



DBV Technologies presents detailed results of a clinical study showing that VIASKIN® is safe and well-tolerated by peanut-allergic patients at the European Academy of Allergy and Clinical Immunology (EAACI) congress

BAGNEUX, France, June 18, 2012 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin®, a new standard in the treatment of allergy, announced today the presentation for the first time of the detailed results of its phase Ib clinical study completed earlier this year, representing the **first clinical study showing the safety and well-tolerability of Viaskin® in peanut-allergic patients**. DBV Technologies also continued to **showcase its knowledge in the cellular mechanism implicated during the specific EPIT process and in the Viaskin® Technology** with four additional communications presented during the congress.

Pierre-Henri Benhamou, M.D., Chairman and CEO of DBV, said: *“The intense clinical and scientific newsflow at EAACI reflects the exceptional dynamism of DBV’s R&D teams. With the detailed results of our phase Ib in peanut allergy presented yesterday, we have shown that Viaskin has a good safety profile, representing a real breakthrough in this life-threatening disease. Thanks to our preclinical work, we also continued to make good progress in the understanding of allergies and the way these pathologies can be influenced and subsequently treated via Epicutaneous Immunotherapy (EPIT). This EAACI Congress therefore marks an important date for DBV, with demonstrated safety, encouraging signs of efficacy through the interim results of the ARACHILD study and fundamental work opening new hopes in the treatment of allergies. We strongly believe that with this data, DBV is well placed to be the next leader in the treatment of food allergies, a very high unmet medical need.”*

The phase Ib U.S. clinical study of Viaskin Peanut demonstrated that the patch is “safe and well-tolerated” by adults, adolescents and children with peanut allergy. The study was conducted at five centers in the U.S: Duke University Medical Center, National Jewish Medical Research Center, Arkansas Children’s Hospital, CRI Worldwide, and Aspen Clinical Research. In total, 100 peanut-allergic subjects, of those 70 non-severe and 30 severe, were randomized and treated for 2 weeks by Viaskin® at doses varying from 20 µg to 500 µg peanut proteins per patch or placebo. **Overall Viaskin Peanut was well tolerated and there was no major safety concern up to the highest dose tested in the different cohorts, i.e. 500 µg peanut proteins in the adolescent and in the adult cohorts regardless the severity of the allergy, and 250 µg peanut proteins in the child cohorts.**

Detailed results of the phase Ib clinical study

Characteristics of the whole Population, (non-severe and severe, severe subjects being defined as subjects with history of severe anaphylactic reactions to peanut such as dyspnea, and/or wheezing, and/or cyanosis, and/or hypotension, and/or hypoxia): the median and mean peanut-specific IgE values were 11.20kU/L and 25.45kU/L respectively (range: 0.71 to >100kU/L). All subjects but one (99/100) were polyallergic, 63/100 had asthma, 45/100 had allergic rhinitis, 13/100 had atopic dermatitis and 24/100 had eczema. **There were no SAEs (Serious Adverse Events)** and 4/100 subjects dropped prematurely (3/80 in the Viaskin peanut-treated subjects and 1/20 in the placebo-treated subjects): 1 non-severe adult for protocol non-compliance after an AE (Adverse Event) (received placebo); 1 non-severe adolescent withdrew consent (received Viaskin peanut); 1 non-severe child for AE (received Viaskin peanut); and 1 severe adult for AE (received Viaskin peanut). Expected local cutaneous AEs (pruritus, erythema, edema or urticaria) at site of patch application seemed to occur more frequently with Viaskin Peanut (86.3% subjects) than with placebo (60% subjects) but this was not statistically significant. In majority, these **local AEs were mild to moderate in intensity and resolved progressively over the treatment course**, in non-severe as in severe subjects. Viaskin Peanut did not trigger more systemic allergic AEs: there was no significant difference in the frequency of apparition of systemic allergic AEs in both groups of treatment (37.5% with Viaskin Peanut vs 20% with placebo). These systemic allergic AEs were in majority mild and transient; half of them resolved spontaneously without any treatment, in non-severe as in severe peanut-allergic subjects. Viaskin Peanut had no impact on pre-existing and morbidity factors such as asthma (no change of FEV1 or PEF), lab parameters, vital signs, ECG, or pre-existing skin diseases (no change in Atopic dermatitis scores or eczema). The non-severe adolescents and adults received up to 500 µg Viaskin Peanut safely by EPIT; the non-severe-children received up to 250 µg Viaskin Peanut safely by EPIT; and the severe adults received up to the 500 µg Viaskin Peanut safely by EPIT.



The oral communication at the EAACI 2012, “Epicutaneous immunotherapy for treating peanut allergy: results of the first double-blind placebo-controlled safety study” was presented during the Oral Abstract Session 12 “Clinical aspects of allergen immunotherapy” on June 17, 2012.

Since its inception, DBV Technologies has developed rigorous and demanding scientific capabilities, matching the highest standards. **Several scientific communications of DBV are presented at the EAACI, and abstracts are available on the EAACI website as well as on the DBV website.**

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 developmental clinical 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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