Additional Phase IIb Trial Results with Viaskin Peanut Presented at the 2016 AAAAI Meeting Continue to Support Treatment Safety, Efficacy and Compliance

DBV Technologies (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced that results from the OLFUS-VIPES trial were presented at the 2016 AAAAI meeting in Los Angeles, California. During the late-breaking oral session Clinical/Translational Sciences, Dr. Hugh Sampson, Principal Investigator of the OLFUS-VIPES study, presented data that continued to support the favorable safety, efficacy and tolerability of Viaskin Peanut in peanut allergic patients.

OLFUS-VIPES is the ongoing, open-label, two year follow-up study of VIPES, the company’s Phase IIb clinical trial of Viaskin® Peanut. DBV reported positive topline results for OLFUS-VIPES in October 2015, and presented additional data at the 2016 AAAAI meeting.

Clinical trial results continued to support the safety and tolerability profile of Viaskin® Peanut. There were no treatment-related serious adverse events observed during the trial nor use of epinephrine associated with treatment. No trial participant drop-outs due to drug-related adverse events were reported. The majority of adverse events were mild and moderate, consisting primarily of application site symptoms, with frequency decreasing over time. Additionally, high treatment adherence was also observed – a compliance rate of more than 96% across all cohorts was reported.

Dr. Sampson also showed during his presentation that 80% of children ages six to 11 years responded to Viaskin Peanut 250 µg in the trial. After 24 months, the average cumulative reactive dose (CRD) in this treatment group was 1,883 mg (1,440 mg median) peanut protein compared to 84 mg (44 mg median) at baseline. A doubling in response rates at 1,000 mg or more during the oral food challenge was observed during the second year of treatment in children dosed with Viaskin Peanut 250 µg, which increased to 60%. For reference, one peanut contains approximately 250 mg of peanut protein.
Dr. Hugh Sampson, Director of the Jaffe Food Allergy Institute at the Kravis Children’s Hospital at Mount Sinai; Principal Investigator of the OLFUS-VIPES study; and Chief Scientific Officer, DBV Technologies, said: "Data from OLFUS-VIPES support an increase in treatment response over time. Patients were highly motivated and we saw excellent treatment compliance and no treatment-related dropouts. I believe this is a unique feature of Viaskin Peanut, which continues to show a strong safety profile," said Dr. Sampson. “We also continue to observe a significant increase in the level of peanut protein consumed by patients that have been treated for two years”

Chosen by AAAAI as a late-breaking presentation, in "Enhanced Efficacy and Confirmed Safety of a Two-Year Epicutaneous Immunotherapy (EPIT®) Treatment of Peanut Allergy with Viaskin® Peanut: The Continuation of the VIPES Phase IIb Randomized Controlled Trial" Dr. Sampson concluded that Viaskin® Peanut continued to demonstrate a favorable safety profile along with an observed increase in treatment response over time. The open-label extension included 171 subjects from the VIPES Phase IIb clinical trial, who transitioned to the 250 µg dose of Viaskin® Peanut during OLFUS-VIPES.

Viaskin was also observed to maintain response rates in adolescents and adults over time. Based on these results, DBV intends to explore additional Viaskin Peanut dose regimens in populations not included in the ongoing Phase III trial, which is studying Viaskin Peanut in children four to 11 years of age.

Other DBV Technologies Presentations at AAAAI

Two additional oral presentations at the AAAAI meeting featured new clinical data with Viaskin® Peanut. Presented by investigators from the Consortium of Food Allergy Research (CoFAR) funded by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIH), results from the CoFAR6 study showed that treatment with Viaskin® Peanut was observed to be safe and well-tolerated, and it led to statistically significant desensitization compared to placebo. The data showed that cohorts treated with both Viaskin Peanut 100 µg (p=0.005), and Viaskin Peanut 250 µg (p=0.003) met the primary endpoint in all populations, with an enhanced treatment response observed in children four to 11 years of age.

An oral presentation and seven poster sessions highlighting the use of Epicutaneous Immunotherapy (EPIT) were also featured during the AAAAI meeting. Clinical data from Viaskin Milk in cow’s milk allergic patients was highlighted in a poster session and several mechanistic models showing EPIT’s novel mechanism of action were also showcased.

About OLFUS-VIPES Section

OLFUS enrolled 171 subjects who had previously received either placebo or one of three 12-month dose regimens administered during VIPES. During the first year of OLFUS, patients were to receive a daily application of Viaskin® Peanut 50 µg or Viaskin® Peanut 100 µg or Viaskin® Peanut 250 µg for 12 months. According to a study protocol change implemented in March 2014, all patients were switched to receive Viaskin® Peanut 250 µg during OLFUS. 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. As in VIPES, a responder in the OLFUS trial was defined as a subject who could reach a peanut protein eliciting dose equal to or greater than 1,000 mg peanut protein during the 12-month DBPCFC or a subject with a ≥10-fold increase of the eliciting dose compared to the initial eliciting dose after 12 months of treatment. Patients enrolled in OLFUS who received placebo in VIPES were analyzed separately from subjects who initially received Viaskin® Peanut.

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

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. 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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