

Press Release Bagneux, France, June 4, 2015

# DBV Technologies Announces EMA Paediatric Committee (PDCO) positive opinion on the Paediatric Investigation Plan for Viaskin® Peanut for the Treatment of Peanut Allergic Children

Acceptance of this Paediatric Investigation Plan (PIP) paves the way for the potential submission of a Marketing Authorization Application (MAA) in Europe following completion of the Viaskin<sup>®</sup> Peanut Phase III program

DBV Technologies, (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinicalstage specialty biopharmaceutical company, announced today that the Pediatric Committee (PDCO) of the European Medicines Agency (EMA) adopted a positive opinion agreeing the company's PIP for Viaskin<sup>®</sup> Peanut.

As part of the regulatory process for the registration of new medicines in Europe, pharmaceutical companies are required to provide a PIP outlining their strategy for investigation of the new medicinal product in pediatric population. An accepted PIP is a prerequisite for the filing for marketing authorization for any new medicinal product in Europe.

DBV Technologies' PIP provides a comprehensive clinical development plan for Viaskin<sup>®</sup> Peanut in pediatric population from 1 to 17 years of age, in particular the features of the phase III program in children. The positive opinion on the Company's PIP already takes into account the statistically significant Phase IIb trial results with Viaskin Peanut. The Viaskin<sup>®</sup> Peanut Efficacy and Safety trial, or VIPES, is a Phase IIb study demonstrating that Viaskin Peanut 250µg improved the peanut allergy disease in children. Available safety data from past and ongoing studies with Viaskin Peanut demonstrate a robust safety profile in children, adolescents and adults.

**Dr. Pierre-Henri Benhamou**, M.D., Chairman and CEO of DBV Technologies said: *"This PIP acceptance is the first regulatory milestone in Europe for Viaskin Peanut, and we are thrilled to see that our clinical program continues to move forward."* Dr. Benhamou continued, *"We are now well positioned to focus on the launch of our Viaskin Peanut Phase III trial in children."* 



## **About Viaskin® Peanut**

DBV is developing the Viaskin<sup>®</sup> technology platform, which delivers biologically active compounds, including allergens, via intact skin. Viaskin<sup>®</sup> is an electrostatic patch, based on Epicutaneous Immunotherapy, or EPIT<sup>®</sup>, which administers an allergen directly onto the superficial layers of the skin to activate the immune system by specifically targeting antigen-presenting cells without allowing passage of the antigen into the bloodstream.

Viaskin® Peanut is currently being investigated in clinical trials for treatment of peanut allergy.

### **About the VIPES Clinical Trial**

VIPES is a completed Phase IIb, double-blind placebo-controlled safety and efficacy study of Viaskin Peanut at 3 dose-levels (50 µg, 100 µg, 250 µg peanut protein) versus placebo for 12 months in an adult and pediatric populations of 221 subjects aged 6-55 years in 2 age strata (113 children aged 6-11 years, 108 adolescents and adults). A treatment responder was defined as a subject with a peanut protein eliciting dose equal to or greater than 1,000 mg peanut protein based on the results of the double blind, placebo controlled peanut challenge after 12 months of treatment or a subject with a  $\geq$ 10-fold increase of the eliciting dose at 12 months, compared to the initial eliciting dose. The trial met its primary efficacy endpoint at the highest explored dose (Viaskin Peanut 250 µg), which showed a higher proportion of responding patients (50.0%) versus placebo (25.0%) after 12 months of Epicutaneous Immunotherapy (EPIT); this difference reached statistical significance (p=0.0108). Overall, Viaskin Peanut 250 µg showed better results than Viaskin Peanut 100 µg or 50 µg.

#### **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

#### **Forward Looking Statements**

This press release contains forward-looking statements, including statements about the potential safety and efficacy of Epicutenaous Immunotherapy (EPIT) via Viaskin<sup>®</sup> Peanut and the regulatory pathways afforded by Breakthrough Therapy designation granted by the U.S. Food and Drug Administration or by the acceptance of the Paediatric Investigation Plan by the European Medicines Agency, which do not change the standards for approval and are not a guarantee of success. 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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