



Positive interim clinical data in peanut allergic children treated with VIASKIN PEANUT

Promising safety and efficacy interim clinical results after 6 months of treatment in peanut-allergic children using Viaskin® Peanut presented at the European Academy of Allergy and Clinical Immunology EAACI

ARACHILD Study is currently still ongoing

BAGNEUX, France, June 18, 2012- DBV Technologies (Euronext: DBV - ISIN: FR0010417345), creator of Viaskin®, a new standard in the treatment of allergy, announced today that AP-HP (Assistance Public - Hôpitaux de Paris) sponsor of the ARACHILD study presented at the EAACI Congress a late breaking oral presentation on safety and efficacy data after six months of epicutaneous immunotherapy in peanut allergy using Viaskin® Peanut. Peanut allergy is a potential life threatening disease for millions of people without any available effective medical treatments. DBV Technologies is developing Viaskin® Peanut for the global market with several ongoing clinical studies in both Europe and in the US.

The ongoing ARACHILD study which is a multicenter double blind placebo-controlled 18 month clinical trial is designed to assess the efficacy and safety of Viaskin® Peanut in 54 randomized children aged 5 to 17 years with a confirmed peanut allergy. Importantly, the 6 months interim data show no drop-out of patients from the study due to adverse events or any serious adverse events related to the treatment.

The interim data also show statistically significant efficacy of Viaskin® Peanut versus placebo on the primary efficacy endpoint of the study. Results show that **18.5% of patients in the treated group were able to consume at least 10-fold more peanut at the 6-month oral food challenge vs 0% in the placebo group (p=0.05).** Viaskin® Peanut also showed **highly significant immunological changes** (secondary efficacy endpoints), with an increase of peanut-specific IgE (immunoglobulin E) (p= 0.036) and peanut-specific IgG4 (immunoglobulin G4) (p<0.0001). IgG4 increase may be considered as an indicator during immunotherapy of successful desensitization and induction of tolerance to the peanut allergen. Detailed results are highlighted below.

Professor Christophe Dupont, main Investigator of ARACHILD study and co-founder of DBV Technologies said: *“This is the first time a treatment seems to act on food allergy without risk for the patient since there is no oral intake of the offending food at all.”*

Pierre-Henri Benhamou, M.D., Chairman and CEO of DBV Technologies said: *“The results of the ARACHILD study, coordinated by Professor. Christophe Dupont, and sponsored by our partner AP-HP are very encouraging and promising. Beyond the statistical significance for desensitization between the treated group and the placebo group, **biological data show that Viaskin® triggers a strong immune response starting early. This is even more true as the ARACHILD results are statistically significant on a very severely allergic patient population, treated at a low dose (100 µg) for only 6 months.** We believe this important set of data is another step in the right direction in demonstrating that the Viaskin® platform will be a new treatment paradigm in desensitization, notably in children and adolescents with severe food allergy, thereby opening up a decisive new approach for the treatment of a high unmet medical need.”*

ARACHILD, a remarkable public-private collaboration

ARACHILD, a multicenter double blind placebo-controlled clinical trial was designed to assess the efficacy and safety of EPIT in 54 randomized children aged 5 to 17 with a confirmed peanut allergy. Patients with peanut allergy were tested by classical allergy tests (Prick test and IgE), and allergy was finally confirmed during a standardized double blind placebo-controlled food challenge (DBPCFC). Subjects who reacted to a cumulative dose of peanut proteins <300mg were eligible and were randomized to either Viaskin Peanut patch dosed at 100µg of peanut proteins (active group) or to Viaskin Placebo patch (Placebo group) in a 1:1 ratio.

The hospitals included in the study were: Necker Hospital for Sick Children, Paris; Lenval Hospital, Nice; Hospices Civils, Strasbourg; Saint-Vincent de Paul Hospital, Lille; and, Central Hospital, Nancy, France. Viaskin was applied daily until a second DBPCFC after 6 months of treatment (in an 18-month treatment scheduled trial). Specific IgE (Immunoglobulin E) and IgG4 (Immunoglobulin G4), key indicators of the desired immune response, were monitored at specific time points over the treatment period.

The mean \pm standard deviation (sd) cumulated reactive dose of peanut at entry was 65.8 \pm 88.8mg (active group) and 81.87 \pm 104.59mg (placebo group). During the DBPCFC **after 6 months of treatment, 18.5% of patients in the active group multiplied by \geq 10-fold the cumulated reactive dose of peanut proteins versus 0% patients in the placebo group (Fisher's exact test, p=0.05).**

Important immunologic changes occurred in the active group within 6 months: the mean net increase \pm sd and median net increase of peanut-specific IgE were 92.8 \pm 136 and 30.2KU/L (active) vs 30.8 \pm 145 and 1.8 KU/L(placebo)respectively; (Wilcoxon test, p=0.036). The mean net increase \pm sd and median net increase of peanut-specific IgG4 were 0.92 \pm 1.2 and 0.6 mg/L (active) vs 0.1 \pm 0.65mg/L and 0 mg/L (placebo) respectively;(Wilcoxon test, p<0.0001).

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 AP-HP

The most important university hospital of Europe, the Assistance Publique-Hôpitaux de Paris is the university hospital of Ile-de-France. With 12 million of people, AP-HP offers 37 hospitals united in 12 hospital groups, 7 million of patient, and more than 2 800 clinical research projects underway in 2011.

Care of nearness to the coverage of the gravest emergencies and rare diseases, AP-HP meet a need of million patients, every year. It turns out thousands of professionals, and manage many research project (2 800 in 2011) in order to make the medicine of the future. AP-HP spreads its medical, paramedical and hospital expertise around the world. With the same aim of excellence, the 90 000 professionals offer to the patient and their relatives the best cares.

The DRCD (Clinical Research and Development Department) is responsible for developing research at AP-HP and implanting all sponsorship regulations pursuant to the provision of article L1121 et seq. of the French Public Health Code. In this context, it attends to funding, implementation, supervision and quality control (monitoring) of research protocols sponsored by AP-HP

Facts and figures

- More than 2 800 clinical research projects underway in 2011 within AP-HP, all sponsors combined.
- 865 research projects (as 31/12/2011) sponsored or managed by AP-HP, including 570 clinical trials with AP-HP institutional sponsorship.
- 20 020 patients included in clinical trials sponsored or managed by AP-HP.
- 839 professionals dedicated to research and managed by the DRCD.
- 442 portfolios of active patents filed.



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 (incorporated in 2002) 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. 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 designed two products: Viaskin® Peanut and Viaskin® Milk. The development 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

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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