



## **Clinical Development Program receives FDA “Fast Track Designation” and encouraging phase Ib safety results for Viaskin Peanut**

**Viaskin Peanut, the first epicutaneous skin patch for the treatment of peanut allergy, is recognized as a unique and promising desensitization product**

BAGNEUX, France, February 28, 2012 - DBV Technologies announced today that it has received “Fast Track Designation” for the Clinical Development Program of its Viaskin<sup>®</sup> Peanut, a product designed for the treatment by Epicutaneous Immunotherapy (EPIT) of patients with peanut allergy. Products in the FDA’s Fast Track program normally receive priority review, and DBV could also be eligible to submit a U.S. BLA (Biologics License Application) on a rolling basis. This permits the FDA to review sections of the BLA in advance of receiving the complete set of clinical data.

A phase Ib clinical study in peanut allergic subjects, currently being finalized, is demonstrating the safety of Viaskin<sup>®</sup> Peanut.

Viaskin<sup>®</sup> Peanut’s development is of high interest to many key opinion leaders in allergy in the U.S. and in Europe. Efficacy studies will be launched in US and Europe to prove the efficacy of Viaskin<sup>®</sup> Peanut to desensitize peanut-allergic patients.

DBV Technologies is opening up a decisive new approach to the treatment of allergies – a major public health concern that is constantly increasing in prevalence. More specifically, treatments of food allergies represent a major unmet medical need, as these allergies are a true handicap in the everyday life of millions of people. DBV Technologies has developed a unique, proprietary, worldwide-patented technology, the Viaskin<sup>®</sup> technology, for administering allergens to intact skin while avoiding any massive transfer to the blood. Lead product based on the Viaskin<sup>®</sup> technology, Viaskin Peanut is designed to combine efficacy and safety as part of a treatment that seeks to improve the patient’s tolerability to peanut and thus considerably lower the risk of a systemic, allergic reaction in the event of accidental exposure to the allergen. The company has taken this revolutionary method through to the industrial stage.

*“We are extremely encouraged by the FDA’s decision to fast-track the clinical development program of Viaskin<sup>®</sup> Peanut. This decision means that Viaskin<sup>®</sup> Peanut is recognized as a specific and unique allergen product with a breakthrough potential to safely treat patients with peanut allergy, a very serious disease,”* said **Pierre-Henri Benhamou, M.D.**, co-founder, Chairman and CEO of DBV Technologies. *“Because there are no known treatments for food allergies, many patients and their families live with the constant fear of ingesting a life-threatening food”.*

**NOTE: Viaskin<sup>®</sup> Peanut is only for investigational use at the moment in the USA and in Europe.**

## **About DBV Technologies**

DBV Technologies is opening up a decisive new approach to the treatment of allergies – a major public health concern that is constantly increasing in prevalence. More specifically, treatments of food allergies represent a major unmet medical need, as these allergies are a true handicap in the everyday life of millions of people. DBV Technologies (incorporated in 2002) has developed a unique, proprietary, worldwide-patented technology, the Viaskin® technology, for administering allergens to intact skin while avoiding any massive transfer to the blood. The Viaskin® technology should combine 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 has taken this revolutionary method through to the industrial stage.

DBV Technologies is currently focusing on food allergies (peanut and milk), both highly prevalent in children and for which there are currently no effective treatments. For that purpose, DBV has designed two products: Viaskin® Peanut and Viaskin® Milk.

The company will subsequently develop a Viaskin® patch for treating young children with house dust mite allergy – a true public health concern considered to be one of the main risk factors for childhood asthma.

For more information on DBV Technologies, please visit our website: [www.dbv-technologies.com](http://www.dbv-technologies.com)

## **For more information**

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