

DBV Technologies Provides Update on Viaskin Peanut for Children Four to 11 Years of Age

BLA withdrawn following discussions with FDA regarding insufficient data on manufacturing procedures and quality controls

DBV to work with the agency to pursue resubmission as quickly as possible

The FDA did not cite concerns related to the safety or efficacy of Viaskin Peanut in the BLA

DBV Technologies (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced that after discussions with the U.S. Food and Drug Administration (FDA), its Biologics License Application (BLA) for Viaskin Peanut in children four to 11 years of age has been voluntarily withdrawn. DBV is currently working closely with the agency to resubmit the application for Viaskin Peanut as quickly as possible.

This action was based on verbal and written correspondence with the FDA on December 18th, 2018. Following feedback from the agency, DBV Technologies concluded that the current BLA, which was submitted on October 18th, 2018, lacks sufficient detail regarding data on manufacturing procedures and quality controls. The FDA did not cite concerns related to the clinical module of the BLA for Viaskin Peanut, and the Company believes that the additional information needed to support this filing is available without further clinical studies.

*“Although the agency did not reference any medical or clinical questions with the submission of Viaskin Peanut, the FDA did communicate that the level of detail with regards to data on manufacturing and quality controls was insufficient in the BLA,” said **Daniel Tassé**, Chief Executive Officer of DBV Technologies. “We remain confident in the clinical profile of Viaskin Peanut and its potential to offer treatment to peanut-allergic children. Our plan is to address these concerns as quickly as possible and to work closely with the FDA to provide an updated and complete file.”*

Viaskin Peanut previously received Breakthrough and Fast Track designations for the treatment of peanut-allergic children from the FDA in 2015 and 2012,



respectively. DBV anticipates that all ongoing clinical trials with Viaskin Peanut will continue as planned.

DBV will be hosting an investor call today at 5:30 pm ET. The information for joining is as follows:

Dial-In: **1 (888) 424-8151 Audience US Toll Free**
1 (847) 585-4422 Audience US Toll
Passcode: **6097 919#**

[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 Montrouge, France, October 22, 2018 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, particularly with respect to the Company's expectations regarding its plan to resubmit its BLA to the FDA and whether any additional clinical trials may be required to support the BLA resubmission. 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 related to the Company's ability to address the concerns raised by the FDA with respect to its BLA, as well as those associated with regulatory reviews and approvals and clinical trials more generally. 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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