



## Press Release

Montrouge, France, September 12, 2018

# DBV Technologies Announces Positive DSMB Review of Part A of Phase III Study in Peanut-Allergic Toddlers

**No safety concerns identified by independent DSMB**

**Part B expected to commence in 4Q 2018 with Viaskin Peanut 250 µg**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that the independent Data and Safety Monitoring Board (DSMB) completed its planned safety review of Part A of the EPITOPE (EPIT in TOddlers with PEanut Allergy) trial of Viaskin Peanut in peanut-allergic toddlers ages one to three. The DSMB did not identify any safety concerns for patients enrolled in Part A of the trial, recommending that the study continue as planned with the 250 µg dose selected for investigation in Part B. Following this positive DSMB recommendation, the Company plans to initiate Part B of the EPITOPE study in the fourth quarter of 2018 to assess the efficacy and safety of Viaskin Peanut 250 µg for 12 months.

Part A enrolled 51 patients at seven centers in the United States. A planned interim safety analysis was conducted by the DSMB following three months of treatment with Viaskin Peanut 100 µg, Viaskin Peanut 250 µg or placebo. Both active doses were reported to be well tolerated, with no treatment-related serious adverse events (SAEs). No patients discontinued during the three-month period.

*“EPITOPE is the first Phase III trial in these younger children, an important underserved peanut-allergic population. Although peanut allergy is usually diagnosed between 1-3 years of age, there is limited research and development ongoing for these young children. Completing this initial part of the study and observing a favorable safety profile is an important milestone for the patients we serve,”* said **Dr. Wesley Burks**, Curnen Professor of Pediatrics, University of North Carolina School of Medicine, and Principal Investigator of the EPITOPE study. *“We are thankful to all the patients, parents, caregivers and clinicians who have helped make this crucial trial a reality.”*

### About EPITOPE

EPITOPE is expected to enroll approximately 400 patients (51 in Part A and 350 in Part B) in approximately 35 – 50 centers across North America (Canada and the United States), Europe, and Australia.

The EPITOPE trial is a two-part trial: Part A was designed to assess the safety of Viaskin Peanut 100 µg and 250 µg and to determine the highest safe dose, and Part B is designed to assess the efficacy and



safety of the selected dose. In Part A, 51 patients were randomized 1:2:2 to receive either placebo or Viaskin Peanut 100 µg or 250 µg. A planned safety analysis was performed after three months of treatment to determine the highest safe dose to be studied in Part B. There were no safety concerns observed with either of the two doses, and patients will continue on their respective treatment and remain on the same active dose or placebo they received in Part A up to month-12. In Part B, patients will be randomized 2:1 to receive Viaskin Peanut 250 µg or placebo.

The primary endpoint is based on a responder analysis after 12 months of treatment with the selected dose of Viaskin Peanut. Efficacy will be assessed using a double-blind, placebo-controlled food challenge (DBPCFC). For patients with a baseline peanut protein eliciting dose (ED) equal to or less than 10 mg, a responder is 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 is 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), will also be evaluated in EPITOPE to establish the total quantity of peanut protein that triggers patient reactions at month 12 of active treatment versus placebo. Serological markers will also be measured at baseline, 3, 6, and 12 months in order to characterize the immunological changes in patients.

Following the completion of EPITOPE, all eligible patients will have the option to rollover into EPOPEX, a long-term, open-label extension study of Viaskin Peanut 250 µg. In the EPOPEX study, patients who were randomized to active treatment during EPITOPE will receive Viaskin Peanut 250 µg for two additional years; patients who were previously receiving placebo during EPITOPE will be treated with Viaskin Peanut 250 µg for three years. Patients enrolling in the EPOPEX study will remain blinded to their respective treatment group in EPITOPE until the EPITOPE study results become publicly available.

### 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 in toddlers ages one to three years and of the Company's clinical development and regulatory plans regarding Viaskin Peanut in this patient population. 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.

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