

Press Release

Montrouge, France, February 10, 2017

## DBV to Present Data at the 2017 AAAAI Meeting Highlighting the Therapeutic Potential of EPIT®

Eight abstracts, including detailed two-year follow-up data to the VIPES Phase IIb trial supporting the long-term efficacy and safety of Viaskin Peanut for the treatment of peanut allergy, will be presented during the meeting

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), today announced that eight abstracts, seven of which will highlight data from the company's Viaskin technology platform, were accepted for oral and poster presentation at the 2017 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in Atlanta, Georgia, March 3-6, 2017. These abstracts became available on the AAAAI meeting website at 9:30 AM CT on February 10 <http://annualmeeting.aaaai.org/>.

Detailed results from the OLFUS-VIPES trial, which followed patients for a total of 36 months, will be presented during the Late Breaking Oral Abstract Session on Sunday, March 5. Topline results from OLFUS-VIPES, which evaluated the long-term efficacy and safety of Viaskin Peanut for the treatment of peanut-allergic children, were previously announced in October 2016. Viaskin Peanut is the company's lead product candidate based on its proprietary EPIT platform, which aims to deliver biologically active compounds to the immune system through the skin, and is currently being evaluated in a global, pivotal Phase III program in peanut-allergic children 4 to 11 years of age.

*"The long-term clinical data we are presenting at AAAAI provide further insight into the promise of Viaskin Peanut as a potential treatment option for peanut-allergic children," said Dr. Lucia Septián, Chief Medical Officer of DBV Technologies. "These detailed results, combined with pre-clinical data that will be presented at the meeting, also underscore the tremendous potential of EPIT to help address a wide range of unmet medical needs."*

Additional abstracts to be presented at the meeting include two pre-clinical studies, which tested the therapeutic potential of EPIT in type 1 diabetes and in the vaccination against respiratory syncytial virus (RSV).

Selected abstracts of interest:

### Peanut Allergy Data

- *"Efficacy and Safety of Long-Term Epicutaneous Immunotherapy (EPIT) Treatment of Peanut Allergy with Viaskin® Peanut: Results of the Two-Year Extension of the VIPES Phase IIb Clinical*

*Trial*” will be presented by Dr. Wayne G. Shreffler, Division of Allergy and Immunology, Department of Pediatrics, Massachusetts General Hospital, Harvard Medical School.

- *Oral Presentation*
- *Session Number: 3611*
- *Poster Number: L7*
- *Session Title: Late Breaking Oral Abstract Session: Clinical/Translational Science*
- *Date/Time: Sunday, March 5 / 2:15 PM to 2:30 PM*

## FARRP (Food Allergy Research & Resource Program) Data

- *“Increasing Clinical Peanut Thresholds Through Immunotherapy: Quantitative Assessment of the Safety Benefits Associated with Achieving a 300 or 1000 mg Peanut Protein Threshold”* will be presented by Dr. Joseph L. Baumert, Food Allergy Research and Resource Program, University of Nebraska-Lincoln.
  - *Oral Presentation*
  - *Session Number: 3604*
  - *Poster Number: 561*
  - *Session Title: Immunotherapy for Food Allergy*
  - *Date/Time: Sunday, March 5 / 2:45 PM to 3:00 PM*

## RSV Data

- *“Preclinical evaluation of a novel non-invasive epicutaneous vaccine against respiratory syncytial virus”* will be presented by Dr. Pierre-Louis Hervé, DBV Technologies.
  - *Session Number: 3802*
  - *Poster Number: 589*
  - *Session Title: Immunotherapy: How to Reprogram the Immune System*
  - *Date/Time: Sunday, March 5 / 4:45 PM to 6:15 PM*

## Type 1 Diabetes Data

- *“EPIT decreases T1D incidence in sensitized non obese diabetic mice: a likely bystander effect of EPIT-induced Tregs”* will be presented by Dr. Benjamin Pelletier, DBV Technologies.
  - *Poster Session*
  - *Session Number: 2203*
  - *Poster Number: 52*
  - *Session Title: Immune Modulation*
  - *Date/Time: Saturday, March 4 / 9:45 AM to 10:45 AM*

## EPIT Mechanism of Action Research

- *“Treatment of eosinophilic gastritis by Epicutaneous Immunotherapy (EPIT) in peanut allergic piglets”* will be presented by Dr. Lucie Mondoulet, DBV Technologies.
  - *Poster Session*
  - *Session Number: 2208*
  - *Poster Number: 153*
  - *Session Title: Eosinophilic Gastrointestinal Disorders and Non-IgE Mediated Food Allergy*

- *Date/Time:* Saturday, March 4 / 9:45 AM to 10:45 AM
- ***“Allergen Capture by DCs during Epicutaneous Immunotherapy is Enhanced by Modulating the Dose and the Surface Area of the Patch”*** will be presented by Dr. Sophie Wavrin, DBV Technologies.
  - *Poster Session*
  - *Session Number:* 4210
  - *Poster Number:* 806
  - *Session Title:* Allergen Extracts and Other Forms of Immunotherapy
  - *Date/Time:* Monday, March 6 / 9:45 AM to 10:45 AM
- ***“Crucial Role of Langerhans Cells in Allergen Uptake and Regulatory T Cell Induction in Epicutaneous Immunotherapy”*** will be presented by Dr. Vincent Dioszeghy, DBV Technologies.
  - *Poster Session*
  - *Session Number:* 4210
  - *Poster Number:* 805
  - *Session Title:* Allergen Extracts and Other Forms of Immunotherapy
  - *Date/Time:* Monday, March 6 / 9:45 AM to 10:45 AM
- ***“Foxp3+ CD62L+ Tregs induced by EPIT have the potency to suppress effector T cells proliferation in specific and bystander conditions”*** will be presented by Dr. Benjamin Pelletier, DBV Technologies.
  - *Session Number:* 4210
  - *Poster Number:* 801
  - *Session Title:* Allergen Extracts and Other Forms of Immunotherapy
  - *Date/Time:* Monday, March 6 / 9:45 AM to 10:45 AM

Full data will be shared following embargo lift; at the time the studies are presented. All abstracts are available online at <http://annualmeeting.aaaai.org/>, and will also be published in a supplement to the February *Journal of Allergy and Clinical Immunology (JACI)* at <http://www.jacionline.org/>.

#### **About the PEPITES Study**

The Peanut EPIT Efficacy and Safety Study (PEPITES) is 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. During PEPITES, patients' response will be assessed using a double-blind, placebo controlled food challenge (DBPCFC). Patients are randomized 2:1 to receive either Viaskin Peanut 250 µg or placebo for 12 months. The primary endpoint is 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 is 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 is 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), will also be 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 will also be measured at baseline, 3, 6, and 12 months in order to characterize the immunological changes in patients.

Following the completion of PEPITES, all patients are eligible to rollover into PEOPLE, a long-term, open-label extension study of Viaskin Peanut 250 µg. In the PEOPLE study, patients who were randomized to active treatment during PEPITES will receive Viaskin Peanut 250 µg for two additional years; patients who were previously receiving placebo during PEPITES will be treated with Viaskin Peanut 250 µg for three years.



Patients enrolling in the PEOPLE study will remain blinded to their respective treatment group in PEPITES until the PEPITES study results become publicly available.

#### About the REALISE Study

REALISE is a multicenter, randomized, double-blind, placebo-controlled Phase III study designed to assess the use of Viaskin Peanut 250 µg in routine medical practice and generate safety data after six months of blinded treatment in patients four to 11 years of age. At the six-month time point, patients in both the placebo and active arms will be able to opt into an open-label portion of the study, which will continue monitoring patients for a total of 36 months of active treatment. Exploratory criteria will also include scores from subjects' Food Allergy Quality of Life Questionnaire (FAQLQ) and the Food Allergy Independent Measure (FAIM), as well as the evolution of peanut-specific serological markers over time. The study is expected to be conducted in approximately 30 to 40 centers in North America. No oral food challenges are required in REALISE. Patients in the study will be selected based on a well-documented medical history of IgE-mediated reactions to peanut, including children with a history of severe anaphylaxis, as well as analyses of peanut-specific immunological markers. During the first six months of trial, patients will be randomized 3:1 active versus placebo. Key assessments of safety parameters will include treatment-emergent adverse events observed in both the placebo and active treatment groups after the initial 6 months, which will continue to be monitored during the open-label portion of the study. DBV intends to enroll approximately 335 subjects in REALISE.

#### About the OLFUS-VIPES Study

OLFUS-VIPES (Open-Label Follow-Up Study-Viaskin Peanut's Efficacy and Safety), or 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. 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 subjects 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 subjects who initially received Viaskin Peanut. At month 24 in OLFUS, patients who were unresponsive to a cumulative dose above 1,440 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 DBV Technologies

DBV Technologies is developing Viaskin<sup>®</sup>, a proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT<sup>®</sup>, 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](http://www.dbv-technologies.com)

#### Forward Looking Statements



This press release contains forward-looking statements, including statements regarding the potential safety and efficacy of Viaskin Peanut and statements reflecting management's expectations for clinical development of our product candidates and the commercial potential of our product candidates. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. 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 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, 2015 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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