DBV Technologies Announces Enrollment of First Patient in Phase IIA Study in Pediatric Eosinophilic Esophagitis

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

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced that the first patient has been enrolled in SMILEE (Study of efficacy and safety of the Viaskin® MILk in Milk-Induced Eosinophilic Esophagitis), a Phase IIA clinical trial assessing the safety and efficacy of Viaskin® Milk for the treatment of milk allergy-induced Eosinophilic Esophagitis (EoE) in children ages 4-17. 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. The SMILEE trial is conducted under an Investigational New Drug (IND) application held by Dr. Jonathan Spergel at The Children’s Hospital of Philadelphia.

It is estimated that EoE, a chronic disease, affects one in every 2,000 children. EoE is a serious condition, which causes the swelling of the esophagus triggering severe symptoms such as vomiting, abdominal pain, regurgitation, dysphagia, and in young children and infants, feeding difficulties and failure to thrive. Many studies suggest that food allergies are the main cause of EoE in children, including allergy to cow’s milk. If left untreated, EoE may cause acute and chronic complications including food impaction, esophageal stricture, narrow-caliber esophagus, and esophageal perforation.

Dr. Pierre-Henri Benhamou, Chairman and CEO of DBV Technologies, said: “The launch of SMILEE is yet another step forward in DBV’s commitment to improve the life of patients suffering from food allergies. EoE is a debilitating and painful condition, and while we are still learning about its long-term impact, if left untreated, EoE may cause permanent damage to the esophagus.” Dr. Benhamou continued, “With the epicutaneous approach, it is potentially the first time that Specific Immunotherapy can be used to switch off the process of eosinophilic infiltration responsible of EoE. This new concept has the potential to transform the management of the patients suffering from EoE.”
About 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. Approximately 20 subjects, 15 in the active treatment group and five in the placebo group, will be randomized and 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 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 Allergy (CMA) 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 created the Viaskin® patch, 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 while avoiding compound transfer to the blood. With this new class of self-administered and non-invasive product candidates, the company is dedicated to safely transforming the care of food allergy patients, for which there are currently no approved treatments. DBV’s food allergy programs include ongoing clinical studies with Viaskin Peanut and Viaskin Milk, one experimental program with Viaskin Egg and a human proof concept clinical study in Eosinophilic Esophagitis. DBV is also exploring platform indications in vaccines, and selected immune diseases with unmet medical needs.

DBV Technologies has global headquarters in Paris, France and New York, NY, USA. 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

Forward Looking Statements
This press release contains forward-looking statements, including statements about the potential safety and efficacy of Epicutaneous Immunotherapy (EPIT®) via Viaskin® Milk and DBV’s anticipated clinical development of Viaskin Milk and other product candidates. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. The Company’s product candidates have not been approved for sale in any jurisdiction. Among the factors that could cause actual results to differ materially from those described or projected herein are 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, 2014 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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