IND Acceptance from FDA for a proof-of-concept trial using Viaskin® Milk in Milk-Induced Eosinophilic Esophagitis in Children

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted an investigator-sponsored investigational new drug (IND) application for a Phase IIA clinical trial for the potential treatment of milk-induced eosinophilic esophagitis (EoE) in children using the Company’s Viaskin Milk. This IND acceptance enables Dr. Jonathan Spergel at The Children’s Hospital of Philadelphia to initiate SMILEE (Study Efficacy and Safety of the Viaskin® Milk in milk-induced Eosinophilic Esophagitis), a clinical trial designed to assess the efficacy and safety of Viaskin Milk in children four to 17 years of age suffering from milk-induced EoE. The SMILEE trial is expected to begin in the second half of 2015.

SMILEE is expected to be 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 treatment group and five in the placebo group, will be randomized and treated for nine months while remaining on a milk-free diet. The treatment group will then continue the trial 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 be evaluated as the maximum esophageal eosinophil count in the 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 a recently recognized allergic inflammatory disease, characterized by 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 is developing Viaskin®, an innovative new approach to the treatment of allergies – a major public health issue that has been increasing in prevalence. DBV Technologies, incorporated in France in 2002, has developed a proprietary, patented technology for administering an allergen to intact skin while avoiding transfer to the blood, and thus lowering the risk of a systemic, allergic reaction in the event of accidental exposure. DBV Technologies is focusing on food allergies, including milk and peanut, for which there are currently no effective treatments. DBV Technologies has designed two products candidates: Viaskin® Peanut and Viaskin® Milk. The clinical development program for Viaskin® Peanut has received Fast Track designation and Breakthrough Therapy designation from the U.S. Food and Drug Administration.

DBV Technologies shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345) and on the Nasdaq Stock 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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