DBV Technologies Provides Update on Viaskin Peanut BLA for Children Ages 4-11 Years

Conference call today, March 16, at 5:00 PM ET / 10:00 PM CET

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 informed the Company that during its ongoing review of the Biologics License Application (BLA) for investigational Viaskin™ Peanut, it has identified questions regarding efficacy, including the impact of patch-site adhesion. Therefore, the Allergenic Products Advisory Committee (APAC) meeting to discuss the BLA will no longer take place as previously scheduled on May 15, 2020.

The Company is in communication with the FDA regarding the potential submission of additional information on patch-site adhesion from its clinical program as well as long-term efficacy results from the three-year open-label extension study, PEOPLE, to answer FDA’s questions, as part of the ongoing BLA review.

At this time, DBV Technologies has received no additional information regarding the timeline of the BLA review, and to the Company’s knowledge, the target action date of August 5, 2020 remains unchanged. However, the submission of additional information to the FDA may constitute a major amendment to the BLA and could extend the target action date.

“We appreciate the ongoing dialogue with the FDA and look forward to further discussions in the coming weeks,” said Daniel Tassé, Chief Executive Officer of DBV Technologies. “We believe in the clinical benefit observed in Viaskin Peanut clinical trials to date and will continue to work closely with the FDA to potentially bring Viaskin Peanut to children as quickly as possible.”

Conference Call Information
The Company will host a conference call and webcast to discuss this update on Monday, March 16, 2020 at 5:00 PM ET (10:00 PM CET). To participate in this conference call, please dial (800) 758-0741 (domestic) or (786) 815-8401 (international). The passcode for the call is 4138917#. The conference call will also be
webcast live on DBV’s website, www.dbv-technologies.com, under the Investor Relations & Media section and will be archived there for 30 days.

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 trial 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 Viaskin™ Peanut as a treatment for peanut-allergic children and the Company’s regulatory plans regarding Viaskin Peanut, including the Company’s planned interactions with the FDA and the target action date for the Company’s BLA. 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. Furthermore, the timing of any action by the FDA and possible regulatory paths forward cannot be guaranteed. 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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