DBV Technologies Announces Submission of Biologics License Application for Viaskin Peanut to the U.S. Food and Drug Administration

DBV Technologies (Euronext: DB - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for Viaskin Peanut for the treatment of peanut allergy in children four to 11 years of age. Viaskin Peanut is the Company’s lead product candidate, which is based on epicutaneous immunotherapy (EPIT), a proprietary technology platform that delivers biologically active compounds to the immune system through the skin.

“This submission represents a significant step forward for those families living with peanut allergy. We are thankful for the patients, investigators and DBV employees’ efforts in making this milestone possible,” said Dr. Pierre-Henri Benhamou, Chairman & Chief Executive Officer of DBV Technologies. “We have been developing Viaskin Peanut for over 10 years, with over 1,000 patients studied in our clinical trials, and we are excited about the possibility of helping patients suffering from peanut allergy.”

Viaskin Peanut previously received Breakthrough and Fast Track Designation from the FDA in 2015 and 2012, respectively. The BLA for Viaskin Peanut is supported by a global development program comprised of seven clinical trials. Data from Phase III studies, PEPITES and REALISE, which studied patients four to 11 years of age for 12 months, as well as supportive long-term data from the Company’s open-label Phase II program, were included in this submission.

Dr. Hugh Sampson, Chief Scientific Officer of DBV Technologies and Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai said, “We believe that the safety and efficacy data generated in our clinical trials support our mission to potentially offer EPIT, a proprietary desensitization treatment, to peanut-allergic children in an easy and convenient manner for families.”

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 and Company’s regulatory plans regarding Viaskin Peanut. 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 related regulatory reviews and approvals and clinical trials. 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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