



DBV Technologies completes enrollment of Phase IIb VIPES study, the first-ever global trial in desensitization to peanut allergy

- **VIPES' results expected in 2H 2014**
- **First global desensitization trial in peanut-allergic children, adolescents and adults**

Bagneux, France, July 8, 2013 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin[®], a new standard in the treatment of allergy, announced today the completion of enrollment in its global phase IIb clinical trial, VIPES (**Viaskin Peanut's Efficacy and Safety**), a 12-month treatment study with Viaskin[®] Peanut. VIPES started in August 2012 and is being conducted in Europe (France, The Netherlands and Poland) and in North America (Canada and USA) with a total of 22 investigators, who collectively screened and randomized 315 and 221 peanut-allergic subjects respectively. VIPES' patient population includes 113 children (6-11 years), 73 adolescents (12-17 years) and 35 adults (18-55 years). DBV anticipates reporting 12-month topline data during the second half of 2014. Viaskin[®] Peanut was granted Fast Track designation by the U.S. Food and Drug Administration.

Three doses of Viaskin[®] Peanut, i.e. 50 µg, 100 µg and 250 µg peanut protein compared to placebo are being evaluated in VIPES. A total of 221 peanut-allergic subjects (55 subjects per treatment group) were randomized following a double-blind, placebo-controlled food challenge ('food challenge') that established the baseline threshold of peanut reaction. Patients receive a daily application of the Viaskin[®] Peanut patch over a 12-month treatment period. Each patch will be applied for 24 hours, either on the upper arm for adults (18-55 years) and adolescents (12-17 years) or on the back of children (6-11 years).

The principal coordinating investigator for North America is Pr. Hugh Sampson, M.D., Chief of the Division of Allergy & Immunology in the Department 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. Pr. Sampson is also a member of DBV's Scientific Advisory Board as well as Principal Investigator of the National Institutes of Health-sponsored Consortium of Food Allergy Research clinical study with Viaskin[®] Peanut (CoFAR6). The principal coordinating investigator for Europe is Christophe Dupont, M.D, Ph.D., Head of the Pediatric-Gastroenterology Ambulatory Department at the Necker Hospital (AP-HP). He is a member of the European Society for Pediatric Gastroenterology, Hepatology and Nutrition and of the Committee of Nutrition of the French Pediatric Society. Pr. Dupont is also Chairman of DBV's Scientific Advisory Board.

Charles Ruban, MBA, DBV's Chief Development Officer said: *"VIPES is designed to confirm the optimal treatment dose of Viaskin[®] Peanut in each of the relevant patient populations. The study protocol will benefit from an improved, standardized methodology for the food challenge, as well as cutting-edge monitoring tools. Most importantly, tVIPES' results will guide the design of the subsequent Phase III clinical trial."* Charles Ruban concluded: *"VIPES is the largest trial ever conducted in desensitization to peanut allergy, and we take great pride in paving the way."*

Viaskin[®] Peanut demonstrated positive efficacy trends in severely peanut-allergic children after 18-months at a 100 µg dose. These findings were recently reported in the ARACHILD pilot study, a multicenter double-blind, placebo-controlled Phase II clinical trial in 54 randomized subjects aged 5 to 17 that was sponsored by AP-HP (Assistance Publique – Hôpitaux de Paris). Overall, the data showed that two-thirds of children under 12 years old met the primary efficacy endpoint over 18 months of treatment. The serological response observed during the treatment period also suggested efficacy of the ongoing desensitization process.

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

In the United States, about 1.1% of the general population, or over 3 million people, is allergic to peanuts. Peanut allergy causes about 100 to 150 deaths per year. This allergy affects both adults and children, and it has been estimated that peanut allergy affects 1.8% of young children in the United Kingdom. The prevalence of peanut allergy in other Western countries (e.g., Canada, France and Spain) has been studied by many researchers and ranges from 0.9% to 1.5%. This allergy is generally considered to be persistent; many studies indicate that fewer than 20% of children will outgrow their peanut allergy. Peanut allergy is more severe than other common food allergies (e.g. milk and egg allergies).



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® 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® Peanut and Viaskin® Milk. The clinical development program for Viaskin® Peanut has received Fast Track designation from the US Food and Drug Administration. 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 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

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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