





DBV Technologies, BioNet-Asia and Geneva University Hospitals Complete Dosing in First Cohort of Phase I Study of Viaskin rPT for Booster Vaccination Against Pertussis

DSMB expressed no safety concerns with Viaskin rPT 25 µg

Following positive DSMB review, dosing with Viaskin rPT 50 µg has been initiated

PARIS, BANGKOK and GENEVA November 17, 2016 - DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), the Geneva University Hospitals (HUG) and BioNet-Asia Co. Ltd today announced that in a planned interim assessment of the Phase I trial of Viaskin rPT for booster immunization against Bordetella pertussis, the independent Data and Safety Monitoring Board (DSMB) concluded that there were no safety concerns with the administration of Viaskin rPT 25 ug in the first subject cohort. Based on this review, enrollment in the trial has continued as planned, with dosing of Viaskin rPT 50 ug commencing in the second subject cohort.

The Viaskin rPT pertussis booster vaccination program intends to test the ability of DBV's needleless and adjuvantfree patch technology, Viaskin, to epicutaneously deliver two different doses of BioNet's genetically detoxified, recombinant pertussis toxin for boosting immunity against whooping cough.

In the first dosing cohort, subjects received two applications of either Viaskin rPT 25 ųg or placebo. Following the DSMB's positive recommendation, a second cohort of subjects will receive two applications of Viaskin rPT 50 ųg or placebo at two-week interval. This 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 sponsored by DBV Technologies.

About the Phase I Viaskin rPT Trial

This Phase I dose-escalation, randomized, double-blind, placebo-controlled safety and immunogenicity study is assessing the safety of BioNet's genetically-detoxified recombinant pertussis toxin 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 is being conducted in the Clinical Research Center of the Geneva University Hospitals. Men and women aged 18 to 40 years who have been vaccinated during childhood against pertussis will be randomized into two cohorts of 30 subjects each. 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 first cohort has received two applications of Viaskin rPT 25 ug or placebo. Following a positive DSMB review, dosing in the second patient cohort, which is expected to receive two applications of Viaskin rPT 50 ug or placebo has commenced.

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-of-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: <u>www.dbv-technologies.com</u>

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 hospitalized 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's pertussis vaccines are produced from a new proprietary *Bordetella pertussis* strain expressing genetically detoxified Pertussis Toxin (PTgen[™]). The unique properties of BioNet's PTgen enables the vaccines to induce superior anti-PT immune response. For additional information, please visit <u>www.bionet-asia.com</u>

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 forwardlooking 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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