



## DBV Technologies initiates a long-term follow-up study of Viaskin Peanut

### OLFUS-VIPES will be the largest clinical study designed to assess efficacy, safety and long-term tolerance of peanut allergy treatment

**Bagneux (France), September 4, 2013** - 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 in the open-label follow-up study (OLFUS) of VIPES phase IIb study to evaluate long-term efficacy and safety of Viaskin<sup>®</sup> Peanut. OLFUS-VIPES is an extension study for subjects who previously were randomized and have completed the VIPES study. It is planned to include 21 sites in 4 countries. Up to a maximum of 218 subjects can enroll in the OLFUS-VIPES study from the VIPES study.

Subjects enrolled in this follow-up study will receive an additional 24 months of Viaskin<sup>®</sup> Peanut treatment followed by a 2 months period without treatment in order to assess the level of sustained tolerance. This study will address the crucial question of tolerance post treatment. OLFUS-VIPES is a multicenter study conducted in Europe and in North America.

**Charles Ruban**, MBA, Chief Development Officer of DBV Technologies said: *“We are pleased to report on the inclusion of the first patient in our open label follow-up study. This important milestone marks the beginning of a two-year period that will help us understand the long term benefits of Viaskin, and better characterize the potential induction of sustained tolerance in peanut allergic patients. No other specialty pharmaceutical company has ever achieved what DBV is currently in the process of demonstrating: safely treat peanut allergic patients by modulating the immunological response over time.”*

Subjects entering the OLFUS-VIPES study who had previously received Viaskin<sup>®</sup> Peanut at any of the three doses in the VIPES study will continue at the same dose (i.e., 50 µg or 100 µg or 250 µg of peanut protein). Subjects entering the OLFUS-VIPES study who had previously received placebo in the VIPES study will be re-randomized in a 1:1:1 ratio to receive Viaskin<sup>®</sup> Peanut. The transition from the VIPES to the OLFUS-VIPES study will be blinded to investigators.

Repeated daily application of Viaskin<sup>®</sup> Peanut will continue as in the VIPES study. A new patch will be applied every 24 hours on the inner side of both upper arms for adults (≥18 years) and adolescents (12-17 years), or on the inter-scapular area of the back for children (7-11 years).

The objectives of this 24-month long-term efficacy and safety of the Viaskin<sup>®</sup> Peanut are as follows:

- To assess the efficacy of Viaskin<sup>®</sup> Peanut up to 36 months of Epicutaneous Immunotherapy (EPIT) in peanut-allergic subjects.
- To evaluate the safety of long-term treatment with Viaskin<sup>®</sup> Peanut.
- To evaluate the sustained tolerance to peanut after specific immunotherapy using Viaskin<sup>®</sup> Peanut.

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 Coordinator is **Christophe Dupont**, M.D, Ph.D., Necker Sick Children's Hospital, Paris, France.



### **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<sup>®</sup>, 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<sup>®</sup> 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<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 and is currently being studied in Phase II program. 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 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](http://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.

### **DBV Contacts**

#### **DBV Technologies**

David Schilansky  
Chief Financial Officer  
Tél. : +33(0)1 55 42 78 75  
[david.schilansky@dbv-technologies.com](mailto:david.schilansky@dbv-technologies.com)

#### **US & UK investors**

The Trout Group  
Investor Relations  
Alan S. Roemer  
Tél. : +1 (646) 378-2945  
[aroemer@troutgroup.com](mailto:aroemer@troutgroup.com)

#### **French investors**

NewCap.  
Financial Communication and investor relations  
Emmanuel Huynh / Valentine Brouchet  
Tél. : +33(0)1 44 71 94 94  
[dbv@newcap.fr](mailto:dbv@newcap.fr)

#### **US press & media**

Ronald Trahan Associates Inc.  
Press relations  
Ronald Trahan, APR  
Tél. : +1 508 359 4005  
[rcarahan@ronaldtrahan.com](mailto:rcarahan@ronaldtrahan.com)