

## **DBV Technologies Announces First Patient Screened in VITESSE Phase 3 Clinical Trial in Peanut-Allergic Children 4 – 7 Years Old**

- First patient screened at Midwest Allergy Sinus Asthma in Normal, Illinois
- VITESSE is DBV's Phase 3 clinical study evaluating the modified Viaskin Peanut patch in peanut-allergic children ages 4 – 7 years

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Market: DBVT), a clinical-stage biopharmaceutical company, today announced that the first patient has been screened in the Company's VITESSE (Viaskin Peanut Immunotherapy Trial to Evaluate Safety Simplicity and Efficacy) Phase 3 clinical trial that will evaluate the modified Viaskin™ Peanut 250 µg patch (DBV712) in peanut-allergic children ages 4 through 7 years.

Viaskin Peanut 250 µg is a novel treatment designed to re-educate the immune system by introducing microgram amounts of peanut allergen to the immune system through intact skin. The VITESSE trial will use the modified Viaskin Peanut 250 µg patch and enroll 600 subjects, randomized 2:1 active versus placebo. The study will involve approximately 80 trial sites across the United States, Canada, Australia, and Europe. The primary efficacy endpoint of the study is the percentage of treatment responders in the active versus placebo arms at Month 12. Secondary efficacy endpoints include changes in cumulative reactive dose (CRD), eliciting dose (ED) and severity of allergic reaction at Month 12 food challenge.

*"I am pleased that the first trial participant has been screened in the VITESSE study," said David Fleischer, MD, FAAAAI, FACAAI, Children's Hospital Colorado and Global Principal Investigator for the VITESSE study, "These peanut-allergic children represent a cohort of patients that are eagerly awaiting potential treatment options. I am looking forward to leading the team of highly skilled VITESSE investigators and their staff as we generate these critical data that may one day potentially support a BLA submission for Viaskin Peanut."*

Last year, following productive exchanges with the U.S. Food and Drug Administration (FDA), DBV finalized the VITESSE protocol and received the FDA's support to advance the study. Previously, the FDA had requested changes to certain elements of the VITESSE protocol with the intent for the trial to support a future Biologics License Application (BLA).

*"The initiation of the VITESSE Phase 3 Study in peanut-allergic children ages 4 - 7*



*years represents a culmination of years of research and collaboration between DBV, FDA, patient groups, site investigators, trial centers, and, of course, the support and unwavering encouragement from food-allergic families,” said Pharis Mohideen, MD, Chief Medical Officer, DBV Technologies. “DBV is proud to see that patient screening has begun in Q1 2023. This important milestone reflects incredible work from the DBV team and swift action in beginning enrollment from Principal Investigators like Dr. Dareen Siri and others. We are grateful for the strong collaboration that will continue throughout the VITESSE study.”*

Principal Investigator, Dr. Dareen Siri, FAAAAI, FACAAI from Midwest Allergy Sinus Asthma, in Normal and Springfield, Illinois was the first to conduct a screening visit for a potential new enrollee.

*“I am thrilled that our talented team of clinicians was the first to screen a patient for the VITESSE clinical study,” said Dareen Siri, MD, Midwest Allergy Sinus Asthma, Normal, IL. “The initiation of patient enrollment in VITESSE reinforces our commitment to peanut-allergic children and their families and is an important step in generating the data needed to potentially advance Viaskin Peanut to market. I am grateful that peanut-allergic children have the opportunity to participate in a trial that may one day help other kids just like them living with peanut allergy. There is a lot of excitement around the VITESSE study, and I am proud our team will be an integral part of it.”*

DBV anticipates screening the last patient in 1H 2024 and announcing topline results in 1H 2025.

### About VITESSE

The VITESSE trial will enroll 600 subjects, randomized 2:1 active versus placebo. The study will involve approximately 80 trial sites across the United States, Canada, Australia and Europe. Dr. David Fleischer, Colorado Children’s Hospital, will act as the global study Principal Investigator.

The primary efficacy endpoint is the percentage of treatment responders in the active versus placebo arms at Month 12. The primary efficacy analysis includes the success criterion of a lower bound of the confidence interval of the difference in responder rates between active and placebo groups being greater than or equal to 15%.

A treatment responder is defined as either a subject with a baseline ED  $\leq 30$  mg who reaches an ED  $\geq 300$  mg of peanut protein at Month 12, or a subject with a baseline ED = 100 mg who reaches an ED  $\geq 600$  mg of peanut protein at Month 12. A double-blind, placebo-controlled



food challenge (DBPCFC) will be administered at baseline and Month 12 to determine a subject's ED at both timepoints.

During the screening period, subjects will undergo an initial visit with assessment for eligibility according to peanut skin prick test (SPT) and serum peanut IgE. Those meeting these criteria will proceed to a DBPCFC to confirm their peanut allergy and establish an entry peanut ED. The entry DBPCFC will be 1 mg peanut protein, and will escalate up to a highest single dose of 100 mg peanut protein. Subjects who react with an ED at or below the dose of 100 mg peanut protein and meet all other inclusion and no exclusion criteria are considered eligible. At Month 12, a post-treatment DBPCFC will be performed, with a starting dose of 3 mg peanut protein, escalating to a highest dose of 1,000 mg peanut protein according to the following schedule: 3, 10, 30, 100, 300, 600, 1,000 mg. Secondary efficacy endpoints include changes in CRD, ED and severity of allergic reaction at Month 12 food challenge.

### 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 may contain forward-looking statements and estimates, including statements regarding the therapeutic potential of Viaskin™ Peanut as a treatment for peanut-allergic children and the potential benefits of EPIT™, DBV Technologies' clinical development and regulatory plans, timing and projections of VITESSE study milestones, and timing and anticipated results of interactions with regulatory agencies. All statements about VITESSE study milestones, enrollment and anticipated results contained herein are DBV's best estimates and projections are based on performance of previous studies and are subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance and achievements with respect to the VITESSE study to differ materially from the estimates and projections contained herein. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties and may be impacted by market conditions as well as 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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