



Press Release

Montrouge, France, June 7, 2022

DBV Technologies Announces Positive Topline Results from Phase 3 EPITOPE Trial of Viaskin Peanut in Peanut-Allergic Toddlers

- 67.0% of subjects treated with Viaskin Peanut 250 µg met response criteria at 12 months, compared with 33.5% of subjects in the placebo arm
- Pivotal trial met primary endpoint: lower bound of the 95% confidence interval (CI) of the difference between treatment arms was 22.4%, exceeding the pre-specified threshold of 15%
- Safety results were generally consistent with safety profile of Viaskin Peanut 250 µg observed in children with peanut allergy ages 4 years and older in prior clinical trials
- High treatment compliance rate observed over trial duration, with low rate of discontinuation due to adverse events
- DBV will hold a conference call today at 5:00 p.m. ET to discuss the results

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that its pivotal Phase 3 trial EPITOPE (**EPIT** in **TO**ddlers with **PE**anut Allergy), assessing the safety and efficacy of Viaskin™ Peanut 250 µg for the treatment of peanut-allergic toddlers ages 1 to 3 years, met its primary endpoint.

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%).

DBV intends to further analyze the data from EPITOPE and explore regulatory pathways for Viaskin Peanut in children ages 1 to 3 years, given the high unmet need and absence of approved treatments for this vulnerable population. Separately, DBV continues productive dialogue with the U.S. Food and Drug Administration (FDA) on the protocol design of VITESSE, a pivotal Phase 3 trial of the modified Viaskin Peanut patch in peanut-allergic children ages 4 years and older.



“Most peanut-allergic children are diagnosed between 1 to 3 years of age; however, there are currently no FDA-approved therapies for this age group. Furthermore, there is growing evidence on the benefits of treatment from a younger age,” said Dr. Hugh Sampson, Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai, Director Emeritus of the Jaffe Food Allergy Institute and Chairman of the DBV Scientific Advisory Board. *“We believe these positive findings support the potential clinical benefit of Viaskin Peanut in this important, and underserved, population.”*

These results represent the second and final part of the EPITOPE trial, which enrolled 362 subjects ages 1 to 3 years, of which 244 and 118 were in the active and placebo arms, respectively. Enrollment was balanced for age and baseline disease characteristics between the active and placebo treatment arms. The median subject baseline eliciting dose (ED) was 100 mg in each treatment arm. A double-blind, placebo-controlled food challenge (DBPCFC) was administered at baseline and month 12 to determine a subject's ED at each timepoint. A treatment responder was defined as either a subject with a baseline ED ≤ 10 mg who reached an ED ≥ 300 mg of peanut protein at month 12, or a subject with a baseline ED > 10 mg who reached an ED $\geq 1,000$ mg of peanut protein at month 12.

In an additional pre-specified efficacy analysis, treatment response was defined as achieving an ED $\geq 1,000$ mg of peanut protein regardless of baseline ED. Using this response criterion, Viaskin Peanut demonstrated a statistically significant treatment effect ($p < 0.001$), with 64.2% of subjects in the Viaskin Peanut arm meeting this treatment responder criterion after 12 months as compared to 29.6% of subjects in the placebo arm (difference in response rates = 34.7%; 95% CI = 23.6% - 45.7%). The response rate observed in the placebo arm appears consistent with the approximately 22% natural resolution rate in this patient population.¹

The EPITOPE safety results were generally consistent with the safety profile of Viaskin Peanut 250 μ g 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.

Overall, 21 subjects (8.6%) in the Viaskin Peanut arm and 3 subjects (2.5%) in the placebo arm experienced a serious adverse event (SAE). Only 1 of the SAEs (0.4%), which was



mild periorbital edema (swelling around the eye) in the Viaskin Peanut arm, was deemed related to treatment.

The most commonly reported adverse events were skin reactions localized to the administration site, the majority of which were mild to moderate in nature. Fifty-five subjects (22.5%) in the Viaskin Peanut arm experienced an application site reaction that was assessed as severe by an investigator compared with 10 subjects (8.5%) in the placebo arm. Based on investigators' reported observations from examinations of the skin at each study visit, using the skin grading systems defined in the protocol, the severity of administration site skin reactions following patch application decreased throughout the course of the 12-month treatment period.

Four (1.6%) subjects in the Viaskin Peanut arm experienced an anaphylactic reaction determined to be related to, or possibly related to, treatment. Among these anaphylactic reactions, 3 resolved with a single dose of epinephrine and 1 resolved without epinephrine. All anaphylactic reactions were mild to moderate in severity and were characterized mainly by skin and respiratory symptoms.

Eight subjects (3.3%) in the Viaskin Peanut arm discontinued due to adverse events.

In the 12-month treatment period, the trial completion rate was 84.8% and was balanced between the Viaskin Peanut and placebo arms. Mean subject compliance to daily patch treatment was above 95% in both the active and placebo arms.

"We are thrilled by the topline results of EPITOPE, our second Phase 3 clinical trial to evaluate the safety and efficacy of Viaskin Peanut," said Dr. Pharis Mohideen, Chief Medical Officer of DBV Technologies. "We are grateful to the toddlers and their parents, caregivers and allergists who are contributing to a brighter future by having participated in this first-of-its kind trial."

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. There are currently 304 subjects (88% of all eligible subjects) enrolled in EPOPEX.

DBV plans to present full EPITOPE trial results at future medical congresses as well as submit them for publication in a peer-reviewed journal.



“The EPITOPE data advance our understanding of investigational epicutaneous immunotherapy’s ability to induce an immune response with minimal amounts of allergen,” said Daniel Tassé, Chief Executive Officer of DBV Technologies. *“These results further inform EPIT’s potential in other food allergies and immunological conditions, which are areas of research DBV remains highly committed to pursuing.”*

DBV will host a conference call and live audio webcast on Tuesday, June 7, 2022, at 5:00 p.m. ET to discuss the results. This call is accessible via the below teleconferencing numbers, followed by the reference ID: 23143278#

- United States: 866 374 5140
- Canada: 866 455 3403
- United Kingdom: 808 238 9813
- France: 805 102 712

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 is 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.



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 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, including statements regarding DBV Technologies' Viaskin Peanut, such as the regulatory pathway for approval by the FDA in children ages 1 to 3 years and the planned VITESSE Phase 3 clinical trial in older children discussed in this press release. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. These forward-looking statements may be impacted by market conditions as well as other risks and uncertainties set forth in DBV Technologies' regulatory filings with the AMF, DBV Technologies' filings and reports with the SEC, including in DBV Technologies' Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 9, 2022, and future filings and reports made with the AMF and SEC by DBV Technologies. 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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¹ Peters RL, Allen KJ, Dharmage SC, et al. Natural history of peanut allergy and predictors of resolution in the first 4 years of life: A population-based assessment. *J Allergy Clin Immunol*. 2015;135(5):1257-66.e662. doi:10.1016/j.jaci.2015.01.002