DBV Technologies Announces Completion of Recruitment in Global Phase III Study of Viaskin Peanut for the Treatment of Peanut Allergic Children

Company Expects to Report Topline Results for PEPITES in 2H 2017

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced that it has reached its patient recruitment objective for PEPITES (PEanut EPIT® Efficacy and Safety), the company’s pivotal Phase III trial of Viaskin® Peanut for the treatment of peanut allergic children. Recruitment in PEPITES exceeded initial expectations, with a total of 500 patients screened. As a result, the company increased its initial randomization target of 330 patients to at least 350 patients. 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. Topline results from PEPITES are expected in the second half of 2017.

“Today marks an important milestone for peanut allergic patients worldwide, as PEPITES is the first Phase III clinical trial in this disease to successfully finalize recruitment,” said Dr. David Fleischer, Principal Investigator for the PEPITES trial and Associate Professor of Pediatrics, Children’s Hospital Colorado. “We hope that the results in PEPITES will reflect the positive data that we have observed in other Viaskin Peanut trials.”

“We are extremely proud to see that due to the enthusiasm from our trial’s investigators and strong patient demand we were able to complete the recruitment milestone earlier than anticipated and well ahead of our expectations, taking us one step closer to the approval phase for Viaskin Peanut,” said Dr. Pierre-Henri Benhamou, Chairman and Chief Executive Officer DBV Technologies. “This excitement for PEPITES captures the real need for a safe and effective treatment for peanut allergy, and we are deeply thankful for our patients, caretakers and clinicians’ support during this short recruitment process.”

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 μg in children ages four to 11 years. During PEPITES, patients’ response will be assessed using a double-blind, and placebo controlled food challenge (DBPCFC). Patients will be randomized 2:1 to receive either Viaskin Peanut 250 μg or placebo for 12 months. The combined 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 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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