Press Release
Montrouge, France, May 10, 2023

DBV Technologies Announces New England Journal of Medicine Publication of Phase 3 EPITOPE Trial Data Evaluating Viaskin™ Peanut in Toddlers

- The New England Journal of Medicine (NEJM) published results that demonstrated epicutaneous immunotherapy (EPIT™) with Viaskin Peanut was statistically superior to placebo in desensitizing children to peanut by increasing the peanut dose that triggers allergic symptoms.
- As stated in an accompanying editorial piece, these data are seen as "very good news" for toddlers with peanut allergy, as there are currently no approved treatment options for peanut-allergic children under the age of 4 years.
- DBV is advancing regulatory efforts for Viaskin Peanut in toddlers ages 1 – 3 years old with a confirmed peanut allergy.

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that its Phase 3 EPITOPE trial of epicutaneous immunotherapy (EPIT) with Viaskin™ Peanut in children 1 – 3 years was published in the *New England Journal of Medicine*, reinforcing the potential of a new food allergy treatment option for this community.

"We are thrilled to see the EPITOPE Phase 3 data published in the New England Journal of Medicine, highlighting exciting results for toddlers with peanut allergy and their loved ones," said Daniel Tassé, Chief Executive Officer of DBV Technologies. *"This publication comes shortly after receiving pre-BLA feedback from the FDA, which outlined the regulatory path for our Viaskin Peanut program in 1 – 3-year-olds. Parents and caregivers are eagerly awaiting FDA-approved treatment options for this age group. We are pleased that the NEJM has confirmed what we know to be true: the EPITOPE data represent a 'next step towards a future with more [approved] treatments for food allergies.'."*[1]

Peanut allergy is the most common food allergy in children in the United States, with growing prevalence and increasing impact on patients, families, and health systems. Despite this substantial burden, there are limited treatment options for peanut allergy and no FDA approved options for children younger than 4 years of

[1] Togias, Alkis, M.D., "*Good News for Toddlers with Peanut Allergy*." New England Journal of Medicine. 388;19. May 11, 2023.

age.

Viaskin Peanut, a novel form of EPIT, has the potential to offer a new and breakthrough science that modifies an individual's underlying food allergy by re-educating the immune system to increase tolerance to allergens. As stated in the article "the developing immune system may be particularly amenable to desensitization, which provides an important rationale for prioritizing treatments that target younger children."

The NEJM highlights that EPIT with Viaskin Peanut, as a patch-based nonoral immunotherapy option, has shown in clinical studies consistent evidence of efficacy, safety, and high treatment adherence. The EPITOPE trial was designed to allow participants to go about their normal daily activities such as playing, showering, or swimming, without restrictions.

"*I see peanut-allergic patients in my clinical practice daily. I speak with parents who are experiencing increased anxiety and a decreased quality of life due to fear of life-threatening reactions*," said Matthew Greenhawt, M.D., MBA, MSc of Children's Hospital Colorado and lead author of the publication. "*This publication shows that, if approved, the Viaskin Peanut patch has the potential to give new hope to toddlers and their families who currently have no approved treatment options and must instead rely on avoidance, which can severely impact quality of life. The EPITOPE data are a meaningful advancement in potentially offering the first-ever FDA approved treatment option for peanut-allergic toddlers*."

EPITOPE was a Phase 3, randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of Viaskin Peanut in children 1 through 3 years of age with a diagnosed peanut allergy.

After one year of treatment, Viaskin Peanut resulted in statistically superior desensitization compared with placebo, with treatment responder rates of 67.0% and 33.5%, respectively. Additionally, a shift towards less severe food challenge reactions was seen following 12 months of treatment with Viaskin Peanut. Similar to previous studies of Viaskin Peanut in children, the most common adverse events were local application site reactions, which decreased in frequency and severity over time. Low rates of treatment-related anaphylaxis and epinephrine use were observed. This study demonstrated that 12 months of daily EPIT with a patch containing 250 µg peanut protein (1/1000th of one peanut) resulted in greater desensitization compared with placebo, sufficient to decrease the likelihood of experiencing an allergic reaction following accidental peanut exposure.

Viaskin Peanut was well-tolerated by a majority of participants and had low discontinuations due to AEs and high compliance rates. Subjects were able to wear the patch daily without restrictions around activities for a sufficient duration over the course of the treatment period to induce desensitization.

"*As a parent who has raised children with food allergies and as a voice for the food allergy community, I am encouraged to see the EPITOPE trial results published by the New England Journal of Medicine*," said Kenneth Mendez, CEO of the Asthma and Allergy Foundation of America and its food allergy division, Kids with Food Allergies. "*Many caregivers worry about their food-allergic toddler's accidental exposure to a food allergen. This sometimes means that they will limit their toddler from everyday activities. Caregivers need a treatment option that provides peace of mind for them and for their children. I am excited by this innovative potential treatment option and hopeful that one day, toddlers with peanut allergy will have multiple treatment options to choose from.*"

To view the full publication, accompanying QuickTake video, and editorial from the NEJM please visit the following:

Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy

NEJM QuickTake

Good News for Toddlers with Peanut Allergy

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. There were no limitations on activities of daily living in this trial. Participants were able to go about their normal lives without restrictions, including playing, showering, or swimming.

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, and the timing and anticipated results of interactions with regulatory agencies. 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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