

Press Release

Montrouge, France, August 2, 2017

## DBV Technologies Initiates Phase III Study of Viaskin Peanut in Peanut-Allergic Patients One to Three Years of Age

Expansion of clinical program into younger children reinforces commitment to developing potential treatments for patients suffering from peanut allergy

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced that the first patient has been enrolled in EPITOPE (**EPIT** in **TO**ddlers with **PE**anut Allergy), a global, Phase III clinical trial assessing the safety and efficacy of Viaskin Peanut for the treatment of peanut-allergic patients one to three years of age. Viaskin Peanut is the company's lead product candidate, which is based on epicutaneous immunotherapy (EPIT), a proprietary technology platform that delivers biologically active compounds to the immune system through the skin.

*“With results from our ongoing Phase III trial of Viaskin Peanut in peanut-allergic children four to 11 years of age expected later this year, the launch of EPITOPE, our second Viaskin Peanut Phase III program, highlights our commitment to accelerating innovation in the field of food allergies,”* said **Dr. Hugh Sampson**, Chief Scientific Officer of DBV Technologies, Director of the Jaffe Food Allergy Institute at Mount Sinai, and the Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai. *“Recent studies in the field suggest that treating patients from a younger age may lead to significant therapeutic benefit, and Viaskin may be able to offer a safe, effective and convenient treatment for these younger children.”*

EPITOPE is a two-part, pivotal, double-blind, placebo-controlled Phase III trial designed to evaluate the safety and efficacy of Viaskin Peanut in children one to three years of age. Part A of the trial will assess the safety of two doses of Viaskin Peanut, 100 µg and 250 µg in approximately 50 patients for three months. Based on the results from Part A, the highest safe dose will be studied in Part B, which will enroll approximately 281 additional patients to evaluate the safety and efficacy of the identified dose versus placebo for 12 months. The primary efficacy endpoint of the study is based on a responder analysis after 12 months of treatment of Viaskin Peanut. Efficacy will be assessed using a double-blind, placebo controlled food challenge (DBPCFC).

**Dr. Wesley Burks**, Curnen Professor of Pediatrics, University of North Carolina School of Medicine, and Principal Investigator of the EPITOPE study, said: *“Seeing the first patient enrolled in this trial represents another important step forward towards exploring treatments for patients suffering from peanut allergy. We have seen an increase in the diagnosis of this disease within the first few years of life, representing a high unmet medical need for these young children.”*



### About EPITOPE

EPITOPE is expected to enroll approximately 331 patients (50 in Part A and 281 in Part B) in approximately 20 – 40 centers across North America (Canada and the United States), Ireland, and Australia.

The EPITOPE trial is a two-part trial: Part A is designed to assess the safety of Viaskin Peanut 100 µg and 250 µg to determine the highest safe dose, and Part B is designed to assess the safety and efficacy of the highest safe dose selected in Part A. In Part A, patients are randomized 1:2:2 to receive either placebo or Viaskin Peanut 100 µg or 250 µg for three months. A safety analysis will be performed after three months to determine the highest safe dose to be studied in Part B. If there are no safety concerns with either of the two doses, patients will continue on their respective treatment and remain on the same active dose or placebo they received in Part A. In Part B, patients will be randomized 2:1 to receive the selected dose of Viaskin Peanut 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.

### About DBV Technologies

DBV Technologies is developing Viaskin<sup>®</sup>, a proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT<sup>®</sup>, 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: FRO010417345), 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. 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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