# DBV Technologies Announces Completion of Enrollment in Phase III Extension Study of Viaskin Peanut

93% of patients completing PEPITES opted to enroll in follow-up study

Company to report topline results from PEPITES in October 2017

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced that PEOPLE (PEPITES OPen Label Extension Study), a Phase III extension trial assessing the long-term efficacy and safety of Viaskin Peanut 250 µg in children for up to 36 months of open-label treatment, has enrolled 300 patients. PEOPLE is a follow-up study to PEPITES, the Company's pivotal Phase III safety and efficacy trial in patients four to 11 years of age.

Patients completing the blinded 12-month treatment period in PEPITES were eligible to enroll in the PEOPLE study. In line with Company expectations, 323 patients (91%) completed PEPITES, and 300 patients (93%) elected to roll over into the extension study, exceeding target enrollment objectives.

The Company anticipates topline data for PEPITES in October 2017 based on the last patient visit in August 2017.

"With peanut allergy on the rise and no approved treatments available today, we look forward to expanding our knowledge about the potential efficacy and safety of Viaskin Peanut in PEOPLE, and we are sincerely grateful for all of our patients, caretakers and clinicians' efforts," said **Dr. Pierre-Henri Benhamou**, Chairman & Chief Executive Officer of DBV Technologies. "As we embark on the longest trial to date in this patient population, we remain committed to finding a safe and effective treatment for all peanut allergy sufferers."

### **About PEPITES**

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  $\mu$ g in children ages four to 11 years. PEPITES is being conducted in 31 centers across North America (Canada and the United States), Germany, Ireland and Australia. The last patient visit for PEPITES occurred in August 2017.

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  $\mu$ g or placebo for 12 months. The primary endpoint is based on a responder analysis after 12 months of treatment with Viaskin Peanut 250  $\mu$ g. 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 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 PEOPLE**

PEPITES OPen Label Extension Study (PEOPLE) is a global, Phase 3 extension trial of Viaskin Peanut in 300 patients. After patients completed the 12-month placebo-controlled period in PEPITES, they were eligible to enroll in PEOPLE to receive up to 36 months of open-label treatment with Viaskin Peanut 250 μg. In the PEOPLE study, patients who were randomized to active treatment during PEPITES will receive Viaskin Peanut 250 μg for 24 additional months; patients who were previously receiving placebo during PEPITES will be treated with Viaskin Peanut 250 μg for 36 months. Patients enrolling in PEOPLE will remain blinded to their respective treatment group in PEPITES until the PEPITES 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. 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: <a href="https://www.dbv-technologies.com">www.dbv-technologies.com</a>

## **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 PEPITES 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.

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