# DBV Technologies, Geneva University Hospitals and BioNet-Asia Presented Additional Phase I Data on the Use of an Investigational Epicutaneous Patch in Boosting Pertussis Vaccination at the European Congress of Immunology

**PARIS, GENEVA and BANGKOK September 5, 2018** - DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), the Geneva University Hospitals (HUG) and BioNet-Asia Co. Ltd presented new data from a Phase I study evaluating the safety and immunogenicity of boosting young adults against pertussis toxin (PT) with an investigational epicutaneous patch containing recombinant PT (Viaskin-PT). The new results, which were presented at the 5th European Congress of Immunology (ECI) in Amsterdam, Netherlands, September 2-5, 2018, by Dr. Olga Chatzis and Prof. Claire-Anne Siegrist from HUG, highlighted data from two additional cohorts showing that following skin preparation with an epidermal laser, anti-PT booster responses elicited by Viaskin-PT were comparable to those elicited by Boostrix® dTpa, an injectable approved booster vaccine. In March 2017, data from this study reported no detectable immunogenicity signal following the application of Viaskin-PT on intact skin.

Data presented at ECI showed favorable safety and immunogenicity responses in healthy adults who received two applications of Viaskin-PT following skin preparation with an epidermal laser. No serious adverse events (SAEs) were reported. Most reported adverse events (AEs) were mild application-site reactions, and there were no AEs leading to study discontinuation. After the second application of Viaskin-PT, anti-PT IgG concentrations, which best correlate with a protective response against pertussis, were observed to be significantly higher in both Viaskin-PT cohorts (Viaskin-PT 25 µg, n=5, $p<0.001$; Viaskin-PT 50 µg, n=25, $p<0.001$) compared to placebo. Anti-PT concentrations elicited by two applications of a needle-less, adjuvant free vaccine were similar to those elicited by the injection of Boostrix® dTpa.

*"We are excited by such strong immunogenicity results, which may be the result of the combination of a greater immunogen (recombinant PT) and a novel approach to vaccination and look forward to further exploring the use of this needle-less patch to boost immunity. We believe that the micro-pores created by the laser facilitate antigen entry in the epidermis, allowing for more antigen to be captured by lymph nodes and thus more effectively reactivate pertussis-specific memory cells. This represents an important next step in exploring the use of novel technologies for vaccination,"* said Prof. Siegrist.

This Phase I proof of concept study was conducted under the supervision of Prof. Siegrist from the Clinical Research Center of HUG in collaboration with DBV Technologies and BioNet-Asia. The Company continues to evaluate these positive proof of concept results to determine potential next steps in vaccination.

**About the Phase I Viaskin-PT Trial**

This Phase I dose-escalation, randomized, double-blind, placebo-controlled safety and immunogenicity study assessed the safety of BioNet's genetically-detoxified recombinant pertussis toxin administered by DBV's Viaskin patches in 102 young healthy adults in four cohorts. Secondary endpoints assessed the subjects' humoral responses elicited by Viaskin-PT 25 µg and 50 µg compared to placebo. Immune cellular responses were also monitored as exploratory endpoints.

The trial was conducted in the Clinical Research Center of the Geneva University Hospitals. Men and women aged 18 to 40 years who were vaccinated during childhood against pertussis were randomized into the four cohorts of subjects. The Viaskin patches were applied for 48 hours, with a two-week interval between applications. Four weeks after the second Viaskin application, participants received 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 PT). All subjects were observed after each application. Local and systemic adverse events were monitored.

The first cohort received two applications of Viaskin-PT 25 µg (n=25) or placebo (n=5). Following a positive DSMB review, the second cohort received two applications of Viaskin-PT 50 µg (n=25) or placebo (n=5).

Following review of preliminary data released in 2017, DBV, HUG and BioNet added in cohorts 3 & 4 to receive Viaskin-PT following preparation of the skin with an epidermal laser (P.L.E.A.S.E., Pantec) before each patch application. The third cohort received two applications of Viaskin-PT 25 µg (n=5) or placebo (n=2). Following positive DSMB review, the fourth cohort received two applications of Viaskin-PT 50 µg (n=25) or placebo (n=10).

## 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. The Company's ordinary shares are traded on segment A of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and the Company's ADSs (each representing one-half of one ordinary share) are traded on the Nasdaq Global Select Market (Ticker: DBVT).

## About Geneva University Hospitals

The Geneva University Hospitals (HUG), a reference academic institution at both national and international level, gather eight public hospitals and two health clinics of Geneva. Their missions include providing health care to the community in all medical specialties, contributing to training physicians and health professionals, and conducting medical research as well as finding treatments. The HUG operate as a national reference centre for influenza and emerging viral infections, as well as for liver disease in children and paediatric liver transplant. They are a WHO Collaborating Centre in seven areas. Their 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 11,560 employees, the HUG welcome each year over 60,000 hospitalized patients and assure 120,000 emergencies, and more than a million consultations or ambulatory care and 27,000 surgical procedures. More than 900 physicians, 2,200 interns and 200 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 is a Biotech company focused on the development and production of Nextgen vaccines in Asia. BioNet aims to provide a rapid access to life-saving vaccines to the neediest on all continents.

BioNet is the only manufacturer of recombinant acellular Pertussis vaccines, produced by using a patented recombinant DNA technology. They contain a genetically-inactivated Pertussis Toxin (PTgen) which induces higher anti-PT immune response as demonstrated in several clinical trials. Two PTgen-containing vaccines are already available in Thailand: Pertagen®, a monovalent acellular Pertussis (aP) vaccine and Boostagen®, a Tetanus-diphtheria-acellular Pertussis (TdaP) combination vaccine which are used for booster immunization in adolescents and adults including pregnant women.

BioNet has also been offering access to vaccines and technologies through global partnerships that have led to the supply of billions of doses of vaccines worldwide. For additional information, please visit www.bionet-asia.com

## Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding the potential of Viaskin-PT. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties. At this stage, the products of the Company have not been authorized for sale in any country. 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. 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, 2017 and future filings and reports by the Company. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release.

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