

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

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced the receipt of written responses from the U.S Food and Drug Administration (FDA) to questions provided in the Type A meeting request the Company submitted in October 2020. The Type A meeting request was submitted following the Company's receipt of a Complete Response Letter (CRL) in connection with its Biologics License Application (BLA) for Viaskin™ Peanut (DBV712), an investigational, non-invasive, once-daily epicutaneous patch to treat peanut allergy in children ages 4 to 11 years.

DBV believes that the feedback received from the FDA provides a well-defined regulatory path forward. In exchanges with the FDA, DBV proposed potential resolutions to two main concerns identified by the FDA in the CRL: the impact of patch adhesion and the need for patch modifications. DBV will address details about a new human factor (HF) validation study and additional chemistry, manufacturing and controls (CMC) data in subsequent interactions with the FDA.

The FDA agreed with DBV's position that a modified Viaskin™ Peanut patch should not be considered as a new product entity provided the occlusion chamber of the current Viaskin™ Peanut patch and the peanut protein dose of 250 µg (approximately 1/1000 one peanut) remains unchanged and performs in the same way it has performed previously.

In order to confirm the consistency of efficacy data between the existing and modified patches, FDA has requested an assessment comparing the uptake of allergen (peanut protein) between the patches in peanut allergic children ages 4-11. The FDA also recommended conducting a 6-month, well-controlled safety and adhesion trial to assess the modified Viaskin™ Peanut patch in the intended patient population.

DBV plans to initiate the selection of modified prototype patches in the first quarter of 2021. Additionally, DBV will submit the protocol for the safety and adhesion trial



in children with peanut allergy to FDA for review and comments in the second quarter of 2021 before initiating the trial.

"We are very encouraged by the positive feedback received from the FDA, and we appreciate the clarity provided," stated **Daniel Tassé**, Chief Executive Officer of DBV Technologies. *"I want to thank the DBV team for their dedication in working to address the FDA's findings over the past few months. We intend to advance a remediation plan for Viaskin™ Peanut and work closely with FDA to review protocols and re-file our BLA as soon as possible, so that we can bring Viaskin™ Peanut, if approved, to patients suffering from peanut allergies."*

"We look forward to working with our investigators, clinical trial sites, and key stakeholders as we continue in our development of investigational Viaskin™ Peanut," said **Dr. Pharis Mohideen**, Chief Medical Officer of DBV Technologies. *"Everyone at DBV remains highly committed to the possibility of bringing this innovative treatment option to patients and families."*

Based on the guidance received from the FDA and DBV's plans to implement such guidance, DBV continues to expect that the organization-wide cost reduction measures resulting from its previously announced global restructuring plan will extend its cash runway to the second half of 2022.

The Company will host a conference call and webcast to discuss this update on Thursday, January 14, 2021 at 5:00 PM ET (11:00 PM CET). To participate in this conference call, please dial (866) 939-3921 (US Toll-free) or (678) 302-3550 (US Toll). To access the call using an international dial-in number, please see this link:

<https://www.yourconferencecenter.com/AlternateNumbers/alternatenumbers.aspx?100899&t=A&o=UAvBpVOITNgJB>. The reference number for this call is 50075790.

A live webcast is available 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. 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), 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 design of DBV's anticipated clinical trials, the anticipated timeline for regulatory submissions and trial initiation, potential future interactions with the FDA, the potential benefits of Viaskin™ Peanut DBV's continued development of epicutaneous immunotherapy the implementation of DBV's global restructuring plan, potential cost savings anticipated from the global restructuring plan, and DBV's forecast of its cash runway. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties. At this stage, the Company's products 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 are risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as to DBV's ability to meet other anticipated deadlines and milestones, presented by the ongoing COVID-19 pandemic; uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals; risks related to whether results from a clinical trial will be predictive of the results of future trials; the risk that trials and studies may be delayed and may not have satisfactory outcomes; potential adverse effects arising from the testing or use of DBV's product candidates; expectations for regulatory approvals to conduct trials or to market products; and DBV's ability to successfully execute on its restructuring plans. Furthermore, the timing of any action by any regulatory agency cannot be guaranteed, particularly in light of the COVID-19 pandemic. A further list and description of risks and uncertainties that could cause actual results to differ materially from those set forth in the forward-looking statements in this press release can be found in DBV's regulatory filings with the French Autorité des Marchés Financiers, DBV'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 DBV. 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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