

## DBV Technologies Forms Research Collaboration with Inserm to Develop Viaskin® for Refractory Hemophilia A Disease

**This Proof of concept study aims to capitalize on DBV's safe and non-invasive technology and Inserm's unique expertise to address refractory Hemophilia A, a severe orphan disease with no cost-effective and convenient treatment today available to patients**

**BAGNEUX, FRANCE, October 22nd, 2013** - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin®, a new standard in the treatment of allergies, announced today that it has entered into a research collaboration with Institut national de la Santé et de la recherche médicale, Inserm and Inserm Transfert, to investigate the effect of epicutaneous delivery of recombinant Factor VIII (FVIII) protein via Viaskin in an animal model of hemophilia A. DBV and Inserm are teaming up to combine the Viaskin® technology and a world-class expertise in hemophilia A to develop a potential standard of care for refractory hemophilia A patients, by providing a cost-effective, and non-invasive treatment.

**Dr. Sébastien Lacroix-Desmazes**, CNRS (Inserm Team UMRS 872, Immunopathology and Therapeutic Immunointervention), said, *“Preventing the immune response to therapeutic proteins upon induction of tolerance is the approach of choice for patients with hemophilia A. To date, the only strategy to induce tolerance to FVIII in patients who have developed anti-FVIII antibodies consists in flooding the immune system with enormous amounts of FVIII every day, for periods that can extend up to several months or years. This obviously faces issues with patients' compliance and treatment costs. Being able to induce FVIII-specific tolerance in hemophilia A patients using low doses of antigen, such as is the case with the Viaskin delivery system, would drastically improve the life of alloimmunized hemophilia A patients and solve a crucial societal burden.”*

**Dr. Pierre-Henri Benhamou**, Chairman and CEO of DBV Technologies, said, *“The establishment of a partnership with Dr. Sébastien Lacroix-Desmazes and Inserm, with their extensive expertise in Hemophilia A, can potentially open a new path for Viaskin to become the future of hemophilia A treatment as a non-invasive, prophylactic alternative against an alloimmune response to therapeutic Factor VIII.”* Dr. Pierre-Henri Benhamou concluded: *“This research should reinforce the relevance of the Viaskin® platform, as a technology enabling deep and durable modulation of inappropriate immune responses.”*

The protective effect conferred by the immunological response induced by epicutaneous immunotherapy using Viaskin® will be tested at the humoral level, and is expected to induce tolerance to FVIII in mice with severe hemophilia A. The DBV-Inserm research collaboration will last 12 months. Different mice cohorts will be treated with Viaskin containing the FVIII protein versus placebo for 45 days. After 45 days, all mice will be subject to a protocol of replacement therapy for 4 weeks. The levels of anti-FVIII IgG and of FVIII inhibitors will then be assessed by immunological and functional assays. Various approaches have investigated treatments aimed at inducing tolerance to exogenous FVIII in hemophilic mice. Through the Viaskin platform, DBV Technologies has developed a first-in-class approach to deliver antigens of choice to immunosensitized organisms as a method to induce antigen-specific tolerance, and in this case, tolerance to therapeutic FVIII in hemophilia A.

### About Hemophilia A

Hemophilia A is a rare X chromosome-linked recessive hemorrhagic disorder that affects one individual out of 5,000–10,000. Genetic abnormalities in the gene encoding FVIII result in the absence of production of FVIII or in the production of defective FVIII molecules. In up to 30% of the patients, replacement therapy is complicated by the occurrence of anti-drug antibodies, referred to as inhibitory anti-FVIII antibodies (or FVIII inhibitors), that preclude the use of FVIII as treatment. Inhibitory anti-FVIII antibodies are of the IgG isotypes, and mostly part of the IgG1 and IgG4 subclasses. Mortality is high and ranging between 12.5% and 22%, usually because of fatal hemorrhage.



**Inserm**

Institut national  
de la santé et de la recherche médicale

## About Inserm

### Understand and improve human health

Founded in 1964, the French National Institute of Health and Medical Research (Inserm) is a **public scientific and technological institute** which operates under the joint authority of the French Ministry of Health and French Ministry of Research.

As the **only French public research institute to focus entirely on human health**, in 2008 Inserm took on the responsibility for the strategic, scientific and operational coordination of biomedical research. This key role as coordinator comes naturally to Inserm thanks to the scientific quality of its teams and its ability to conduct translational research, from the laboratory to the patient's bed.

In April 2009, national coordination was strengthened by Aviesan, the [Alliance nationale pour les sciences de la vie et de la santé](#) (French National Alliance for Life and Health Sciences), which Inserm co-founded with other research institutes and the Conférence des présidents d'université (Association of University Presidents).

## 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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