

Viaskin Peanut demonstrates strong efficacy trend in severely peanut-allergic children in 18-month results of ARACHILD pilot study

- **Two-thirds of 5-11 years old children reached efficacy endpoint after 18-month treatment**
 - **ARACHILD provides a very good baseline for DBV's ongoing phase IIb ('VIPES') study**

Bagneux, France, June 19, 2013 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin[®], a new standard in the treatment of allergy, announced today the 6-, 12- and 18-month efficacy data of Arachild, a study sponsored by Assistance Publique-Hôpitaux de Paris (AP-HP). The analysis of the data shows that two-thirds of children less than 12 years old reach the efficacy endpoints after 18-month treatment with Viaskin Peanut 100 µg. The serological response observed over the period was robust and strong, implying efficacy of the ongoing desensitization process..

Pr. Jean-Marc Tréluyer of *the Unité de Recherche Clinique* at Tarnier Hospital (AP-HP, Paris, France) successfully led ARACHILD, one of the largest study ever conducted in food allergy. Pr Christophe Dupont, coordinator of the study, provided DBV with cleaned and comprehensive top-line efficacy data, which were presented to DBV's Scientific Advisory Board on June 14, 2013. The complete efficacy and safety study results should be published in the coming months by Pr. C. Dupont

ARACHILD, a multicenter double blind, placebo-controlled clinical trial was designed to assess the efficacy and safety of epicutaneous immunotherapy (EPIT) using DBV's Viaskin Peanut in 54 randomized subjects aged 5 to 17 with a confirmed severe peanut allergy. Subjects who reacted to a cumulative dose of peanut proteins of less than 300mg were eligible and randomized to either Viaskin Peanut at 100µg of peanut proteins (active group) or to Viaskin Placebo (placebo group) in a 1:1 ratio. At 6 months, all patients were switched to active treatment and received Viaskin Peanut for an additional 12 months.

In the active group (28 subjects), the 12- and 18-month data shows consistent and sustained improvement across the study population, with 20% and 40% of subjects respectively consuming at least 10 times more peanut protein than at the beginning of the trial (defined as 'success' or 'responders'). The preliminary 6-month data released in June 2012 was partially validated after database cleaning; serological results were fully confirmed while no statistical difference appeared anymore in the treated versus placebo groups at food challenge. After 6-month treatment, the analysis (pooled on 50 subjects) shows that 5 children multiplied by at least 10-fold the cumulated reactive dose of peanut proteins compared to baseline versus 2 children in the placebo group (26 subjects).

A specific sub-analysis of results in 19 adolescents (12-17 years old) and 35 children (5 to 11 years old) shows clear-cut trends. Despite a positive serological response, adolescents showed no responders at 6-, 12- and 18-month, while children showed constant and progressive increase in number of responders, with respectively 14.7%, 28.1% and 66.7% of responders at 6-, 12- and 18-month. Overall, children were able to eat on average, after 18 months of Viaskin Peanut treatment, a cumulated reactive dose of approximately 1.5 peanut, compared with traces at the start of the trial. Among the 10 children who passed the food challenge, 4 reached the cumulative reactive dose of more than 1000mg of peanut protein (equivalent to 4 peanuts).

Viaskin[®] Peanut also showed significant immunological changes (secondary efficacy endpoints) in the overall population, with clear-cut results in children. In treated children, peanut-specific IgE (immunoglobulin E) were increased by more than two-fold at 6-month, before decreasing and approaching toward initial levels at 18-month, while Peanut-specific IgG4 (immunoglobulin G4) increased by more than eight-fold over 18-month of treatment. The trends observed in both indicators suggest – as expected – a successful desensitization process in children while the response observed in adolescents was clear, but not robust enough to generate significant clinical outcomes for that specific patient population.

The Arachild results provide strong support for the continued development of epicutaneous immunotherapy" stated Pr. Hugh Sampson, Chief of the Division of Allergy & Immunology in the Department of Pediatrics, Director of the Jaffe Food Allergy Institute, and Dean of Translational Biomedical Science at The Mount Sinai Medical Center in New York, USA. Pr. Sampson is also a member of DBV's Scientific Advisory Board as well as International Coordinating Investigator for DBV's Phase IIb VIPES clinical trial and Principal Investigator of the National Institutes of Health-sponsored Consortium of Food Allergy Research clinical study with Viaskin Peanut (CoFAR6). "There is an unmet medical need for new therapeutic approaches that could lead to meaningful quality of life improvements for patients who are in constant fear of violent allergic reactions."

Pr. Christophe Dupont, French National Coordinating Investigator of ARACHILD study and Head of the Pediatric-Gastroenterology Ambulatory Department at the Necker Hospital (AP-HP) said: *"The Arachild data reveal an interesting trend toward efficacy as the change in peanut consumption observed at 18 months represents an important improvement in the quality of life of patients."*

Dr. Pierre-Henri Benhamou, Chairman and CEO of DBV Technologies, said: *"The objective of the Arachild study, that was launched in 2010, at a time when DBV had little evidence of the efficacy of its platform in humans, was to gauge the safety and efficacy of Viaskin in severe peanut allergic patients. The results observed at 18-months in children show that the response is robust enough to claim that Viaskin has a clear efficacy."* Dr. Pierre Henri Benhamou continued: *"I would like to thank the team at AP-HP for leading the way with this first pilot study, that has notably allowed DBV to optimize the development of Viaskin. Thanks to ARACHILD, we have optimized the protocol, methodology and design for DBV's on-going Phase IIb VIPES clinical trial in North America and Europe."* Dr. Pierre-Henri Benhamou concluded: *"Overall, we believe that Viaskin Peanut has a strong potential to safely treat peanut allergic patients, and that VIPES should provide evidence of efficacy in adolescents and adults, at higher doses."*

The French hospitals included in the study were: Necker Hospital (AP-HP, Paris), Lenval Hospital (Nice), Hospices Civils (Strasbourg), Saint-Vincent de Paul Hospital (Lille), and Central Hospital (Nancy).

Meeting and audio Webcast for French-speaking analysts and investors on June 20, 2013

DBV will host an analyst & investor meeting on 20, June 2013 at 11:00 AM (Paris time, CET) at NYSE Euronext, 39 rue Cambon – 75001 Paris.

An audio webconference call will take place simultaneously. The web conference will be available on DBV' homepage: www.dbv-technologies.com. Participants in the conference call should dial in approximately 5 to 10 minutes prior to its start. No reservation is required to participate.

Telephone numbers in order to connect to the conference from France +33(0)1 76 77 22 21, with an access code: 7980610.

A recording will be available shortly after the call. Phone numbers to access the replay of the conference from France is +33 (0) 1 74 20 28 00 and access code is 7980610. This replay will be available for one week following the meeting.

Audio Webcast for English-speaking analysts and investors on June 20, 2013

DBV will host an analyst & investor call on 20, June 2013 at 5:00 PM (Paris time, CET) or 11:00 AM (NY time, EST). The presentation will be available on the DBV' homepage: www.dbv-technologies.com. Participants in the conference call should dial in approximately 5 to 10 minutes prior to its start. No reservation is required to participate. The conference ID is 6029386.

Telephone numbers in order to connect to the conference are: from France and continental Europe +33(0)1 76 77 22 25, from UK +44(0)20 3427 1906 and from the United States +1646 254 3362, access code: 6029386. A recording will be available shortly after the call.

Phone numbers to access the replay of the conference are: from France and continental Europe +33 (0)1 74 20 28 00, from UK +44 (0)20 3427 0598 and from the United States +1 347 366 9565 and access code is 6029386. This replay will be available for one week following the meeting.

About peanut allergy: a life-threatening risk for millions of people

In the US, about 1.1% of the general population, or over 3 million people, are allergic to peanuts, which results in about 100 to 150 deaths per year. This allergy affects both adults and children, 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 generally considered to be persistent; many studies indicate that fewer than 20% of children will outgrow their allergy. Peanut allergy is more severe than other common food allergies, including milk and egg allergies.

About DBV Technologies

DBV Technologies is developing Viaskin[®], 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[®] 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[®] Peanut and Viaskin[®] Milk. The clinical development program for Viaskin[®] 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[®] 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

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.

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.
- 480 portfolios of active patents filed.
- 183 license agreements.
- 50 start-ups

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