

## DBV Technologies initiates VIPES phase IIb clinical study, the first global trial ever in desensitization of peanut-allergic children and adults

*Investigators team led by Pr. Hugh Sampson in the U.S.  
and Pr. Christophe Dupont in Europe*

**BAGNEUX, France, August 2<sup>nd</sup>, 2012** - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin<sup>®</sup>, a new standard in the treatment of allergy, announced today that the first patient has been enrolled, on July 31<sup>st</sup>, in the VIPES phase IIb clinical study (Double-Blind, Placebo-Controlled, Randomized Phase IIb trial to study Viaskin<sup>®</sup> Peanut's Efficacy and Safety in peanut allergy). VIPES is a 12-month, multicenter and multinational study conducted in Europe and in North America, encompassing 6 countries, with a total of approximately 20 to 25 Investigators. The 220 Peanut-allergic subjects will range from 6 to 55 years of age with a history of immediate hypersensitive reaction to peanut protein. **VIPES was granted Fast Track designation by the Food and Drug Administration ('FDA') and is part of a development plan with 3 clinical studies ongoing in the coming months.**

**Pierre-Henri Benhamou**, M.D., Chairman and CEO of DBV Technologies said: *"We are proud to be the first company ever to launch a global clinical trial in desensitization to peanut allergy. Today, there are no treatments available on the market for this life-threatening disease, and Viaskin Peanut represents a real hope for millions of patients. We are more and more confident, thanks to the data generated so far, notably with the interim efficacy data showed in the ARACHILD study, that Viaskin could become the new standard of care in food and pediatric allergies."*

Peanut is an ubiquitous ingredient in food, and contaminations of foods that are not supposed to contain peanut occur quite regularly. As a consequence, strict avoidance is difficult to achieve and accidental ingestion of peanuts by peanut-allergic subjects is frequent, with severe and potentially life-threatening reactions ensuing. The only available countermeasure in case of severe systemic and/or life-threatening reactions/anaphylaxis to peanuts is injectable epinephrine as recommended by the WHO.

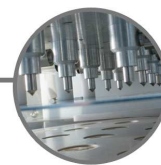
### About the VIPES Study

Three doses of peanut proteins, i.e. 50 µg, 100 µg and 250 µg per patch will be evaluated in the study versus placebo. To be eligible and enrolled in the study, the subjects must be truly allergic to peanut as confirmed by a double blind placebo-controlled food challenge to peanut. Repeated daily application of Viaskin will be made over a 12-month double-blind treatment period, each Viaskin being applied for a duration of 24 hours, either on the upper arms for adults (18-55 years) and adolescents (12-17 years) or on the back for children (6-11 years). **At least 220 subjects (55 subjects per treatment group) will be randomized in this study.**

The objectives of this 12-month dose-finding study with Viaskin<sup>®</sup> Peanut are as follows:

- In terms of efficacy, the desensitizing effect of each active treatment dose compared to placebo will be studied. Efficacy of desensitization is defined as the difference of success rate of treated arm versus placebo. Success per patient is objectivized by the ability to consume symptom-free an amount of peanut significantly higher after 12 months of treatment;
- Safety of Viaskin Peanut in peanut-allergic subjects will also be studied: frequency, duration and severity of Adverse events triggered by Viaskin versus placebo.

The Principal Coordinating Investigator for North America is **Hugh Sampson**, M.D., Professor of Pediatrics and Director of The Jaffe Food Allergy Institute at Mount Sinai School of Medicine. In Europe, the Principal Coordinating Investigator is **Christophe Dupont**, M.D, Ph.D., Necker Sick Children's Hospital, Paris, France and co-founder of DBV Technologies. VIPES results would be available first half 2014.



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

In the US about 1.1% of the general population (i.e. over 3 million people) is allergic to peanut. In the US, 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](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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