DBV Technologies to Present New Clinical Data from Viaskin Platform at the 2018 EAACI Meeting

Results from positive Phase II study of second product candidate, Viaskin Milk, to be presented as a late breaking oral abstract

Seven abstracts accepted, including additional data from Viaskin Peanut program

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that seven abstracts, including three clinical data presentations from Phase III and Phase II studies of Viaskin Peanut, were accepted for oral and poster presentation at the 2018 European Academy of Allergy and Clinical Immunology (EAACI) Annual Meeting in Munich, Germany, May 26-30, 2018. All abstracts will be available on the EAACI meeting website on May 26, 2018.

In addition to data from Viaskin Peanut, detailed results from the MILES Phase II trial, a dose-finding trial of Viaskin Milk, will be presented during the Late Breaking Oral Abstract Session on Sunday, May 27. Topline results from MILES, which evaluated the safety and efficacy of three dose regimens of Viaskin Milk in children and adolescents with IgE-mediated cow’s milk protein allergy (CMPA), were previously announced in February 2018. Viaskin Milk is the company’s second product candidate based on its proprietary epicutaneous immunotherapy (EPIT) platform, which aims to deliver biologically active compounds to the immune system through the skin.

“Following completion of our Phase III program for Viaskin Peanut in 2017, we continue progressing toward our goal of bringing the first peanut allergy treatment to patients, and we are excited to continue adding to the body of clinical evidence supporting the potential benefit of Viaskin Peanut at this year’s EAACI meeting,” said Dr. Hugh Sampson, Chief Scientific Officer of DBV Technologies and Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai. “We will also present new data from Viaskin Milk, underscoring the potential of the Viaskin platform technology and our commitment to improving the lives of patients with food allergies.”
Additional abstracts to be presented at the meeting include three research presentations on EPIT mechanistic data.

Peanut Allergy Data

- “Quantitative Risk Reduction Through Peanut Immunotherapy: Assessment for the Peanut-Allergic Population Undergoing Epicutaneous Immunotherapy (EPIT)” will be presented by Dr. Benjamin Remington, TNO, Ziest, The Netherlands.
  - Oral Presentation
  - Session Title: OAS 20 – Management of Food Allergy
  - Date/Time: Monday, May 28 / 15:45 to 17:15 CEST
  - Location: Hall 13b

- “Sustained Unresponsiveness Following Long Term Epicutaneous Immunotherapy (EPIT) with VIASKIN® Peanut: Results of the OLFUS-VIPES Phase IIb Study” will be presented by Dr. Terri Brown-Whitehorn, Children’s Hospital of Philadelphia, Philadelphia, PA, USA.
  - Poster Presentation
  - Session Title: PDS 19 - Management of Food Allergy
  - Date/Time: Monday, May 28 / 15:45 to 17:15 CEST
  - Location: Poster Discussion Zone 2

- “Biomarker Assessment After 12 Months of Peanut Epicutaneous Immunotherapy (EPIT) for Peanut Allergy” will be presented by Dr. Matthew Greenhawt, Children’s Hospital Colorado, Aurora, CO, USA.
  - Poster Presentation
  - Session Title: PDS 19 - Management of Food Allergy
  - Date/Time: Monday, May 28 / 15:45 to 17:15 CEST
  - Location: Poster Discussion Zone 2

Milk Allergy Data

- “A Double-Blind, Placebo-Controlled Phase I/II Dose-Finding Study of Viaskin Milk in Children and Adolescents for the Treatment of IgE-Mediated Cow’s Milk Protein Allergy (CMPA): Results from MILES” will be presented by Dr. Robert Wood, Johns Hopkins University, Baltimore, MD, USA.
  - Oral Presentation
  - Session Title: LB OAS – New Frontiers in Allergen Immunotherapy
  - Date/Time: Sunday, May 27 / 15:30 to 17:00 CEST
  - Location: Hall 2

EPIT Mechanism of Action Research

- “Sustained Gata3 Hypermethylation in Th2 cells and Foxp3 Hypomethylation in CD62L+ Tregs Following EPIT in Peanut-Sensitized Mouse Model” will be presented by Dr. Jorg Tost, CEA - Institut de Génomique, CNG, Evry, France.
  - Poster Presentation
  - Session Title: PDS 04 – Immunological Responses to Allergen Immunotherapy
  - Date/Time: Sunday, May 27 / 10:30 to 12:00 CEST
  - Location: Poster Discussion Zone 4
• “Specific miRNA Expression Changes Influencing T cell Plasticity and Th2 Cytokine Production in a Mouse Model of Peanut Sensitized Mice Treated with Epicutaneous Immunotherapy” will be presented by Dr. Jorg Tost, CEA - Institut de Génomique, CNG, Evry, France.
  o Poster Presentation
  o Session Title: PDS 04 – Immunological Responses to Allergen Immunotherapy
  o Date/Time: Sunday, May 27 / 10:30 to 12:00 CEST
  o Location: Poster Discussion Zone 4

• “Preexisting Humoral Immunity Facilitates Antigen Capture by Skin DC Upon Epicutaneous Administration and Enhances Their Migration to Local Lymph Nodes” will be presented by Dr. Pierre-Louis Hervé, DBV Technologies.
  o Poster Presentation
  o Session Title: PDS 04 – Immunological Responses to Allergen Immunotherapy
  o Date/Time: Sunday, May 27 / 10:30 to 12:00 CEST
  o Location: Poster Discussion Zone 4

About the MILES Study

The Viaskin Milk Efficacy and Safety (MILES) trial is a multi-center, double-blind, placebo-controlled, randomized Phase I/II trial to study the safety and efficacy of Viaskin Milk conducted at 17 sites in North America. The study was divided into two consecutive parts. Part A of the MILES trial was completed with no safety concerns. Part B was designed to determine a safe and effective dose in two age groups: children ages two to 11 and adolescents ages 12 to 17 with IgE-mediated cow’s milk protein allergy, or CMPA.

198 patients (18 patients from Part A and 180 patients from Part B) were randomized 1:1:1:1 into four treatment arms to evaluate three doses of Viaskin Milk, 150 μg, 300 μg and 500 μg, compared to placebo. Each patient underwent a DBPCFC at screening and after 12 months of treatment. The challenge was halted once the patient exhibited an objective allergic symptom. Patients in MILES received a daily application of the Viaskin Milk patch over 12 months. Each patch was applied for 24 hours on the back of children (age 2-11) or on the upper arm for adolescents (age 12-17).

The primary efficacy endpoint was the percentage of treatment responders for each active treatment group compared to placebo. Responders at month-12 were defined as patients with either 1) a cow’s milk protein CRD equal to or greater than 1,444 mg (approximately 45 mL of milk) or 2) a 10-fold or greater increase in CRD compared to baseline and at least 144 mg cow’s milk protein (approximately 4.5 mL of milk).

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. The Company’s ordinary shares are traded on segment A of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, 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 potential of Viaskin Peanut and Viaskin Milk and of the Company’s and clinical development and regulatory plans regarding Viaskin Peanut and Viaskin Milk. 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, the risk that results of historical clinical trials will not be replicated in future clinical trials 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, 2017 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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