

Press Release

Montrouge, France, September 21, 2016

## DBV Technologies Receives FDA Fast Track Designation for Viaskin Milk for the Treatment of Cow's Milk Protein Allergy

DBV first to announce Fast Track designation for IgE-mediated CMPA; Viaskin Milk is currently being investigated in a Phase IIb study

Second Fast Track designation for the Viaskin platform in food allergies reinforces DBV's commitment to improve the lives of food allergic patients

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for Viaskin Milk, the Company's investigational treatment for pediatric patients two years of age and older with Immunoglobulin E (IgE)-mediated cow's milk protein allergy (CMPA), currently under clinical investigation in a Phase IIb trial. There are currently no approved treatments for CMPA, the most common food allergy in infants and young children. Fast Track is a process designed by the FDA to facilitate the development, expedite the review of drugs to treat serious conditions and fill an unmet medical need.<sup>1</sup>

Chief Development Officer of DBV Technologies, **Laurent Martin**, said, *"This achievement reinforces our commitment to bringing novel therapies to food allergic patients. We are the first to announce Fast Track designation in this indication, and Viaskin Milk is DBV's second product candidate to secure an expedited review designation by the FDA."* **Mr. Martin** continued, *"CMPA is one of the most common food allergies in children, and a life-threatening disease for which there currently is no approved treatment, representing a major public health challenge. We look forward to working closely with the FDA throughout the development process of Viaskin Milk."*

Results from the ongoing Phase IIb portion of the Viaskin **MILk Efficacy and Safety (MILES)** Phase I/IIb study of Viaskin Milk in IgE-mediated CMPA children and adolescents ages two to 17 are expected in the second half of 2017. A Phase II clinical trial assessing Viaskin Milk for the treatment of milk allergy-induced Eosinophilic Esophagitis (EoE) in children ages four to 17 is also ongoing in collaboration with the Children's Hospital of Philadelphia.

*"This milestone underscores the high unmet need for patients suffering from CMPA. Viaskin Milk could potentially bring the first approved treatment to patients suffering from the debilitating burden of CMPA, and we welcome this FDA decision."* said **Alan Kerr**, Senior Vice President, Global Regulatory Affairs of DBV Technologies.



### 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 Eosinophilic Esophagitis

Eosinophilic Esophagitis (EoE) is an allergic inflammatory disease characterized by the swelling of the esophagus. Typical symptoms include vomiting, abdominal pain, regurgitation, dysphagia, and in young children and infants, feeding difficulties and failure to thrive. Because the diverse and non-specific symptoms, EoE can be diagnosed only by esophageal biopsy. In addition to presenting symptoms, acute and chronic complications that may arise if EoE remains untreated include food impaction, esophageal stricture, narrow-caliber esophagus, and esophageal perforation. It is estimated that EoE impacts one in every 2,000 children. EoE is considered to be a chronic condition with no currently approved treatments. Cow's Milk Protein Allergy (CMPA) is believed to be involved in a majority of cases of EoE in children, and therefore a cow's milk-free diet is often able to reduce EoE symptoms.

### 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 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 reflecting management's expectations for clinical development of our product candidates and the commercial potential of our product candidates generally. 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.

#### References

1. Food and Drug Administration. For Patients: Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review. Available at: <http://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm>. Accessed September 2016.

#### 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)