Press Release

Montrouge, France, October 26, 2018

DBV Technologies Announces Initiation of Part B of Phase III Study in Peanut-Allergic Toddlers

Study is expected to enroll a total of approximately 400 toddlers ages one to three at 35-50 clinical trial centers in the United States, Europe, Australia and Canada

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that the first patient has been enrolled in Part B of the EPITOPE (EPIT in TOddlers with PEanut Allergy) trial. EPITOPE is a two-part, pivotal Phase III clinical trial assessing the safety and efficacy of Viaskin Peanut 250 µg for the treatment of peanut-allergic toddlers one to three years of age. This trial is the second Phase III clinical program currently investigating the use of Viaskin Peanut for the treatment of patients with peanut allergy.

"We are grateful to the toddlers and their families who are contributing to future generations by embarking in this important trial, a key milestone for continuing to make progress in advancing potential treatments for peanut allergy," said Dr. Hugh Sampson, Chief Scientific Officer of DBV Technologies and Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai. "*Our family-centric clinical development strategy recognizes that diagnosis typically occurs at an early age, and we are focused on potentially helping patients as soon as they are faced with the challenges of living with a peanut allergy.*"

In September 2018, the Company announced that the independent Data Safety and Monitoring Board (DSMB) completed its review of Part A of EPITOPE, recommending that the dose of Viaskin Peanut 250 µg be evaluated in Part B. Both doses investigated in Part A (100 µg and 250 µg) were reported to be well tolerated, with no treatment-related serious adverse events (SAEs). In Part B, approximately 350 additional patients will be enrolled, and a total of ~380 patients will be evaluated after receiving 12 months of Viaskin Peanut 250 µg or placebo. The primary efficacy endpoint of the study is based on a responder analysis after 12 months of treatment. Efficacy will be assessed using a double-blind, placebo-controlled food challenge (DBPCFC).

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.

An interim analysis will be conducted by the DSMB after the first 50 patients have received 6 months of active treatment to assess the relative change in IgG4 levels in patients treated with Viaskin Peanut 250 µg compared to placebo (n=25). Following this unblinded review, the DSMB will be responsible for issuing a recommendation on study continuation to the Company.

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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