



NIH-sponsored Consortium of Food Allergy Research (CoFAR) starts a Phase II clinical study with DBV Technologies' Viaskin® Peanut in the treatment of peanut allergy

- **Leading US centers in food allergy will be involved in an NIH-funded CoFAR study, coordinated by Dr. Sampson and Dr. Jones in collaboration with DBV' team**
- **CoFAR6 study will help to better characterize the mechanisms of action of epicutaneous immunotherapy**

New-York (USA) and Bagneux (France), October 24, 2013 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin®, a new approach in the treatment of allergies, and the Consortium For Food Allergy Research (CoFAR) announced today that the CoFAR started enrolling patients into a multi-center, randomized, double-blinded, placebo-controlled trial using Viaskin® Peanut to treat children and adults with peanut allergy. The trial "Epicutaneous Immunotherapy (EPIT) for Peanut Allergy: A Randomized, Double-Blind, Placebo-Controlled, Phase II study in Children and Adult" is also known as CoFAR6.

The CoFAR6 study, coordinated by Dr. Hugh Sampson of The Icahn School of Medicine at Mount Sinai (NY) and Dr. Stacie Jones of Arkansas Children's Hospital, will enroll 75 patients from 4 to 25 years of age in the US. Patients will be randomized to two doses of Viaskin® Peanut (100µg or 250µg) versus placebo (1:1:1). Viaskin® Peanut will be applied once a day. Clinical efficacy will be evaluated after 12 months and 30 months of treatment. Immunological status will be assessed at baseline, 1 year and 2.5 years. Safety will be monitored centrally.

Dr. Hugh Sampson, Kurt Hirschhorn Professor of Pediatrics, Director of the Jaffe Food Allergy Institute and Dean of Translational Biomedical Science at The Mount Sinai Medical Center in New York (USA) is the principal investigator of the CoFAR6 study. He said: *"We are delighted to initiate this clinical trial with Viaskin® Peanut in an effort to characterize how food proteins processed through the cutaneous immune system may alter the allergic response."* Dr. Sampson is also international coordinator for 'VIPES' (Viaskin Peanut Efficacy and Safety study), DBV's global Phase IIb clinical trial to evaluate Viaskin® Peanut efficacy and safety.

Dr. Stacie Jones, Professor of Pediatrics at the University of Arkansas for Medical Sciences, Chief of Allergy and Immunology and King Chair in Pediatric Allergy at Arkansas Children's Hospital in Little Rock (USA) said: *"We are excited about the next phase of study for this new therapy that, if effective, will give peanut allergic patients a much needed treatment option for the future."* Previously, Dr. Jones participated actively as one of the Principal Investigators in DBV's Phase Ib study on Viaskin® Peanut.

"We are proud to work with the Consortium of Food Allergy Research, a leading clinical research network in search of effective treatments for food allergies." said **Dr. Pierre-Henri Benhamou**, Chairman and CEO of DBV Technologies. *"The goal of Viaskin® is to safely treat life-threatening allergies, such as peanut allergy, by triggering a specific, robust immune response in the skin. CoFAR6 will help characterize more accurately the immunological mechanism of action of Epicutaneous Immunotherapy. DBV shares a strong commitment with CoFAR to find a therapeutic solution for food allergy, which has become a serious public health concern."*

About CoFAR

The Consortium of Food Allergy Research (CoFAR) was established in July 2005 by the National Institute of Allergy and Infectious Diseases, a part of the National Institutes of Health, to conduct both observational and clinical studies to answer questions related to food allergies. Study sites include: The Mount Sinai Medical Center (New York); Johns Hopkins University (Baltimore); National Jewish Health (Denver); University of Arkansas for Medical Sciences (Little Rock); and, University of North Carolina (Chapel Hill).

About peanut allergy: a life-threatening risk for millions of people

Peanut allergy affects both adults and children. In the US, about 1.1% of the general population, or over 3 million people, are allergic to peanuts and in the United Kingdom, it has been estimated that peanut allergy affects 1.8% of young children. The prevalence of peanut allergy in other Western countries (e.g., Canada, France and Spain) has been studied by many researchers, and the prevalence ranges



from 0.9% to 1.5%. Peanut allergy is persistent throughout life; many studies indicate that fewer than 20% of young children allergic to peanut will outgrow their allergy. The allergic reaction to peanut can range from mild to severe, and in rare cases can be life threatening. Peanut allergy is associated with a higher frequency of severe life-threatening allergic reactions than other common food allergies, including milk and egg allergies.

About DBV Technologies

DBV Technologies is developing Viaskin[®], an innovative new approach to the treatment of allergies – a major public health issue that is constantly increasing in prevalence. Food allergies represent a true handicap in everyday life for millions of people, constituting a major unmet medical need. DBV Technologies, incorporated in France in 2002, has developed a proprietary, worldwide-patented technology for administering an allergen to intact skin while avoiding transfer to the blood. The Viaskin[®] technology combines efficacy and safety as part of a treatment that seeks to improve the patient's tolerability of peanuts, and thus considerably lowers the risk of a systemic, allergic reaction in the event of accidental exposure. The product's clinically proven safety profile enables the application of effective desensitization techniques in the most severe forms of the allergy. 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: Viaskin[®] Peanut and Viaskin[®] Milk. The clinical development program for Viaskin[®] Peanut has received Fast Track designation from the US Food and Drug Administration and is currently being studied in Phase II program. The company will subsequently develop a Viaskin[®] patch for young children with house dust mite allergy – a true public health issue because this pathology is a primary risk factor 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

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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