



## Key Scientific Data Demonstrating that Epicutaneous Administration May Reactivate Protective Immunity against Pertussis in an experimental model published in *Vaccine*

**PARIS, BANGKOK and GENEVA, 10 June 2015** - DBV Technologies Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, the University of Geneva (UNIGE) and BioNet-Asia Co. Ltd announced today the publication of key scientific data in *Vaccine* demonstrating the potential usefulness of the Viaskin® technology to boost protective immunity against *Bordetella pertussis* (whooping cough). This preclinical in vivo, proof-of-concept experiment shows that a single application of DBVs' Viaskin® delivering BioNet's rPT (recombinant Pertussis Toxin) alone or in combination with pertactin and filamentous hemagglutinin effectively reactivated vaccine-induced pertussis immunity and protects against *Bordetella pertussis*.

DBV Technologies, UNIGE and BioNet-Asia are currently preparing a proof-of-concept Phase 1 clinical trial with a pertussis boosting vaccine using DBV's Viaskin® patch technology, which allows the epicutaneous delivery of antigens without adjuvants, loaded with BioNet's genetically-inactivated rPT. It is anticipated that this Phase 1 trial will assess the safety and immunogenicity of Viaskin® rPT in 60 young adults. This trial is expected to be performed under the supervision of Pr. Claire-Anne Siegrist of UNIGE and sponsored by DBV. The proof of concept trial is expected to start in the first quarter of 2016.

**Dr. Pierre-Henri Benhamou**, Chairman and CEO of DBV Technologies, said: *"We would like to congratulate the scientists of the three teams for their outstanding preclinical achievement. This data demonstrates the potential efficacy of the Viaskin® technology to develop a pertussis boosting vaccine without requiring any needles or adjuvants. The growing incidence of pediatric pertussis cases advocates for the need of periodic boosters that would be facilitated by convenient and adjuvant-free vaccines."* Dr. Benhamou continued, *"Viaskin's epicutaneous delivery mechanism enables us to deliver optimized antigens such as BioNet's genetically-detoxified Pertussis Toxin, which could generate a better tolerated and more efficacious booster vaccine product."*

**Pr. Claire-Anne Siegrist**, Director of the Center of Vaccinology of the University of Geneva said: *"It is remarkable that a single application of Viaskin® coated with 3 pertussis antigens on intact skin was capable of reactivating protective immunity against a pathogen as complex as pertussis. Should this be observed in humans, it could tremendously facilitate the administration of this vaccine as frequent boosters are needed to maintain protection at the highest level."*

**Dr. Pham Hong Thai**, CEO of BioNet-Asia, said: *"These results are consistent with the preclinical and clinical results of BioNet-Asia recombinant acellular pertussis vaccine when administered through traditional delivery. I am very happy to see this data published in the public scientific domain. We are eager to continue this exciting collaboration with DBV and the University of Geneva to open the prospect for a needle free recombinant pertussis vaccine."*

In order to mimic the human conditions under which vaccine-induced memory cells persist while antibodies disappear, the experiment featured in *Vaccine* used a novel adoptive transfer murine model in which immune splenocytes were transferred to syngeneic recipients prior to immunization and/or challenge. The data showed that a single 48-hour application of Viaskin® delivering rPT, pertactin and filamentous hemagglutinin on the intact skin of primed mice effectively triggers the reactivation of vaccine-induced memory B cells into plasma cells producing high titers of anti-PT IgG1 and IgG2a antibodies and protecting against intranasal challenge with live *B. pertussis*. Thus, combining the use of an optimally immunogenic rPT and Viaskin®, a novel epicutaneous delivery system, enabled reactivating protective pertussis immunity using an adjuvant-free, needleless, patient-friendly technology.

This scientific publication, entitled *"Needle-free and adjuvant-free epicutaneous boosting of pertussis immunity: preclinical proof of concept"*, is available online in *Vaccine*: [http://ac.els-cdn.com/S0264410X15007628/1-s2.0-S0264410X15007628-main.pdf?\\_tid=d811c4a6-0e97-11e5-b4b3-00000aacb35e&acdnat=1433848283\\_beca05adb892343d43cc6efefb92adde](http://ac.els-cdn.com/S0264410X15007628/1-s2.0-S0264410X15007628-main.pdf?_tid=d811c4a6-0e97-11e5-b4b3-00000aacb35e&acdnat=1433848283_beca05adb892343d43cc6efefb92adde)

### **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 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 then 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 contacts 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 DBV Technologies**

DBV Technologies is developing Viaskin<sup>®</sup>, an innovative new approach to the treatment of allergies – a major public health issue that has been increasing in prevalence. DBV Technologies, incorporated in France in 2002, has developed a proprietary, patented technology for administering an allergen to intact skin while avoiding transfer to the blood, and thus lowering the risk of a systemic, allergic reaction in the event of accidental exposure. DBV Technologies is focusing on food allergies, including milk and peanut, for which there are currently no effective treatments. DBV Technologies has designed two products candidates: Viaskin<sup>®</sup> Peanut and Viaskin<sup>®</sup> Milk. The clinical development program for Viaskin<sup>®</sup> Peanut has received Fast Track designation and Breakthrough Therapy designation from the U.S. Food and Drug Administration.

DBV Technologies shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345) and on the Nasdaq Stock 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 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](http://www.unige.ch)

### **About BioNet-Asia**

BioNet-Asia is an independent vaccine company with a focus on technological innovation and market access. BioNet has built several strategic alliances fostering vaccine self-reliance leading to the production and supply of billions of doses of vaccines worldwide. In its vaccine manufacturing plant in Thailand, BioNet is developing a broad pipeline of vaccines in R&D and clinical stages, such as recombinant Pertussis, CRM197 protein carrier, Dengue and Hepatitis B vaccines. The company has successfully transferred the technology in Asia to produce Hib meningitis vaccine which is now commercialized and pre-qualified as a pentavalent vaccine. BioNet has also filed a patent application for a new Recombinant Acellular Pertussis Vaccine that has been shown safe and highly immunogenic in a Phase I/II study. BioNet has several collaborations with first-class biopharmaceutical companies, vaccine manufacturers and academic organizations around the globe. For additional information about the company, please visit [www.bionet-asia.com](http://www.bionet-asia.com)

#### *Forward Looking Statement related to DBV Technologies*

*This press release contains forward-looking statements, including statements about the potential safety and efficacy of Epicutaneous Immunotherapy (EPIT<sup>®</sup>). 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 are 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, 2014 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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