



# Consortium of Food Allergy Research Completes Recruitment of NIH-sponsored CoFar6 Phase II Trial with DBV's Viaskin® Peanut in Treatment of Peanut Allergy

Leading US centers in food allergy involved in an NIH-funded CoFAR6 study, co-chaired by Dr. Hugh Sampson and Dr. Stacie Jones

New York, NY (USA) and Bagneux (France), July 17, 2014 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin®, a new paradigm for the treatment of food allergies, and the Consortium of Food Allergy Research (CoFAR) announced today that enrollment into the CoFAR6 study, a multi-center, randomized, double-blinded, placebo-controlled phase II clinical trial of Viaskin® Peanut for the treatment of peanut allergic children and adults (4 to 25 years of age), has been completed.

CoFAR6 study enrollment started on October 18, 2013, with Dr. Hugh Sampson of The Icahn School of Medicine at the Mount Sinai Hospital in New York and Dr. Stacie Jones of the University of Arkansas for Medical Sciences and Arkansas Children's Hospital serving as Co-chairs for the study. Baseline peanut reactivity for patients was established during a double-blind, placebo-controlled food challenge ('food challenge'). Clinical efficacy and Immunological responses will be evaluated after 12 months and 30 months of treatment. Safety will be monitored over time. The CoFAR6 study is being conducted by the 5 US-based investigators, who have collectively randomized 75 (ages 4-25 years) with peanut allergy. Patients have been randomized to two doses of a daily Viaskin® Peanut, 100µg or 250µg versus placebo on a 1:1:1 ratio.

**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. Dr Sampson said: "We are very excited to have the opportunity to evaluate this novel form of therapy for peanut allergy and are undertaking a number of basic laboratory studies designed to help us better understand how this approach affects the immune system and allergic response."

**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: "this study is an important next step in developing effective treatments for children and adults with peanut allergy, and we are very excited to be working with DBV on this study." Previously, Dr. Jones participated actively as one of the Principal Investigators in DBV's Phase Ib study on Viaskin® Peanut.

**Dr. Pierre-Henri Benhamou**, Chairman & CEO of DBV Technologies, also commented. "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. The team was impressed by the seamless recruitment process for CoFAR6, precisely on time with the timelines announced at the beginning of the study. DBV and CoFAR share a strong commitment to find a therapeutic solution for peanut allergy, which has become a serious public health concern."

#### **About CoFAR**

The Consortium of Food Allergy Research (CoFAR) has been funded continually by the National Institute of Allergy and Infectious Diseases, a part of the National Institutes of Health, since 2005. The Consortium conducts clinical trials and observational studies to prevent and treat food allergy, with an additional focus on understanding the mechanisms of food allergy. 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 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 allergy is a serious health concern 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: <a href="www.dbv-technologies.com">www.dbv-technologies.com</a>





#### **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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