

Press Release

Montrouge, France, November 14, 2017

DBV Technologies Announces Publication of Positive Data from Phase IIb Trial and Long-Term Study of Viaskin Peanut in the *Journal of the American Medical Association*

Primary endpoint of Phase IIb study was met after 12 months of treatment

Long-term extension data showed treatment benefit increases over time

Ongoing Viaskin Peanut Phase III program includes three global studies in children

DBV Technologies (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced that detailed results from the VIPES Phase IIb trial and the OLFUS-VIPES extension study of Viaskin Peanut in peanut-allergic patients were published in the *Journal of the American Medical Association* (JAMA). After 12 months, treatment with Viaskin Peanut 250 µg resulted in a statistically significant response rate compared to placebo, which was followed by an increase in the observed treatment effect during the extension study.

“Epicutaneous immunotherapy represents a new paradigm for how we can potentially treat peanut and other food allergies in a safe and effective way,” said **Dr. Hugh Sampson**, Chief Scientific Officer of DBV Technologies, the Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai, and the lead author of this manuscript. *“This first-ever publication of a large clinical trial of epicutaneous immunotherapy is a significant milestone, highlighting the potential for this new class of immunotherapy. With our ongoing comprehensive Phase III program in peanut-allergic children, we continue to expand our understanding of the long-term benefits of Viaskin Peanut.”*

VIPES was a 12-month dose-ranging trial designed to assess the efficacy and safety of Viaskin Peanut in 221 peanut-allergic patients six to 55 years of age. In this study, the primary efficacy endpoint, which was defined as the percentage of treatment responders for each active treatment group compared to placebo, was met with the 250 µg dose of Viaskin Peanut. Patients who completed VIPES were eligible to enroll in OLFUS-VIPES, a 24-month, open-label extension study assessing the long-term benefit of Viaskin Peanut.

In VIPES, the greatest treatment benefit was observed in children (ages six to 11) treated with Viaskin Peanut 250 µg compared to placebo (response rate of 53.6% vs. 19.4%, p=0.008). A statistically significant improvement in the Cumulative Reactive Dose (CRD), which measures

threshold reactivity to peanut protein during the double-blind, placebo-controlled food challenge (DBPCFC), was also observed compared to placebo ($p < 0.001$). At month 12, children treated with Viaskin Peanut 250 μg achieved an increase in CRD of 1,121.0 mg from baseline compared to an increase in CRD of 60.8 mg from baseline in the placebo arm. In this subgroup, treatment benefit also continued to increase over time, with 83.3% of patients responding to Viaskin Peanut 250 μg after a total of 36 months compared to 53.6% at the end of 12 months. For 36 months, overall patient compliance was maintained above 95%, and favorable safety and tolerability profiles were observed throughout both studies.

A global Phase III program was launched following the positive results from VIPES. Two Phase III long-term studies in children ages four to 11 are ongoing, as well as a Phase III trial in children one to three years of age.

Topline results from VIPES and OLFUS-VIPES were announced in September 2014 and October 2016, respectively. The long-term data from the studies were presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in March 2017. The publication, entitled "Effect of Varying Doses of Epicutaneous Immunotherapy vs Placebo on Reaction to Peanut Protein Exposure Among Patients with Peanut Sensitivity: A Randomized Clinical Trial," has been published online in [JAMA](#): Volume 318, Number 18.

About VIPES

The VIPES (Viaskin Peanut's Efficacy and Safety) trial was a double-blind, placebo-controlled, multi-center clinical trial conducted at 22 sites in North America and Europe. 221 peanut-allergic subjects were randomized 1:1:1:1 into four treatment arms to evaluate three doses of Viaskin Peanut, 50 μg , 100 μg and 250 μg , compared to placebo. Each patient underwent two DBPCFCs: one at screening and one after 12 months of treatment. The challenge was halted once the subject exhibited an objective allergic symptom. Patients in VIPES received a daily application of the Viaskin Peanut patch over 12 months. Each patch was applied for 24 hours on the upper arm for adults (age 18-55) and adolescents (age 12-17) or on the back of children (age 6-11). The primary efficacy endpoint was the percentage of treatment responders for each active treatment group compared to placebo. Responders in the VIPES trial were defined as patients with a peanut protein eliciting dose equal to or greater than 1,000 mg peanut protein or with a greater than 10-fold increase of the eliciting dose compared to their baseline eliciting dose.

About OLFUS-VIPES

OLFUS-VIPES (Open-Label Follow-Up Study-Viaskin Peanut's Efficacy and Safety), or OLFUS, enrolled 171 patients who had previously received either placebo or one of three 12-month dose regimens administered during VIPES. During the first year of OLFUS, patients received a daily application of Viaskin Peanut 50 μg , 100 μg , or 250 μg . Within six months of OLFUS, according to a study protocol change implemented in March 2014, all patients received Viaskin Peanut 250 μg for the remainder of the study. All patients in OLFUS maintained a peanut-free diet during the study. Baseline response levels in OLFUS were based on the results of the last double-blind, placebo controlled food challenge (DBPCFC) in VIPES, and adjusted by the number of patients enrolling in OLFUS. Responders in the OLFUS trial were defined as patients with a peanut protein eliciting dose equal to or greater than 1,000 mg peanut protein or with a greater than 10-fold increase of the eliciting dose compared to their baseline eliciting dose observed in the VIPES study. Patients enrolled in OLFUS who received placebo in VIPES were analyzed separately from patients who initially received Viaskin Peanut. At month-24 in OLFUS, patients who were unresponsive to a cumulative dose above 1,044 mg were eligible to discontinue study drug for two months while maintaining a peanut-free diet. Patients who opted to enter into this additional period performed a DBPCFC at month-26 to assess durability of response.



About PEPITES

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

The last patient visit for PEPITES occurred in August 2017. During PEPITES, patients' response has been assessed using a double-blind, placebo controlled food challenge (DBPCFC). 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 eliciting dose (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, Cumulative Reactive Dose (CRD), has also been used 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.

About PEOPLE

PEPITES OPen Label Extension Study (PEOPLE) is a global, Phase III extension trial of Viaskin Peanut in 300 patients. After patients completed the 12-month placebo-controlled period in PEPITES, they were eligible to enroll in PEOPLE to receive up to 36 months of open-label treatment with Viaskin Peanut 250 µg. In the PEOPLE study, patients who were randomized to active treatment during PEPITES will receive Viaskin Peanut 250 µg for 24 additional months; patients who were previously receiving placebo during PEPITES will be treated with Viaskin Peanut 250 µg for 36 months.

About DBV Technologies

DBV Technologies is developing Viaskin®, a 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 study 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 New York, NY. Company shares are traded on segment A of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and traded on the Nasdaq Global Select 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

Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding the potential of Viaskin Peanut and the anticipated timing of data from the PEPITES clinical trial. 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 and the risk that historical clinical results in one patient population may not be predictive of future clinical trial results in different patient populations. 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, 2016 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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