DBV Technologies Announces Completion of Blinded Period in REALISE Study of Viaskin Peanut

97.5% of patients continue treatment in the open-label arm of the REALISE study and will receive active treatment for a total of 36 months

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced that the blinded portion of the REALISE (REAL Life Use and Safety of EPIT) trial was completed. REALISE is the company’s Phase III study designed to assess the safety and routine clinical use of Viaskin Peanut 250 μg for the treatment of peanut-allergic children four to 11 years of age, including patients with a history of severe anaphylaxis. The Company anticipates announcing topline results from the blinded portion of the trial in November 2017.

Patients completing the double-blinded, placebo-controlled six-month treatment period in REALISE can continue receiving treatment for up to 36 months in the open-label portion of the study. The first part of the trial enrolled 393 patients, and 383 patients (97.5%) continued in the open-label portion of the study. All patients in REALISE are now receiving Viaskin Peanut 250 µg.

Dr. Jacqueline Pongracic, Head, Allergy and Immunology, Ann & Robert H. Lurie Children’s Hospital of Chicago, Professor of Pediatrics and Medicine, Northwestern University Feinberg School of Medicine, and Principal Investigator of REALISE, said: “This novel study is a critical step forward in the development of Viaskin Peanut, and allows us to focus on the safety profile of this potential treatment in routine medical practice. For children and their caregivers who face the burden of coping with peanut allergy, we know that having a safe treatment is paramount.”

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