submitted for presentation at a future medical meeting.

Dr. David Fleischer, Global PI for PEPITES and Associate Section Head at Children’s Hospital Colorado, said, *“For the past 15 years that I have been involved in food allergy research, parents of peanut-allergic patients have been asking me is there anything more we can do to manage our child’s allergy besides strict avoidance. To lead the pivotal Phase III global trial has been an amazing honor, but to know I may be able to finally answer this question is even more incredible. Given the significant psychosocial and financial burdens placed on food-allergic patients and families that negatively impacts their quality of life, I am hopeful that we are one step closer to having a food allergy treatment that may improve the lives of peanut-allergic patients and families around the world.”*

The Company continues to anticipate announcing the topline results of the REALISE Phase III trial in November 2017.

DBV Technologies will host a conference call today, October 20, 2017, at 5:00 p.m. ET (11:00 p.m. CEST), to discuss these topline results. The conference call may be accessed by dialing +1 888 424 8151 for U.S. callers and +1 847 585 4422 for international callers. The conference call ID number is 5556432. A replay of the call will be available for 30 days following the call, beginning at 7:00 p.m. EST (1:00 a.m. CEST). The replay number is +1 888 843 7419 for U.S. callers or +1 630 652 3042 for international callers. The conference call ID number is 5556432.

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.

The last patient visit for PEPITES occurred in August 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 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 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, patients in both the placebo and active arms continue 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. DBV randomized 393 patients in REALISE.

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

Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding the potential of Viaskin Peanut and the anticipated timing of data from the REALISE clinical trial. 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.

DBV Investor Relations Contact

Sara Blum Sherman

Director, Investor Relations

+1 212-271-0740

sara.sherman@dbv-technologies.com

DBV Media Contact

Roberta Di Giorgio

Head, Corporate Communications

+1 917-612-2861

roberta.digiorgio@dbv-technologies.com