

Press Release

Bagneux, France, June 23, 2015

## DBV Technologies Confirms Planned Initiation of Viaskin<sup>®</sup> Peanut Global Phase III Clinical Trial in Children Following End-of-Phase II Meeting with FDA and PIP approval by EMA

Phase III clinical trial in children expected to begin in Q4 2015

Comprehensive development plan for Viaskin Peanut announced

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced the completion of its End-of-Phase II meeting with the U.S. Food and Drug Administration (FDA). The outcome of this meeting on the clinical development plan for Viaskin Peanut is consistent with the previously announced positive opinion of the Paediatric Committee of the European Medicines Agency (EMA) on Viaskin Peanut's Paediatric Investigation Plan (PIP). Based on these regulatory consultations, DBV Technologies plans to initiate a global Phase III trial with Viaskin Peanut for the treatment of peanut allergic children 4 to 11 years of age in the fourth quarter of 2015. Based on these consultations, additional development plans for Viaskin Peanut in younger and older patients will be discussed with the FDA in the second half of 2015.

**Dr. Pierre-Henri Benhamou**, Chairman & CEO of DBV Technologies: *"We are very pleased with the outcome of our regulatory discussions with the EMA and the FDA, and we are thankful for both Agencies' desire to move forward the development of what may be the first in class treatment for patients suffering from peanut allergy. Our team at DBV has worked diligently to achieve this milestone, and we are now one step closer to our goal of developing a new class of immunotherapies for patients with food allergies."*

In children 4-11 years of age, the anticipated Phase III trial, Peanut EPIT<sup>®</sup> Efficacy and Safety Study (PEPITES) is expected to begin in the fourth quarter of 2015 following the submission of the final clinical trial protocol and updated chemistry, manufacturing and controls information, and review by the FDA, as well as review and approval of Clinical Trial Applications in the other countries where the trial is expected to be conducted.

In addition to the planned pivotal study in peanut allergic children aged 4 to 11, which is essential to support initial European Marketing Authorization Application (MAA) and initial US Biologics License Application (BLA) filings, DBV also intends to conduct additional separate clinical trials in younger

and older patients. DBV expects that further regulatory consultation will help to optimize the clinical development plan for assessing safety and efficacy of Viaskin Peanut in these patient populations.

### PEPITES expected to start in the fourth quarter of 2015

PEPITES is planned as a randomized, double-blind, placebo-controlled pivotal Phase III trial designed to assess the efficacy and safety of Viaskin Peanut 250 µg in approximately 260 pediatric patients from 35 sites in North America (United States and Canada), Australia and Europe (Ireland and Germany). Patients will be randomized 2:1 to receive either Viaskin Peanut 250 µg or placebo for 12 months. This planned Phase III trial is designed to confirm with appropriate statistical considerations in children aged 4 to 11, Viaskin Peanut's treatment effect that was shown during the Phase IIb VIPES trial, while providing sufficient safety data to support initial registration filings in this patient population.

During the trial, patients will be assessed using a double-blind, placebo controlled food challenge (DBPCFC). The primary endpoint for PEPITES is expected to be based on a more stringent treatment responder definition as compared to the criteria used in VIPES. The refined endpoint could potentially increase the clinical relevance by better defining the magnitude of the treatment effect. The FDA and EMA agreed to a combined primary endpoint based on a responder analysis after 12 months of treatment with Viaskin Peanut 250 µg. For patients with a baseline peanut protein eliciting dose (ED) equal to or less than 10 mg, a responder will be 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 subjects with a baseline ED greater than 10 mg, a responder will be defined as a patient with a peanut protein eliciting dose equal to or greater than 1,000 mg of peanut protein after 12 months of treatment.

As a secondary efficacy endpoint, Cumulative Reactive Dose (CRD) will also be used in PEPITES to establish the total quantity of peanut protein that triggers patient reactions at month 12 versus placebo. Serological markers will also be measured at baseline, 3, 6, and 12 months in order to characterize the immunological changes in patients.

A post-hoc analysis of DBV's VIPES data in children 6 to 11 years old using the responder definition proposed in PEPITES showed that statistical significance was achieved with respect to the refined primary endpoint, with 46.5% of patients responding to Viaskin 250 µg compared to a 6.5% response rate in the placebo group ( $p=0.0007$ ).

### Additional Viaskin Peanut Clinical Updates

In the fourth quarter of 2015, DBV expects to report the first year of follow-up data from the OLFUS-VIPES clinical trial, which is an extension trial for subjects having completed the VIPES trial, during which all patients are under active Viaskin Peanut treatment. The OLFUS-VIPES clinical trial includes 171 patients at 21 sites in North America and Europe, representing 83% of the patients who completed 12 months of therapy in the VIPES trial.

Clinical data from a National Institutes of Health sponsored study, CoFAR6, using Viaskin Peanut, is also expected to be reported in late 2015 or early 2016. This study may be important in describing the mechanism of action of epicutaneous immunotherapy (EPIT®) in humans.

#### About the VIPES Phase II Trial

In VIPES, a double-blind, placebo-controlled, multicenter Phase IIb clinical trial, 221 patients highly allergic to peanut were randomized to either a 50 µg, 100 µg or 250 µg peanut protein dose of Viaskin Peanut versus placebo. The trial was prospectively organized across the three dose levels with two patient strata composed of three different patient age groups; children (113 patients, ages 6-11) for the first stratum and adolescents (73 patients, ages 12-17) and adults (35 patients, ages 18-55) for the other stratum. Trial responders were defined as patients who, after 12 months of treatment with Viaskin Peanut and using a DBPCFC, reacted at a dose of peanut protein equal to or greater than 1,000 mg, or at least at a 10-fold higher eliciting dose of peanut protein compared to baseline. With Viaskin Peanut at the 250 µg dose, 53.6% of children responded to treatment compared to a 19.4% response in placebo (p=0.008). The compliance rate was more than 95% across all cohorts, dropout for related adverse events less than 1%, and there were no serious adverse events and no epinephrine injection related to treatment.

#### About DBV Technologies

DBV Technologies is developing Viaskin®, an innovative new approach to the treatment of allergies – a major public health issue that has been increasing in prevalence. DBV Technologies, incorporated in France in 2002, has developed a proprietary, patented technology for administering an allergen to intact skin while avoiding transfer to the blood, and thus lowering the risk of a systemic, allergic reaction in the event of accidental exposure. DBV Technologies is focusing on food allergies, including milk and peanut, for which there are currently no effective treatments. DBV Technologies has designed two products candidates: Viaskin® Peanut and Viaskin® Milk. The clinical development program for Viaskin® Peanut has received Fast Track designation and Breakthrough Therapy designation from the U.S. Food and Drug Administration.

DBV Technologies shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345) and on the Nasdaq Stock Market in the form of American Depositary Shares (each representing one-half of one ordinary share) (Ticker: DBVT). For more information on DBV Technologies, please visit our website: [www.dbv-technologies.com](http://www.dbv-technologies.com)

#### Forward Looking Statements

This press release contains forward-looking statements, including statements about the potential safety and efficacy of Epicutaneous Immunotherapy (EPIT®) via Viaskin® Peanut and DBV's anticipated clinical development of Viaskin Peanut and other product candidates. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. The Company's product candidates have not been approved for sale in any jurisdiction. Among the factors that could cause actual results to differ materially from those described or projected herein are uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, the risk that historical preclinical results may not be predictive of future clinical trial results, and the risk that historical clinical trial results may not be predictive of future trial results. 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, 2014 and future filings and reports by the Company. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release, whether as a result of new information, future events or circumstances or otherwise.



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