

Press Release

Montrouge, France, November 8, 2016

## DBV Technologies Completes Enrollment of Phase II Study of Viaskin Milk for the Treatment of Milk Allergic Patients

Most advanced product candidate for the treatment of IgE-mediated cow's milk allergy in development today

FDA Fast Track designation for Viaskin Milk was granted in September 2016

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), today announced that enrollment for Part B, or Phase II, of the Phase I/II study of Viaskin Milk for the treatment of patients with IgE-mediated cow's milk protein allergy (CMPA) has been completed. The MILES trial is evaluating the efficacy and safety of Viaskin Milk in desensitizing children two to 17 years of age suffering from CMPA. The Viaskin Milk patch is based on DBV's epicutaneous immunotherapy (EPIT), a proprietary technology platform that can deliver biologically active compounds to the immune system through the skin. The blinded part of the MILES study is expected to complete in the second half of 2017.

No safety concerns were observed during Part A of the MILES Study (Phase I), for which study results were presented at the 2016 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in Los Angeles, CA, on March 6, by Karine Rutault, Director, Clinical Projects, DBV Technologies. In Phase II, or Part B of the MILES study, a total of 283 patients were screened. The Company expects approximately 176 children with IgE-mediated CMPA will be randomized 1:1:1:1 to receive one of the three doses of Viaskin Milk (150 µg, 300 µg, 500 µg) or placebo for 12 months.

*"This is an important milestone for the treatment of pediatric CMPA, a disease affecting millions of patients worldwide, who are often times at risk of experiencing life-threatening reactions to undetectable traces of cow's milk protein in their everyday lives,"* said **Dr. Anna Nowak-Wegrzyn**, Associate Professor, Pediatrics, Allergy and Immunology at Jaffe Food Allergy Institute, Mount Sinai School of Medicine in New York and the Principal Investigator of the MILES trial at Mount Sinai Medical Center. *"CMPA is one of the most common food allergies in children today and we look forward to seeing the results from this groundbreaking trial. Viaskin Milk, if proven safe and effective in clinical trials, could be the first product candidate to offer a potential treatment option for these patients, if approved."*

### 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 in pediatric patient populations (age two to 17) suffering from IgE-mediated cow's milk protein allergy, or CMPA, with elevated IgE levels related to



cow's milk protein. The trial is being conducted in select U.S. and Canadian clinical centers. Part A of the MILES trial has been completed with no safety concerns. Approximately 194 subjects are expected to be randomized for treatment at 17 sites, including 18 subjects from Part A and 176 subjects from Part B, under the proposed amended MILES Part B protocol. Eligible subjects with confirmed IgE-mediated CMPA will perform an initial food challenge at screening with escalating doses of cow's milk proteins. Subjects who display objective symptoms of an allergic response to an eliciting dose of 300 mg cow's milk proteins (approximately 9.4 mL of cow's milk) or below will be randomized in the trial. The primary efficacy endpoint will be the percentage of subjects who are treatment responders after 12 months, defined as subjects who meet at least one of the following criteria: (1) a 10-fold or greater increase in the cumulative reactive dose, or CRD, of cow's milk proteins at month 12 of the food challenge as compared to baseline value in addition to reaching tolerance to at least 144 mg of cow's milk protein (approximately 4.5 mL of milk) or (2) a CRD of cow's milk protein greater than or equal to 1,444 mg (approximately 45 mL of milk) at month 12 of the food challenge. Secondary efficacy endpoints include, among others, the percentage of subjects who are treatment responders at month 24, the mean and median CRD of cow's milk proteins at months 12 and 24 as well as the change in CRD from baseline, the change from baseline in the severity of symptoms elicited during the food challenge from baseline to months 12 and 24, and the change from baseline in quality of life assessments at months 12 and 24.

#### About Viaskin Milk

Viaskin Milk is an investigational therapy in development for the treatment of pediatric cow's milk protein allergy (CMPA) and Eosinophilic Esophagitis (EoE). The Viaskin Milk patch is based on epicutaneous immunotherapy (EPIT), a proprietary technology platform that can deliver biologically active compounds to the immune system through intact skin without allowing compound passage into the blood.

#### About Cow's Milk Protein Allergy

Cow's milk protein allergy (CMPA) is the most common food allergy in infants and young children, affecting 2% to 3% of the general population. Symptoms can include gastrointestinal problems such as vomiting and diarrhea, skin rash, angioedema or rapid swelling of the skin, and anaphylaxis. The only option available for CMPA management is the avoidance of cow's milk, which can lead to issues of dietary imbalance, failure to thrive and poor quality of life.

#### 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 B 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 Milk and statements reflecting management's expectations for clinical development of Viaskin Milk and the commercial potential of Viaskin Milk. 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.

#### **DBV Technologies Contact**

##### **Susanna Mesa**

Senior Vice President, Strategy

+1 212-271-0861

[susanna.mesa@dbv-technologies.com](mailto:susanna.mesa@dbv-technologies.com)

#### **Media Contact**

##### **Erinn White, Centron PR**

+1-646-722-8822

[ewhite@centronpr.com](mailto:ewhite@centronpr.com)

#### **Media Contact Europe**

##### **Caroline Carmagnol, Alize RP, Relations Presse**

+33 (0)6 64 18 99 59

[caroline@alizerp.com](mailto:caroline@alizerp.com)