

## **DBV Technologies Announces Publication of PEOPLE Phase III Open-Label Extension Study Evaluating Viaskin Peanut in *The Journal of Allergy and Clinical Immunology***

**PEOPLE is the largest long-term peanut allergy immunotherapy trial to date and showed favorable benefit-to-risk across three-year treatment period with Viaskin Peanut**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that *The Journal of Allergy and Clinical Immunology (JACI)* has published results from its three-year, open-label extension of the Phase III PEPITES study (PEOPLE). The study was published online today and will be in an upcoming print edition of the journal.

Patients demonstrated durable, long-term clinical benefit with an additional two years of treatment with Viaskin™ Peanut (compound name DBV712 250 µg), with low discontinuations due to adverse events. Top-line data from PEOPLE were announced in January 2020 and presented with additional detail at the American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Annual Meeting in March. The Biologics License Application (BLA) for investigational DBV712 for peanut-allergic children ages 4-11 years is currently under review by the U.S. Food and Drug Administration (FDA). If approved, DBV712 would be the first once-daily, non-invasive epicutaneous treatment option for children living with peanut allergy.

*“These data from the largest long-term study of peanut allergy immunotherapy demonstrate continued treatment benefit of DBV712 beyond one year, as well as a decrease in adverse events,”* said David Fleischer, M.D., Principal Investigator of PEPITES and PEOPLE, Professor of Pediatrics and Section Head, Children’s Hospital Colorado. *“In my clinical practice, I see many patients and their families who struggle with the burden of peanut allergy and the fear of accidental exposure. The potential benefit of an easy to use, well-tolerated treatment with long-term effect would be a welcome option for these patients.”*



### PEOPLE Efficacy Results

Data from the PEOPLE trial demonstrate that DBV712 was associated with continued response over a three-year treatment period.

- 75.9% (107/141) saw an improvement in eliciting dose (ED) from baseline to Month 36.
- 51.8% (73/141) achieved an ED of at least 1,000 mg at Month 36.
- 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.
- A treatment effect was seen across the spectrum of baseline sensitivity, including the most sensitive patients; those who entered with an ED of less than or equal to 10 mg (n=18) saw a 22.5-fold increase in geometric mean ED over the treatment period.
- Consistent with the high rate of sustained unresponsiveness reported in a previous clinical study<sup>1</sup>, exploratory analyses in a subset of participants showed that 77.8% (14/18) were able to maintain desensitization, according to predefined study definition, for a two-month period while off therapy and without peanut consumption.

### PEOPLE Safety and Tolerability Results

A favorable tolerability profile was observed with DBV712 in the PEOPLE trial, consistent with that observed in the clinical program to date in nearly 1,000 participants.

- The most commonly reported treatment-emergent adverse events (TEAEs) were application site reactions, which decreased in frequency and severity over time. 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; it resolved without treatment and the patient continued participation in the study.
- There was no epinephrine use deemed related to treatment.
- Treatment compliance remained high throughout PEPITES and PEOPLE at a mean of 98%. Most withdrawals were due to fear or aversion to a double-blind, placebo-controlled food challenge.

*"We are pleased that JACI has published the PEOPLE trial results, ensuring that healthcare providers will have access to these important data supporting an epicutaneous immunotherapy approach to treating one of the most common*



*food allergies in children,” said Pharis Mohideen, M.D., Chief Medical Officer of DBV Technologies, “We believe that data from this landmark study in peanut-allergic children ages 4-11 support the potential long-term treatment benefit in this patient population.”*

### 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 (DBV712 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 planned DBPCFCs after four and five years of treatment, 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 unresponsiveness following a two-month period without treatment.

### About DBV Technologies

DBV Technologies is developing Viaskin<sup>®</sup>, an investigational proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT<sup>™</sup>, 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 (DBV712). 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 may contain forward-looking statements and estimates, including statements regarding the potential of Viaskin™ Peanut (DBV712) as a treatment for peanut-allergic children, the conduct and timing of the Company's clinical trial of Viaskin Peanut and the Company's research, development and regulatory plans for DBV712 and its other product candidates, including the Company's planned interactions with the FDA regarding DBV712 and the target action date for the Company's BLA. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties. At this stage, the products of the Company 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 include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals. Furthermore, the timing of any action by the FDA and possible regulatory paths forward cannot be guaranteed. 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, the Company'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 the Company. 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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<sup>1</sup> Brown-Whitehorn TF, De Blay F, Sampson H. Allergy (EAACI) 2018. Sustained unresponsiveness following long term Epicutaneous Immunotherapy (EPIT) with VIASKIN® peanut: Results of the OLFUS- VIPES PHASE IIb Study. Allergy [Internet]. 2018 Aug 14. Available from: <https://onlinelibrary.wiley.com/doi/10.1111/all.13537>