

**Press Release** 

Montrouge, France, February 3, 2017

# DBV Technologies Announces Completion of Enrollment of Phase IIA Study of Viaskin Milk for the Treatment of Pediatric Eosinophilic Esophagitis

SMILEE will evaluate the efficacy and safety of Viaskin Milk for the treatment of milk-induced EoE in children ages 4-17

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), today announced that enrollment in SMILEE (**S**tudy of Efficacy and Safety of the Viaskin **MIL**k in Milk-Induced **E**osinophilic **E**sophagitis in Children), a Phase IIA investigator-initiated clinical trial assessing the safety and efficacy of Viaskin Milk for the treatment of milk-induced Eosinophilic Esophagitis (EoE) in children ages 4-17 has been completed. In this study, 20 children with milk-induced EoE have been randomized 3:1 to receive Viaskin Milk 500 µg or placebo for up to 11 months. Results for the SMILEE study are expected in the first half of 2018.

"EoE is a progressive and chronic inflammatory disease that can be debilitating and painful for patients. Over the last decade, EoE has increased in incidence in the United States, but no FDA approved therapies are available for patients today. If left untreated, EoE may cause permanent and significant damage to the esophagus and gastrointestinal track," said **Dr. Antonella Cianferoni,** Assistant Professor of Pediatrics at Children's Hospital of Philadelphia (CHOP) and Principal Investigator of SMILEE. "In some instances, food-induced EoE can be caused by milk allergy, and we are eager to explore the safety and efficacy of Viaskin in treating these patients. We look forward to seeing if the encouraging preclinical results observed with Viaskin Milk in EoE can be replicated in this proof of concept Phase IIA trial."

The SMILEE trial is being conducted under an Investigational New Drug (IND) application held by Dr. Jonathan Spergel at Children's Hospital of Philadelphia (CHOP).

### **About the SMILEE Study**

SMILEE is a double-blind, placebo-controlled, randomized 3:1 trial designed to evaluate the safety and efficacy of Viaskin Milk 500 µg for treating milk-induced EoE in children. Subjects with a documented medical history of EoE after ingestion of milk who currently adhere to a strict milk-free diet will be considered for participation in the trial. In this study, 20 subjects, 15 in the active treatment group and five in the placebo group, were randomized and will be treated for nine months while remaining on a milk-free diet. The subjects will then continue their assigned treatment during a milk reintroduction period (1 week to 2 months), for a total of up to 11 months of treatment. The primary efficacy endpoint will evaluate the maximum esophageal eosinophil count in the active treatment group compared to placebo at the end of treatment. Secondary efficacy endpoints will include the change in symptoms score at the end of treatment compared to baseline and mean



esophageal eosinophil count at the end of treatment.

#### **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 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 of 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. EoE in children can be caused by cow's milk allergy (CMA), and therefore a cow's milk-free diet is often able to reduce EoE symptoms.

#### **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 selfadministered 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 onehalf 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, including statements regarding the potential safety and efficacy of Viaskin Milk for the treatment of Eosinophilic Esophagitis (EoE) 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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