

DBV Technologies Submits Biologics License Application to U.S. Food and Drug Administration for Viaskin Peanut for the Treatment of Peanut Allergy

DBV Technologies (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced the submission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for Viaskin[®] Peanut for the treatment of peanut-allergic children ages 4 to 11 years. Viaskin Peanut is the Company's lead product candidate based on epicutaneous immunotherapy (EPIT[®]). Viaskin is the Company's proprietary, investigational platform that is designed to leverage the skin to activate the immune system and induce desensitization to allergens.

This submission addresses the additional data needed on manufacturing procedures and quality controls which were communicated by the FDA in December 2018, when DBV voluntarily withdrew its prior BLA submission for Viaskin Peanut. The FDA did not cite concerns related to the clinical module of the BLA for Viaskin Peanut in December 2018.

"This is an important milestone for DBV, as we are one step closer towards potentially bringing Viaskin Peanut to patients. I want to thank the team for their dedication in working to address the FDA's findings over the past few months. Everyone at DBV is highly committed to potentially addressing the significant unmet medical need facing peanut-allergic patients," stated **Daniel Tassé**, Chief Executive Officer of DBV Technologies. *"We would also like to thank our investigators, clinical trial sites, as well as the children living with peanut allergy and their families for all of their help in the development of Viaskin Peanut. We look forward to working with the FDA throughout its review process."*

Viaskin Peanut 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 eight clinical trials including, two Phase I studies, four Phase II studies and two Phase III studies. The two double-blind placebo-controlled Phase III trials, PEPITES and REALISE, studied patients aged 4 to 11 years for 12 months and 6 months, respectively, and were included in the submission. Additionally, supportive long-term data from the Company's open-



label Phase II program were also included in the submission.

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 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 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, 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. 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.

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