



## DBV Technologies, BioNet-Asia and Geneva University Hospitals Announce Phase I Trial Results of Viaskin rPT in Pertussis Booster Vaccination

**PARIS, BANGKOK and GENEVA March 30, 2017** - DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), the Geneva University Hospitals (HUG) and BioNet-Asia Co. Ltd today announced results from a Phase I trial assessing Viaskin rPT's ability to boost immunity against pertussis by epicutaneously administering two doses of BioNet's recombinant pertussis toxin.

The study evaluated the safety and immunogenicity of Viaskin rPT 25 µg (n=25) and 50 µg (n=25) in 60 healthy adults randomized 5:1 to each dose cohort versus placebo (n=10). The primary endpoint of the study was the incidence of treatment-emergent adverse events (AEs) related to the application of Viaskin rPT, and secondary objectives assessed humoral responses compared to placebo. After further analysis of the data, limitations in the study design and protocol were observed. DBV, HUG and BioNet continue to review preliminary study data, and are evaluating if further development pathways, including optimization of Viaskin rPT, will be explored.

Mild application-site reactions were observed in all cohorts, and no serious adverse events (SAEs) attributed to study drug were reported. After the second application of Viaskin rPT 25 µg and 50 µg, measures of PT-specific antibody responses by enzyme-linked immunosorbent assay (ELISA) were not observed to be statistically significant, but serum samples showed a wide distribution of human anti-PT IgG antibodies. In the placebo, Viaskin rPT 25 µg and 50 µg cohorts, respectively, 30% (n=3), 36% (n=9) and 40% (n=10) of subjects were seropositive at baseline, defined in this study as having anti-PT IgG antibodies greater than or equal to 5 UL/mL, and thus not assessable for seropositivity analysis. In the seronegative population at baseline, two subjects on Viaskin rPT 50 µg (13.3%), one subject on Viaskin rPT 25 µg (6.3%) and no subjects on placebo (0.0%) were seropositive following the second administration of Viaskin rPT. DBV, HUG and BioNet continue to evaluate the immunogenicity findings observed to better understand potential future development plans for Viaskin rPT.

*"We have seen promising preclinical data showing significant immunogenicity with Viaskin rPT. We can now take key learnings from this first clinical trial attempt, and implement the necessary improvements needed to potentially conduct more informative studies and improve the immunogenicity of Viaskin rPT in the future," said Professor Claire-Anne Siegrist, Director of the Center of Vaccinology of HUG. "The application of the novel Viaskin technology platform in immunization enables us to explore potential areas of development for patients that are currently being underserved by approved vaccines today."*

This Phase I proof of concept study was conducted under the supervision of Professor Claire-Anne Siegrist from the Clinical Research Center of HUG and was 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 assessed the safety of BioNet's genetically-detoxified recombinant pertussis toxin administered by DBV's Viaskin patches in 60 young healthy adults. Secondary endpoints assessed the subjects' humoral responses elicited by Viaskin rPT 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 two cohorts of 30 subjects each. 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 rPT). All subjects were observed after each application. Local and systemic adverse events were monitored.

The first cohort received two applications of Viaskin rPT 25 µg or placebo. Following a positive DSMB review, the second patient cohort received two applications of Viaskin rPT 50 µg or placebo.

### 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 A 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](http://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 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](http://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. In December 2016 BioNet received Marketing Authorization Approval from the Thai Food and Drug Administration for its standalone recombinant acellular Pertussis (aP) vaccine Pertagen™ and Tetanus-diphtheria-acellular Pertussis (Tdap) combination vaccine Boostagen™. BioNet's new generation pertussis vaccines are produced from a proprietary *Bordetella pertussis* strain expressing genetically-inactivated Pertussis Toxin (PTgen). The unique properties of PTgen enables the vaccines to induce superior anti-PT immune response as demonstrated in comparative studies. Both BioNet recombinant aP and Tdap vaccines are indicated for booster use in adolescents and adults. For additional information, please visit [www.bionet-asia.com](http://www.bionet-asia.com)

### Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding the potential safety and efficacy of Viaskin rPT and statements reflecting management's expectations for clinical development of Viaskin rPT. 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, 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, 2016 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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