DBV Technologies enters into a strategic manufacturing agreement with Sanofi

Sanofi will manufacture DBV Technologies’ Active Pharmaceutical Ingredients based on whole natural allergens

Bagneux, FRANCE, March 5th 2013 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345), creator of Viaskin®, a new standard in the treatment of allergies, announced today that it entered into a strategic manufacturing agreement with Sanofi to produce Viaskin’s Active Pharmaceutical Ingredients (API), such as the peanut protein extract.

Per the agreement, Sanofi will act as DBV’s Contract Manufacturing Organization (CMO). In this context, Sanofi will scale-up and validate the production process of Viaskin®’s API and full supply at commercial scale.

DBV will benefit from Sanofi’s strong expertise in biologics development and manufacturing in the field of plant extraction and purification of therapeutic proteins to further develop Viaskin. In addition, the manufacturing site at Aramon (France), which manufactures produces DBV’s APIs, is FDA-approved and has all the necessary capabilities to support the registration of Viaskin® for both the EU and US markets.

Dr. Pierre-Henri Benhamou, Chairman and CEO of DBV Technologies, said: “The strategic manufacturing agreement with Sanofi is an important step for DBV in the light of Viaskin’s late-stage development and potentially fast-coming commercialization. We believe that the extraction and protein expertise of Sanofi, notably at the Aramon site, will highly benefit DBV, thereby securing our API procurement in the years to come. We were very impressed by the quality and reactivity of the Sanofi teams, which match perfectly with DBV’s culture and look forward to working closely with them in the months to come.”

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, is 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 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.

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 involves 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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