



## DBV Technologies Announces Clinical Trial Agreement to Develop a Treatment for Milk-Induced Eosinophilic Esophagitis in Children

**BAGNEUX, France, May 13, 2014** - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin<sup>®</sup>, a new paradigm for the treatment of allergies, announced today signing a clinical agreement with Dr. Jonathan Spergel at The Children's Hospital of Philadelphia to conduct a clinical trial on the development of Viaskin Milk in milk-induced eosinophilic esophagitis (EoE).

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. When the diagnosis is established, it is important to treat the disease not only to control the presenting symptoms, but also to prevent acute and chronic complications such as, food impaction, esophageal stricture, narrow-caliber esophagus, and esophageal perforation. In the last decade, EoE's prevalence has rapidly increased to an estimated 1:2000. EoE is considered to be a chronic condition with no currently approved treatments. Cow's Milk Allergy (CMA) is involved in a majority of cases of EoE in children. Cow's Milk free diet is able to reduce EoE symptoms.

A double-blind, placebo-controlled, randomized trial to Study Efficacy and Safety of the Viaskin<sup>®</sup> Milk epicutaneous immunotherapy (EPIT<sup>TM</sup>) in treating milk induced Eosinophilic Esophagitis in children ages from 4 to 17 years old (SMILEE study). Under the terms of the agreement, SMILEE will be conducted at The Children's Hospital of Philadelphia under the supervision of Dr. Spergel.

Viaskin<sup>®</sup> Milk is a ready-to-use and easy-to-administer form of allergen immunotherapy, particularly adapted to the pediatric population. Viaskin<sup>®</sup> Milk is intended to induce clinical desensitization / tolerization to milk in subjects moderately to severely allergic to cow' milk proteins. Specific immunotherapy of CMA might decrease the risk of relapse and might be the first treatment of EoE. Moreover, by utilizing the epicutaneous route of administration, Viaskin<sup>®</sup> Milk is able to initiate an immunomodulatory process while minimizing the potential safety concerns associated with systemic exposure to food allergens.

**Dr. Pierre-Henri Benhamou**, Chairman and CEO of DBV Technologies, said, *"DBV and Pr. Spergel are truly committed to improving the lives of EoE patients. There is a strong scientific rationale for the use of EPIT to treat EoE, and we believe that the Viaskin platform could offer a possible treatment for children suffering from this disease and we are convinced that this is great step forward in increasing Viaskin's reach to allergic patients."*

### About Dr. Jonathan Spergel

Jonathan Spergel, MD, is a Professor of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania. He is also the Chief of the Allergy Section and co-director of the Center for Pediatric Eosinophilic Disorders at The Children's Hospital of Philadelphia. He serves as an international expert on the treatment and diagnosis of food allergies. Dr. Spergel also serves on the DBV Technologies Scientific Advisory Board.

### About DBV Technologies

DBV Technologies is opening up a decisive new approach to the treatment of allergy – a major public health issue that is constantly increasing in prevalence. Food allergies represent a true handicap in everyday life for millions of people and thus constitute a major unmet medical need. DBV Technologies has developed a unique, proprietary, worldwide-patented technology for administering an allergen to intact skin and avoiding massive transfer to the blood. The Viaskin<sup>®</sup> technology combines efficacy and safety as part of a treatment that seeks to improve the patient's tolerability of peanut and thus considerably lower the risk of a systemic, allergic reaction in the event of accidental exposure to the allergen. The company's significant development program has taken this revolutionary method through to the industrial stage in Europe, initially. The product's clinically proven safety of use enables the application of effective desensitization techniques (the efficacy of which is acknowledged worldwide) in the most severe forms of the allergy. DBV Technologies is focusing on food allergies (milk and peanut) for which there are currently no effective treatments. It has developed two products: Viaskin<sup>®</sup> Peanut and Viaskin<sup>®</sup> Milk. The clinical development program for Viaskin<sup>®</sup> Peanut has received Fast Track designation from the US Food and Drug Administration. The company will subsequently develop a Viaskin<sup>®</sup> patch for young children with house dust mite



allergy – a true public health issue because this pathology is one of the main risk factors for childhood asthma. DBV Technologies shares are traded on segment C of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345).

For more information on DBV Technologies, please visit our website: [www.dbv-technologies.com](http://www.dbv-technologies.com)

CAUTION: Viaskin® is not approved for sale in the USA.

#### **Forward Looking Statement**

The forward-looking statements, objectives and targets contained herein are based on the Company's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. Furthermore, the Research and Development process involves several stages each of which involve the substantial risk that the Company may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Company cannot be certain that favorable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. DBV technologies' business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers.

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