DBV Technologies, BioNet-Asia and the Geneva University Hospitals Initiate Phase I Study of Viaskin rPT for Pertussis Booster Vaccination

Proof of concept trial will evaluate the safety and immunogenicity of two doses of Viaskin rPT in healthy adults

Vaccine program to test Viaskin’s needleless and adjuvant-free patch technology in reactivating pertussis toxin immunity

PARIS, BANGKOK and GENEVA September 6, 2016 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, the Geneva University Hospitals (HUG) and BioNet-Asia Co. Ltd today announced that the first subject has been enrolled in a proof of concept Phase I clinical trial testing Viaskin rPT in the reactivation of immunity against Bordetella pertussis (whooping cough) in healthy adults. This pertussis vaccination program intends to test the ability of DBV’s needleless and adjuvant-free patch technology, Viaskin, to epicutaneously deliver two doses of BioNet’s genetically detoxified, recombinant pertussis toxin (rPT) to boost immunity against whooping cough. The Phase I proof of concept study is being conducted under the supervision of Professor Claire-Anne Siegrist from the Clinical Research Center of HUG and is being sponsored by DBV Technologies.

Dr. Pierre-Henri Benhamou, Chairman and Chief Executive Officer of DBV Technologies, said: "Utilizing the skin’s immune properties for vaccination is a paradigm shift in this field. Professor Siegrist and her team recently published a paper with pre-clinical data showing that a single application of Viaskin rPT on intact skin was capable of reactivating whooping cough immunity without the use of adjuvants. This valuable collaboration with HUG and BioNet has the potential to be a breakthrough in vaccinations; if Professor Siegrist and her team can replicate the in vivo results in humans, Viaskin rPT could be the first non-invasive and self-administrable vaccine to be developed for boosting pertussis immunity." Dr. Benhamou continued, "Our commitment to developing transformational products that can improve lives drives our innovation strategy at DBV. Enthusiasm for our unique patient-centric approach to immunotherapy was recently captured by the fast enrollment of our Viaskin Phase III trial in peanut allergy. As in food allergies, our focus in vaccines is to develop novel products that can address unmet medical needs in an effective and safe way. We are excited to launch the rPT program, which continues to highlight the strengths and versatility of our Viaskin technology platform."

A significant increase in the prevalence of pertussis, a highly contagious respiratory illness, has been reported in a number of countries around the world, and it is associated with increased mortality in young infants. Pertussis vaccination is recommended as part of routine childhood immunization, but the immunity acquired through vaccination or infection is short-lived, and its maintenance requires repeated boosting at regular time points. Viaskin’s novel epicutaneous delivery technology may offer a more convenient, needleless and adjuvant-free option for boosting pertussis immunization.
**Professor Claire-Anne Siegrist**, Director of the Center of Vaccinology of HUG, said: “*We know that regular boosters are needed to maintain protection against pertussis, and our preclinical studies showed that the reactivation of immune memory may be achieved using Viaskin. We are eagerly looking forward to assessing whether this is similarly effective in humans, as the possibility of using needleless and adjuvant-free booster vaccines would be a change of paradigm in our approach to the prevention of pertussis and of other vaccine preventable diseases.*”

**Dr. Pham Hong Thai**, Chief Executive Officer of BioNet-Asia, said: “*Given the safety and superior immunogenicity of our recombinant acellular pertussis vaccine as it was demonstrated in a Phase II/III trial, we are excited to explore alternative delivery options for BioNet’s proprietary genetically inactivated pertussis toxin. This promising collaboration with DBV and HUG could be the first step to offering a needle-free recombinant pertussis booster vaccine, and it shows our commitment to deliver innovative solutions for controlling the resurgence of pertussis around the globe.*”

**About the Phase I Viaskin rPT Trial**
A Phase I dose-escalation, randomized, double-blind, placebo-controlled safety and immunogenicity study will assess the safety of BioNet’s genetically-detoxified rPT administered by DBV’s Viaskin patches in 60 young healthy adults. Secondary endpoints will assess the patients’ humoral responses elicited by Viaskin rPT 25 µg and 50 µg compared to placebo. Immune cellular responses will also be monitored as exploratory endpoints.

The trial will take place in the Clinical Research Center of HUG. Men and women aged 18-40 years who have been vaccinated during childhood against pertussis will be randomized into two cohorts of 30 subjects each. The first cohort will receive two applications of Viaskin rPT 25 µg or placebo. The Viaskin patches will be applied for 48 hours, with a two-week interval between applications. Four weeks after the second Viaskin application, participants will receive one dose of Boostrix® dTpa vaccine to ensure the recall of immunity against diphtheria, tetanus and the three pertussis antigens (only a single antigen will be delivered through Viaskin rPT). All subjects will be observed after each application. Local and systemic adverse events will be monitored.

The safety and tolerability of the first dose of Viaskin rPT 25 µg will be analyzed before initiating treatment in the second patient cohort, which is expected to receive two applications of Viaskin rPT 50 µg or placebo, and analysis of the results will follow the same study design as in the Viaskin rPT 25 µg cohort.

**About Bordetella Pertussis**
Pertussis, commonly known as whooping cough, is a highly contagious respiratory illness caused by a type of bacteria known as Bordetella pertussis. Pertussis vaccination is recommended as part of routine childhood immunization. Although the incidence of pertussis has declined as a result of immunization of infants and young children, vaccine-induced immunity does not persist for long. This phenomenon, known as waning immunity, has increased since the introduction of acellular pertussis vaccines in 1996, which tend to provide short-lived protection against the Bordetella pertussis bacteria. According to the U.S. Centers for Disease Control and Prevention (CDC), there are 16 million pertussis cases worldwide each year, mainly in adolescents and adults who often can infect infants who have not yet completed their pertussis immunization. In these young patients, pertussis can be severe and fatal.

Booster immunizations are now recommended for adolescents and adults, but compliance is not always high. A new vaccine technology that is patient-friendly, painless and non-invasive could help increase the compliance for booster immunization against whooping cough.

**About DBV Technologies**
DBV Technologies is developing Viaskin®, a proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT®, DBV’s method of delivering biologically active compounds to the immune system through intact skin. With this new class of self-administered and non-invasive product candidates, the company is dedicated to safely transforming the care of food allergic patients, for whom there are no approved treatments. DBV’s food allergies programs include ongoing clinical trials of Viaskin Peanut and Viaskin Milk, and preclinical development of Viaskin Egg. DBV is also pursuing a human proof concept clinical study of Viaskin Milk for the treatment of Eosinophilic Esophagitis, and exploring potential applications of its platform in vaccines and other immune diseases.

DBV Technologies has global headquarters in Montrouge, France and New York, NY. Company shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and traded on the Nasdaq Global Select Market in the form of American Depositary Shares (each representing one-half of one ordinary share) (Ticker: DBVT). For more information on DBV Technologies, please visit our website: www.dbv-technologies.com
About Geneva University Hospitals
The Geneva University Hospitals (HUG), reference academic institution at both national and international level, gather eight public hospitals of Geneva. Their centres of excellence cover hepato-biliary and pancreatic diseases, cardiovascular diseases, oncology, musculoskeletal and sports medicine, old age medicine, genetic medicine and vaccinology. Its Center of Vaccinology, led by Professor Claire-Anne Siegrist, gained international recognition through the performance of a large first-in-humans Phase I randomized clinical trial that enrolled 115 subjects to characterize the safety and immunogenicity of the VSV-ZEBOV Ebola vaccine candidate.

With their 10,500 employees, the HUG welcome each year 60,000 hospitalised patients and assure 91,000 emergencies, 990,000 consultations or ambulatory care and 26,000 surgical procedures. More than 800 physicians, 3,000 interns and 150 apprentices perform their training here. The HUG are working closely with the Faculty of Medicine of the University of Geneva and WHO in various training and research projects. They develop partnerships with CHUV, EPFL, CERN and other actors from the Lemanic Health Valley. More information on: www.hug-ge.ch

About BioNet-Asia
BioNet-Asia offers access to vaccine and technology through biotech innovation and partnering networks. BioNet has built several international partnerships fostering vaccine self-reliance and leading to the supply of billions of doses of vaccines worldwide. BioNet has also a broad pipeline of vaccines in R&D and clinical stages. BioNet most advanced program is the development of a new generation of pertussis vaccines aimed at overcoming the waning immunity observed with the conventional acellular pertussis vaccines.

BioNet pertussis vaccine is produced from a new proprietary Bordetella pertussis strain expressing genetically detoxified Pertussis Toxin (rPT). The unique properties of BioNet rPT enables the vaccine to induce superior anti-PT immune response. BioNet has successfully demonstrated in a Phase II/III trial that its recombinant acellular pertussis vaccine (containing rPT and FHA), as standalone or in combination, could significantly boost immunity against pertussis in adolescents and adults. For additional information, please visit www.bionet-asia.com

Forward Looking Statements
This press release contains forward-looking statements, including statements about the potential safety and efficacy of Viaskin as a means of delivering recombinant pertussis toxin to boost immunity against Bordetella pertussis. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. The Company’s product candidates have not been approved for sale in any jurisdiction. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, the risk that historical preclinical results may not be predictive of future clinical trial results, and the risk that historical clinical trial results may not be predictive of future trial results. A further list and description of these risks, uncertainties and other risks can be found in the Company’s regulatory filings with the French Autorité des Marchés Financiers, the Company’s Securities and Exchange Commission filings and reports, including in the Company’s Annual Report on Form 20-F for the year ended December 31, 2015 and future filings and reports by the Company. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release, whether as a result of new information, future events or circumstances or otherwise.

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