

DBV Technologies Outlines Regulatory Path for Viaskin Peanut in Children 1 – 3 Years After Receiving Pre-BLA Responses from FDA

- The FDA confirmed that the Company's Phase 3 EPITOPE study met the pre-specified criteria for success for the primary endpoint and did not request an additional efficacy study.
- Additional safety data will be required to augment the safety data collected from EPITOPE in support of a BLA.
- The new safety study will also generate patch adhesion data and include updated Instructions for Use (IFU).
- Company reports cash and cash equivalents of \$192.3 million as of March 31, 2023 based on preliminary and unaudited information.
- Company to host conference call and accompanying webcast at 6:00 p.m. ET (12:00 a.m. CEST) today, Wednesday, April 19, 2023.

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that DBV has received written responses from the U.S. Food and Drug Administration (FDA) on the regulatory path for investigational Viaskin™ Peanut 250 µg patch (DBV712) in toddlers ages 1 – 3 years-old with a confirmed peanut allergy.

In February 2023, DBV submitted a pre-BLA Meeting request to FDA. The Agency granted DBV's pre-BLA Meeting request as a written response only. In the written responses received, the Agency confirmed that the Company's Phase 3 EPITOPE study met the pre-specified criteria for success for the primary endpoint. The FDA did not request an additional efficacy study to support a future BLA but requires that DBV conduct an additional safety study in 1 – 3-year-olds using the original Viaskin Peanut patch to augment the safety data collected from the Phase 3 EPITOPE study. The new safety study is intended to bring the safety database in 1–3-year-olds close to 600 patients on active treatment which is consistent with FDA's position in support of the Company's dossier in 4–7-year-olds. The safety study will not require a food challenge for study participation.

The new safety study will also generate patch adhesion data with updated Instructions for Use (IFU) that aligns with the methodology agreed with FDA for the VITESSE Phase 3 study. DBV is engaging with the FDA on critical design elements of the new safety study and plans to submit a proposed safety study protocol to the



FDA by the end of Q2 2023.

Viaskin Peanut in 1 – 3-year-olds (original patch) and Viaskin Peanut in 4 – 7-year-olds (modified patch) will continue as separate product candidates with independent clinical and regulatory paths.

“We are pleased to have received clear guidance from the FDA on a regulatory path for a BLA in 1 – 3-year-olds for the original Viaskin Peanut patch. Now that we have FDA’s feedback, we are eager to get to work on supplementing our already strong EPITOPE data in children 1 – 3 years old,” said **Daniel Tassé, CEO, DBV Technologies**. *“This is the age group in which most patients are initially diagnosed with a peanut allergy. We know from a growing body of evidence that early exposure to peanuts can help improve outcomes for those at high-risk for allergy. Yet there remain no FDA approved treatments for this important population. DBV is committed to developing treatment options for these toddlers and their families, and we are confident that Viaskin Peanut may one day be approved.”*

Additionally, DBV will conduct a Human Factors (HF) study of Viaskin Peanut to assess the user interface in the intended age group. DBV has conducted a preliminary, pilot HF validation study and will use the information generated as the basis for the final HF validation protocol, which will require FDA protocol review and alignment prior to initiation. Concurrently, DBV continues to progress the Chemistry, Manufacturing, and Controls (CMC) sections of the BLA dossier.

“The foundation of a Viaskin Peanut BLA for peanut-allergic toddlers will be DBV’s EPITOPE data, which demonstrated that 67 percent of subjects treated with Viaskin Peanut 250 µg met response criteria at one-year,” said **Dr. Pharis Mohideen, Chief Medical Officer, DBV Technologies**. *“Developing a well-tolerated, convenient treatment option has always been a central goal of the Company. Generating additional safety data with the original patch will serve to build on the extensive research we have already conducted. It will be critical to fully align with FDA prior to beginning the safety study and we look forward to continued engagement with their dedicated team as we move forward on actions to support a future BLA submission.”*

DBV continues to practice financial discipline to support its ongoing development programs. Cash and cash equivalents amount to \$192.3million as of March 31, 2023 as compared to \$209.2 million as of December 31, 2022, which is a decrease of \$16.9



million due to cash used in operations, including resumption of the VITESSE clinical development program. The Company's cash and cash equivalents as of March 31, 2023 is based on preliminary and unaudited information.

DBV will host a conference call and live audio webcast to discuss the FDA's response today, Wednesday, April 19, 2023, at 6:00 p.m. ET (12 a.m. CEST). This call is accessible via the following:

- USA Toll-Free: 1-844-481-2866
- International: 1-412-317-1859

A live webcast of the call will be available on the Investors & Media section of the Company's website: <https://www.dbv-technologies.com/investor-relations/> A replay of the presentation will also be available on DBV's website after the event.

About EPITOPE

EPITOPE ([NCT03211247](#)) enrolled 413 subjects (51 in Part A and 362 in Part B) in approximately 50 centers across North America (Canada and the United States), Europe and Australia. The EPITOPE trial was a two-part trial: Part A was designed to assess the safety of Viaskin Peanut 100 µg and 250 µg and to determine the highest safe dose, and Part B was designed to assess the efficacy and safety of the selected dose. Based on the results of Part A, the 250 µg dose was selected for Part B. In Part B, subjects were randomized 2:1 to receive Viaskin Peanut 250 µg or placebo.

The primary endpoint was based on a responder analysis after 12 months of treatment with the selected dose of Viaskin Peanut. As a secondary efficacy endpoint, cumulative reactive dose (CRD) was also evaluated in EPITOPE to establish the total quantity of peanut protein that triggers subject reactions at month 12 of active treatment versus placebo. Serological markers were also measured at baseline, 3, 6 and 12 months in order to characterize the immunological changes in subjects.

Following the completion of EPITOPE, all eligible subjects had the option to rollover into EPOPEX, a long-term, open-label extension study of Viaskin Peanut 250 µg. Now that the EPITOPE study results are publicly available, subjects enrolled in the EPOPEX study will be unblinded to their respective treatment group in EPITOPE.

In June 2022, DBV Technologies announced positive topline results from EPITOPE. Viaskin Peanut demonstrated a statistically significant treatment effect ($p < 0.001$), with 67.0% of subjects in the Viaskin Peanut arm meeting the treatment responder criteria after 12 months, as compared to 33.5% of subjects in the placebo arm (difference in response rates = 33.4%; 95% CI = 22.4% - 44.5%). The EPITOPE safety results were generally consistent with the



safety profile of Viaskin Peanut 250 µg observed in children with peanut allergy ages 4 years and older in prior clinical trials. No imbalance in the overall adverse event (AE) rate was observed in the trial between the active and placebo arms. For more information on the EPITOPE results see the [DBV press release](#).

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™, and is DBV Technologies' 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 Technologies' food allergies programs include ongoing clinical trials of Viaskin Peanut. DBV Technologies has global headquarters in Montrouge, France, and North American operations in Basking Ridge, NJ. 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 contains forward-looking statements and estimates, including statements regarding DBV Technologies' clinical development and regulatory plans with respect to Viaskin™ Peanut for the treatment of toddlers ages 1-3 years old, the therapeutic potential of Viaskin™ Peanut as a treatment for peanut-allergic children more broadly, the ability of any of the Company's product candidates, if approved, to improve the lives of patients with food allergies, designs of the Company's anticipated clinical trials, safety studies and HF studies, the timing and anticipated results of interactions with regulatory agencies and the Company's estimates of its cash and cash equivalents as of March 31, 2023. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties, including risks inherent to the clinical development and regulatory process, as well as market conditions and other risks and uncertainties set forth in DBV Technologies' regulatory filings with the Autorité des Marchés Financiers ("AMF"), DBV Technologies' filings and reports with the U.S. Securities and Exchange Commission ("SEC"), and future filings and reports made with the AMF and SEC. 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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