

DBV Technologies Reports Positive Three-Year, Long-Term Data from the PEOPLE Phase III Open-Label Extension Study of Viaskin Peanut in Children with Peanut Allergy

Patients demonstrated durable, long-term clinical benefit with an additional two years of treatment

Low discontinuations due to adverse events observed

Study represents the largest long-term peanut allergy immunotherapy trial to date, with high compliance enabling extended study participation

DBV Technologies (the “Company”) (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced positive topline results of the three-year, open-label extension of the Phase III PEPITES trial (PEOPLE) evaluating the long-term efficacy and safety of investigational Viaskin® Peanut in peanut-allergic children ages 4 to 11 years. The results demonstrate long-term clinical benefit as shown by an increase in eliciting dose (ED), which may decrease the chance of reacting to an accidental peanut exposure. After three years, 75.9% (107/141) of patients had increased their ED from baseline, and 51.8% (73/141) of patients reached an ED of at least 1,000 mg peanut protein by year three.

“These new long-term data support the overall clinical benefit of Viaskin Peanut that we’ve observed to date in Phase II and III clinical trials. We are particularly pleased to see that approximately three out of four patients showed an increase in their eliciting dose over three years, regardless of their individual baseline, with roughly 1 in 7 patients able to consume 5,444 mg peanut protein without reacting during the Month 36 oral food challenge,” said **Dr. David Fleischer**, Principal Investigator of PEPITES and PEOPLE, Director, Allergy and Immunology Center and Section Head, Children’s Hospital Colorado. *“Most peanut-allergic children react to a single peanut (300 mg of peanut protein) or less, with some reacting to as little as 1 mg, leading many children and families to experience constant fear of accidental exposure, loss of normalcy and decreased quality of life. These new data provide further evidence that Viaskin Peanut may reduce the risk of reaction from*



accidental exposure by increasing threshold reactivity through a treatment option that could be safe and convenient.”

The PEOPLE study is an ongoing open-label extension study evaluating the long-term safety, tolerability and efficacy of Viaskin Peanut 250 µg in patients who have completed the Phase III PEPITES trial. Of the 213 patients who were randomized in the active treatment arm of PEPITES and completed the 12-month trial, 198 patients opted to enter the PEOPLE study (safety population). Of these patients, 148 were considered completers after 36 months and 141 patients completed all treatment according to the study protocol without major deviations. Efficacy data were analyzed from these 141 patients (per-protocol).

Topline results from PEOPLE support the long-term tolerability and clinical benefit of Viaskin Peanut, demonstrating desensitization over 36 months of treatment. After 36 months, 51.8% (73/141) of patients reached an ED of at least 1,000 mg peanut protein, an increase relative to Month 12, 40.4% (57/141). In addition, 13.5% (19/141) of patients completed the food challenge without meeting stopping criteria at 36 months (cumulative dose of 5,444 mg). At Month 36, the mean cumulative reactive dose (CRD) was 1,768.8 mg (median 944 mg) compared to 223.8 mg (median 144 mg) at baseline.

The safety profile of Viaskin Peanut was consistent with that observed in the clinical program to date in over 1,000 patients. During PEOPLE, the most common adverse events were mild to moderate skin reactions localized to the administration site and there was no epinephrine use deemed related to treatment. No treatment related serious adverse events (SAEs) were reported. One patient experienced one case of mild anaphylaxis that was determined by the investigator to be possibly related to treatment and resolved without treatment. Treatment compliance remained high throughout the study at a mean of 98% over three years of treatment.

Exploratory analyses suggest Viaskin Peanut may offer sustained effect even after a period without treatment. All participants who reached an ED \geq 1,000 mg at Month 36 were eligible to continue the study for two additional months without treatment while maintaining a peanut-free diet. A further double-blind placebo-controlled food challenge to determine ED was administered at the end of this period (Month 38). The analysis showed that 77.8% (14/18) of the children who completed the oral food challenge at Month 38 maintained desensitization with an ED \geq 1,000 mg.



“Harnessing the important immune properties of the skin, epicutaneous immunotherapy represents a potentially unique mechanism of action that may support the sustained desensitization observed in this study even after a period without treatment. These data further advance our understanding of the profile of Viaskin Peanut, which is currently under review by the U.S. Food and Drug Administration and may offer a simple, once daily, non-invasive treatment option for children living with peanut allergy in the second half of 2020, if approved,” said Dr. Pharis Mohideen, Chief Medical Officer of DBV Technologies. “Importantly, we would like to thank the children, families and investigators for participating in this study, the largest long-term trial in this underserved disease.”

The Company plans to present full study results at future medical congresses as well as submit for publication in a peer-reviewed journal.

About PEOPLE

The PEOPLE study is an open-label extension of the Phase III PEPITES trial designed to evaluate the long-term safety, tolerability and efficacy of Viaskin Peanut 250 µg ([NCT03013517](#)). Participants who completed the 12-month study period of PEPITES were eligible to enroll in PEOPLE. Patients who were randomized to active treatment in PEPITES are eligible to receive up to four additional years of treatment, and those previously receiving placebo are eligible to receive up to five years of treatment.

The study evaluates the eliciting dose after three years (Month 36) of active treatment using a double-blind, placebo-controlled food challenge (DBPCFC). The starting dose of each challenge is 1 mg of peanut protein and escalates to the highest dose of 2,000 mg peanut protein; possibly repeated once to reach a maximum total cumulative dose of 5,444 mg peanut protein. For the next DBPCFCs after four and five years, the starting dose of each challenge is 10 mg of peanut protein and escalates to the highest dose of 3,000 mg peanut protein; possibly repeated once to reach a maximum total cumulative dose of 6,440 mg peanut protein.

The analysis also includes exploratory assessments of safety parameters, immune biomarkers such as immunoglobulin E (IgE) and immunoglobulin G4 (IgG4), and sustained desensitization following a two-month period without treatment.

About PEPITES

The Peanut EPIT Efficacy and Safety Study (PEPITES) was a global, double-blind, placebo-controlled Phase III trial designed to evaluate the safety and efficacy of Viaskin Peanut 250 µg in children ages 4 to 11 years ([NCT02636699](#)). PEPITES was conducted in 31 centers across North America (Canada and the United States), Germany, Ireland and Australia.

Eligible patients were aged 4-11 years at screening with physician-diagnosed peanut allergy, currently following a strict peanut-free diet. Other key inclusion criteria were peanut-specific IgE >0.7 kUA/L, a peanut skin prick test with a largest wheal diameter ≥6



mm (children 4-5 years) or ≥ 8 mm (children ≥ 6 years) at screening, and an ED (the single highest dose at which a patient exhibited objective signs/symptoms of an immediate hypersensitivity reaction) of ≤ 300 mg peanut protein based on a DBPCFC.

PRACTALL, the joint American Academy of Allergy, Asthma & Immunology (AAAAI) and European Academy of Allergy and Clinical Immunology (EAACI) published food challenge methodology that defines strict, 30-minute intervals for peanut protein dosing, was used to evaluate sensitivity to peanut at baseline and exit. Challenges were stopped when patients exhibited clear, objective symptoms based on a pre-specified symptom scoring scale. A Good Manufacturing Practice food challenge matrix was used for all peanut protein and placebo food challenges.

During PEPITES, patients' responses were assessed using DBPCFCs. Patients were randomized 2:1 to receive either Viaskin Peanut 250 μg or placebo for 12 months. The primary endpoint was based on a responder analysis after 12 months of treatment with Viaskin Peanut 250 μg . For patients with a baseline peanut protein ED equal to or less than 10 mg, a responder was defined as a patient with a peanut protein ED equal to or greater than 300 mg of peanut protein after 12 months of treatment. For patients with a baseline ED greater than 10 mg, a responder was defined as a patient with a peanut protein ED equal to or greater than 1,000 mg of peanut protein after 12 months of treatment.

As a secondary efficacy endpoint, CRD was also evaluated in PEPITES to establish the total quantity of peanut protein that triggers patient 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 patients.

During the study, investigators relied on the commonly used National Institute of Allergy and Infectious Diseases (NIAID) definition of anaphylaxis, which has been shown to be highly sensitive but only moderately specific in diagnosing anaphylaxis, in an attempt to capture as many potential reactions as possible.

Two hundred thirteen of the 238 patients randomized to the peanut-patch and 107 of the 118 patients randomized to the placebo-patch completed the study. After 12 months of therapy, patients treated with Viaskin Peanut showed a statistically significant improvement in the ED of peanut required to provoke an allergic reaction at food challenge compared with placebo. After 12 months of treatment, we observed that 35.3% of patients on Viaskin Peanut 250 μg were responders, compared to 13.6% of patients in the placebo group (treatment difference = 21.7%; 95% CI = 12.4% - 29.8%; $p < 0.001$). An increase in the CRD was also observed between the treatment and placebo groups (nominal p -value < 0.001) after 12 months. The median CRD of patients in the treatment group increased from 144 mg at baseline to 444 mg at Month 12, compared with no improvement in the placebo group.

There were no cases of severe anaphylaxis, and only four of 238 patients (1.7%) dropped out due to treatment-emergent adverse events. A low rate of treatment-related epinephrine use was reported (2.9% treatment group vs. 0.8% placebo group). Ten cases in eight Viaskin Peanut patients (3.4%) of possibly or probably treatment-related anaphylaxis occurred; all were classified as mild or moderate without evidence of cardiovascular, neurologic, or



respiratory compromise. Six of these ten cases were treated with epinephrine, and five of the eight patients continued on Viaskin Peanut in the study.

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 self-administered and non-invasive product candidates, the Company is dedicated to safely transforming the care of food allergic patients, for whom there are no approved treatments. 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 contains forward-looking statements, including statements about the potential of the EPIT platform and Viaskin® Peanut as a treatment for peanut-allergic children. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Factors that could cause actual results to differ materially from those described or projected herein include risk associated with uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals. 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 and U.S. Securities and Exchange Commission, including in the Company's Annual Report on Form 20-F for the year ended December 31, 2018. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to update or revise forward-looking statements as a result of new information, future events or circumstances, or otherwise, except as required by law.

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