DBV Technologies Announces FDA Advisory Committee Meeting to Review Viaskin Peanut for the Treatment of Peanut Allergy in Children

DBV Technologies (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has announced an Allergenic Products Advisory Committee meeting to be held on May 15, 2020 to discuss the Biologics License Application (BLA) for Viaskin™ Peanut. Viaskin Peanut, which is based on epicutaneous immunotherapy (EPIT), is an investigational drug currently under review by the FDA as a treatment for peanut allergy in children.

In the United States, nearly one million children suffer from a peanut allergy. For most peanut-allergic children, the burden is lifelong, and about 80% of them will not have outgrown it by the age of 4 years. Fear of life-threatening reactions triggered by everyday activities may lead to significantly increased anxiety and decreased quality of life for patients and their families.

“There remains a significant unmet need for children suffering from peanut allergy, a potentially life-threatening condition,” Daniel Tassé, Chief Executive Officer of DBV Technologies stated. “We welcome the opportunity to present data for the first and only epicutaneous immunotherapy and remain steadfast in our commitment to offer this important new treatment option to patients and their families in the second half of 2020, if approved.”

The Company announced on October 4, 2019, that the FDA had accepted the Viaskin Peanut BLA for filing with a target action date of August 5, 2020. Viaskin Peanut received Breakthrough and Fast Track Designation from the FDA in 2015 and 2012, respectively.

About DBV Technologies
DBV Technologies is developing Viaskin®, an investigational 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 non-invasive product candidates, the Company is dedicated to safely transforming the care of food allergic patients. 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 offices in Bagneux, France, and North American operations in Summit, NJ and New York, NY. The Company’s ordinary shares are traded on segment B 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 the EPIT platform and Viaskin® Peanut as a treatment for peanut-allergic children, the timing of the Advisory Committee meeting, and the 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 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. Furthermore, the timing of any action by the FDA and possible regulatory paths forward cannot be guaranteed, in that, for example, the FDA may miss its own required deadlines (including the target action date assigned under the Prescription Drug User-Fee Act or the date set for the Advisory Committee meeting). 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, 2018 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
Senior Director, Investor Relations & Strategy
+1 212-271-0740
sara.sherman@dbv-technologies.com

DBV Media Contact
Joe Becker
VP, Global Corporate Communications
+1 646-650-3912
joseph.becker@dbv-technologies.com