DBV Technologies Enters into Collaboration Agreement with BioNet-Asia and University of Geneva on Whooping Cough Booster Vaccine

Agreement established after positive pre-clinical results were obtained by DBV and University of Geneva combining DBV’s and BioNet’s unique technologies

A Phase I, clinical proof of concept study will be initiated in H2 2014 by the University of Geneva

PARIS, BANGKOK and GENEVA, 26 November 2013 - DBV Technologies (Euronext Paris: DBV), creator of Viaskin®, announced today that it has entered into a collaboration agreement with BioNet-Asia Co. Ltd and the University of Geneva (UNIGE) to work on a whooping cough (pertussis) booster vaccine. The clinical proof of concept product candidate will combine BioNet’s unique recombinant non-toxic Pertussis Toxin (rPT) with DBV’s Viaskin® technology, which allows for the epicutaneous delivery of the antigen without any adjuvant.

The DBV-BioNet-UNIGE research and development collaboration will consist of a non-clinical component and a clinical development program. The Non-Clinical Study Program will measure the specific immunity and protective responses elicited by a Viaskin® pertussis antigens boost in a Bordetella pertussis respiratory murine model. The Clinical Study Program will be initiated in the second half of 2014 to evaluate the boosting influence of recombinant non-toxic pertussis toxin delivered by Viaskin® in a Phase I, proof-of-concept, study performed under the responsibility of Pr. Siegrist from the University of Geneva, Switzerland. This Phase I clinical trial will assess the safety and immunogenicity of Viaskin®-PT and evaluate the humoral and cellular responses in healthy adults.

Pr. Claire-Anne Siegrist, Director of the Center of Vaccinology of the University of Geneva said: “It is a rare and fantastic opportunity for scientists with a new idea to meet the partners with the expertise required for this idea to become a concept, to challenge this concept in preclinical models and to generate such exciting results that a Phase I clinical trial is the obvious next step. There are a number of diseases and medical conditions for which immune memory must be reactivated at regular intervals, and we are now learning how to do this. If the Viaskin booster immunization platform proves as efficient in humans as in mice, it will not only enable the much needed better prevention of pertussis but be a real breakthrough in vaccinology.”

Dr. Pierre-Henri Benhamou, Chairman and CEO of DBV Technologies, said: “We are honored to collaborate with Pr Claire-Anne Siegrist, Pr Paul Henri Lambert and the team of the University of Geneva on this very exciting new application of the Viaskin Platform for booster vaccination. We consider as a privilege to be the first European partner of BioNet in the frame of such a trustful collaboration with Dr. Pham Hong Thai and Dr. Jean Petre and the rest of BioNet team. This exceptional partnership with BioNet-Asia and the University of Geneva will combine unique world class scientific and technological expertise. With BioNet’s experience in recombinant vaccine antigens, coupled with DBV’s epicutaneous delivery method and the University of Geneva’s outstanding vaccinology track record, this collaboration could open a new field to the delivery of vaccines, allowing to increase compliance and help control diseases such as pertussis that are unfortunately on the rise again. This agreement further underscores the far-reaching potential of the Viaskin® platform beyond food allergies.”

Dr. Pham Hong Thai, Managing Director of BioNet-Asia, said: “We are delighted to join this collaboration which gathers expertise from Switzerland, France and Thailand in the field of vaccinology, delivery systems and development of innovative vaccines. The preclinical results of BioNet’s acellular pertussis vaccine when delivered with the patented DBV’s Viaskin patch confirm the unique profile of our recombinant vaccine in which the genetically-detoxified Pertussis Toxin (rPT) retains the immunological properties of the native protein. This is an important milestone for BioNet as we progress with the development of our Recombinant Acellular Pertussis Vaccine Program worldwide. We are excited to start this phase 1 clinical study in Europe in 2014 and we are confident that the idea proposed by UNIGE to combine both BioNet and DBV technologies will turn into a breakthrough vaccine and delivery solution to the resurgence of pertussis in the developed countries.”
About Pertussis
Pertussis, commonly known as “whooping cough”, is a very contagious respiratory illness caused by a type of bacteria called Bordetella pertussis. Pertussis vaccination is recommended as part of routine childhood immunization. Although the incidence of pertussis has declined through the immunization of infants and young children, vaccine-induced immunity does not persist long. This phenomenon of “waning immunity” was accentuated by the introduction of acellular pertussis vaccines in 1996. According to the Centers for Disease Control and Prevention (CDC), there are 16 million pertussis cases worldwide each year, mainly in adolescents and adults. These therefore pass on the disease to infants who have not yet completed their pertussis immunization series, and in whom pertussis is most severe. Consequently, booster immunizations are now recommended to adolescents and adults, especially those in contact with young infants. A new technology - user friendly and non-invasive– using a recombinant pertussis vaccine could help increase the compliance required for these booster vaccinations.

About BioNet-Asia
BioNet-Asia Co. Ltd is an independent biotechnology company focused on the discovery and development of innovative vaccines to prevent a number of life-threatening diseases. In its state-of-the-art facilities in Thailand, BioNet has built up a unique expertise in genetic engineering, protein conjugation, cell-culture and vaccine formulation. The company has developed a broad pipeline with ten products in R&D and clinical stages, including vaccines and recombinant proteins such as CRM197 protein carrier, dengue and hepatitis B vaccines. BioNet has also filed a patent application for a new Recombinant Acellular Pertussis Vaccine which is about to enter Phase I clinical trial in 2014. BioNet has several collaborations with first-class biopharmaceutical companies, vaccine manufacturers and academic organizations around the globe. Recently, the company has successfully transferred the technology to produce Hib meningitis vaccine which is now commercialized as a pentavalent vaccine in Asia. With a network of international vaccine producers and experts, BioNet is also uniquely positioned as the partner of choice for the development and marketing of vaccines in the emerging countries. Over the years, BioNet has created several strategic alliances fostering vaccine self-reliance and leading to the manufacturing and supply of billions of doses of vaccines on all continents. For additional information about the company, please visit www.bionet-asia.com

About University of Geneva
Founded in 1559 by Jean Calvin and Theodore de Beze, the University of Geneva is the second largest Haute école in Switzerland and is amongst the top 100 best universities in the world. The institution enjoys worldwide recognition and is highly opened to the world. Every year the University welcomes around 16 000 students in its eight faculties teaching science, medicine, humanities, social and economic sciences, law, theology, psychology and educational sciences, translation and interpreting. The University of Geneva has three missions: education, research and knowledge-sharing. The University has been a member of the League of European Research-intensive Universities since 2002. www.unige.ch

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 related to DBV Technologies
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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