DBV Technologies Announces Presentation from NIAID-sponsored CoFAR6 Phase II Trial Reaffirming Viaskin® Peanut Safety and Efficacy

Results Presented at the AAAAI Meeting Showed CoFAR6 Met Primary Endpoint, With a Strong Response Observed in Children

Early Mechanistic Results are In-Line with DBV’s Preclinical Findings

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced the presentation of results from CoFAR6, a Consortium of Food Allergy Research (CoFAR) study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), showing that treatment with Viaskin® Peanut was observed to be safe and well-tolerated, and led to statistically significant desensitization in trial subjects. The 52-week CoFAR6 results were highlighted during two oral presentations at the 2016 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in Los Angeles, CA.

“We are thankful for NIAID’s support of our approach to finding a potential treatment for peanut allergy. CoFAR6 provides us with additional, independent confirmation of our own Viaskin Peanut Phase IIb findings, while also increasing our understanding of the mechanism of action of epicutaneous immunotherapy, which we believe is a potential patient-centered solution for those suffering from food allergies,” said Dr. Pierre-Henri Benhamou, Chairman and Chief Executive Officer of DBV Technologies. “We especially want to thank the patients and their caretakers, as well as the clinicians who participated in CoFAR6, and we continue to be enthusiastic about our ongoing Viaskin Peanut Phase III trial in children.”

The Viaskin Peanut patch is DBV Technologies’ lead product candidate, based on epicutaneous immunotherapy (EPIT®), a proprietary technology platform that can deliver biologically active compounds to the immune system through the immune cells of intact skin.

NIAID-sponsored CoFAR6 is a multi-center, randomized, double-blind, placebo-controlled trial in peanut allergic patients using DBV’s Viaskin Peanut as active treatment. Findings from this study are consistent with clinical data trends previously observed in DBV’s Phase IIb trial, VIPES, and Assistance Publique - Hôpitaux de Paris’ Phase II study, ARACHILD. During the “Epicutaneous Peanut to Treat Peanut Allergy” presentation, Stacie M. Jones, MD, Professor of Pediatrics, University of Arkansas for Medical Sciences, Arkansas Children’s’ Hospital, Little Rock, AR, reviewed CoFAR6 trial data in which Viaskin Peanut was observed to be safe and well-tolerated across treatment groups, with no serious
adverse events (SAEs) or epinephrine use related to treatment observed. Treatment adherence was high (97.1%), dropouts were low (8%), and no withdrawals occurred in the 250 µg treatment group. Cohorts treated with both Viaskin Peanut 100 µg (P=0.005), and Viaskin Peanut 250 µg (P=0.003) met the primary efficacy endpoint in all populations. The treatment response was enhanced in children four to 11 years of age, and also, with Viaskin Peanut 250 µg compared to Viaskin Peanut 100 µg.

Following Dr. Jones’ presentation, Dr. Cecilia Berin, Associate Professor Pediatrics, Mount Sinai Hospital in New York, NY, who also participated in the CoFAR6 study, presented “Insights from New Mechanistic Studies on Food Allergy”, which explored T cell profiling of peanut allergic patients. In Dr. Berin’s presentation, early findings from CoFAR6 support Viaskin Peanut’s mechanistic features that have been observed at the preclinical level. Viaskin Peanut at the 250 µg dose showed a trend of decreased Th2 cell frequency, without any increased trends in the Th1 response. In animal models, DBV has observed that Viaskin’s unique mechanism of action could rebalance the immune reaction by down-regulating the Th2 response to allergens while keeping Th1 responses balanced.

About the CoFAR6 Study

In October 2013, CoFAR launched a multi-center, randomized, double-blind, placebo-controlled trial to evaluate Viaskin Peanut in children, adolescents and young adults allergic to peanuts. This trial is sponsored and funded by the NIAID and coordinated by Dr. Stacie Jones. The CoFAR6 trial is being conducted in five hospitals in the United States, and 75 patients were enrolled; 54 children four to 11 years of age and 21 adolescents and adults 12 to 25 years of age. In CoFAR6, subjects were randomized 1:1:1 to two doses of Viaskin Peanut (100 µg and 250 µg) or placebo. The primary outcome measure was percent of patients desensitized to peanut protein during peanut protein oral food challenge (OFC) at week 52. Responders were characterized as patients who successfully passed a 5044 mg OFC or who successfully consumed a dose ten times greater as compared to baseline.

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 product 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 that 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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