

DBV Technologies Receives Complete Response Letter from FDA for Viaskin Peanut BLA in Children Ages 4-11 Years

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 issued a Complete Response Letter regarding the Company's Biologics License Application (BLA) for investigational Viaskin™ Peanut (DBV712), a non-invasive, once-daily epicutaneous patch to treat peanut allergies in children ages 4 to 11 years.

The Complete Response Letter indicates that the FDA cannot approve the application in its present form. The FDA has identified concerns regarding the impact of patch-site adhesion on efficacy and indicated the need for patch modifications, and subsequently a new human factor study. The FDA has also indicated that supplementary clinical data would need to be generated to support the modified patch. In addition, the FDA requested additional Chemistry, Manufacturing and Controls data. The Agency did not raise any safety concerns related to Viaskin Peanut.

DBV intends to request a meeting with FDA to discuss the FDA's comments as well as requirements for additional clinical data that may be needed to support BLA resubmission. The Company anticipates providing an update following this meeting, including updated cash runway resulting from the recent restructuring announced on June 26, 2020.

"We are very disappointed in the FDA's response, but continue to believe in the potential of Viaskin Peanut. Peanut allergy is one of the most common food allergies, and accidental exposure can result in life threatening reactions," Daniel Tassé, Chief Executive Officer of DBV Technologies, stated. "We plan to fully collaborate with the FDA with regards to the outstanding issues and believe that the EPIT patch technology platform lends itself well to potential modifications to enhance patch functionality. We remain dedicated in our mission to develop innovative treatments for patients with food allergies."



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 benefits of Viaskin Peanut, anticipated regulatory interactions and our ability to modify the EPIT patch as may be necessary to address comments raised by the FDA in the CRL. 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, including the impact of the COVID-19 pandemic. 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, 2019, 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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