Press Release
Montrouge, France, August 1, 2016

DBV Technologies Announces Expansion of Clinical Program of Viaskin Peanut for the Treatment of Peanut Allergy

Strategic Investment Enhances Largest Global Clinical Development Program for Peanut Allergic Patients 4-11 Years of Age

New REALISE Study to Generate Data on the Use and Safety of Viaskin Peanut in Routine Clinical Practice, including its Use in Patients with History of Severe Anaphylaxis, without Oral Food Challenges Required for Entry

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced a strategic investment in the global clinical program of Viaskin Peanut for the treatment of peanut allergic children four to 11 years of age by initiating the REAL LIfe Use and Safety of EPIT (REALISE) study, a Phase III trial designed to assess the use and safety of Viaskin Peanut 250 µg in routine clinical practice. The study will also evaluate the evolution of peanut-specific immunological markers over time. With the ongoing PEPITES trial, the company's pivotal Phase III study of Viaskin Peanut, the launch of REALISE marks the expansion of the largest global clinical development program to date in children suffering from peanut allergy.

Viaskin Peanut is the company's lead product candidate, which is based on epicutaneous immunotherapy (EPIT), a proprietary technology platform that can deliver biologically active compounds to the immune system through the skin. Safety and efficacy results from the PEPITES trial as well as the safety results from the six-month blinded period of the REALISE study are expected to be part of the core regulatory filings for the approval of Viaskin Peanut. Topline results from both trials are expected in the second half of 2017.

"*We believe this investment continues to demonstrate our commitment to providing the best medical care for our patients in the future*" said **Laurent Martin**, Chief Development Officer of DBV Technologies. "*We expect that REALISE will generate valuable data on the use of Viaskin Peanut in routine clinical practice without the constraint of oral food challenges, and we anticipate that the additional safety data will increase the strength of our regulatory filings*."

REALISE is a multicenter, randomized, double-blind, placebo-controlled Phase III study designed to assess the use of Viaskin Peanut 250 µg in routine medical practice and generate safety data after six months of blinded treatment in patients four to 11 years of age. At the six-month time point, patients in both the placebo and active arms will be able to opt into an open-label portion of the study, which will continue monitoring patients for a total of 36 months of active treatment.

Exploratory criteria will also include scores from subjects' 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 expected to be conducted in approximately 30 to 40 centers in North America.

No oral food challenges are required in REALISE. Patients in the study will be 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 peanut-specific immunological markers. During the first six months of trial, patients will be randomized 3:1 active versus placebo. Key assessments of safety parameters will include treatment-emergent adverse events observed in both the placebo and active treatment groups after the initial 6 months, which will continue to be monitored during the open-label portion of the study. DBV intends to enroll approximately 335 subjects in REALISE.

"The successful enrollment of PEPITES reflects the field's enthusiasm for Viaskin Peanut. With REALISE, we want to capture that enthusiasm, and increase the number of patients and centers that are currently participating in one of our four clinical trials with a Viaskin product candidate," said **Dr. Lucia Septien**, Chief Medical Officer of DBV Technologies. *"This trial also gives our investigators the opportunity to study patients with severe anaphylaxis, who have been excluded from pharmaceutical development to date, but are in serious need of treatment."*

About the PEPITES Trial

The Peanut EPIT Efficacy and Safety Study (PEPITES) is 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. During PEPITES, patients' response will be assessed using a double-blind, placebo controlled food challenge (DBPCFC). Patients are randomized 2:1 to receive either Viaskin Peanut 250 µg or placebo for 12 months. The primary endpoint is 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 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 subjects 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 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 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 developed 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 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 B 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 contains forward-looking statements, including statements reflecting management's expectations for clinical development of our product candidates, future financial and operational performance and business outlook our research and development efforts and the commercial potential of our product candidates generally. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. 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 historical preclinical results may not be predictive of future clinical trial results, and the risk that historical clinical trial results may not be predictive of future trial results. 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, 2015 and future filings and reports by the Company. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release, whether as a result of new information, future events or circumstances or otherwise.

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