

Press Release

Bagneux, France, April 9, 2015

## DBV Technologies Receives FDA Breakthrough Therapy Designation for Viaskin Peanut for the Treatment of Peanut Allergy in Children

DBV Technologies is the first company to announce Breakthrough Therapy Designation from FDA in food allergy

Breakthrough Therapy Designation was granted following positive Phase IIb trial results emphasizing the need to provide a safe pharmaceutical treatment for patients suffering from life threatening food allergies

DBV Technologies, (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to Viaskin® Peanut for children.

Breakthrough Therapy Designation is intended to expedite the development and review of drugs/biological products for serious or life-threatening diseases or conditions, such as peanut allergy. Currently, DBV is actively preparing the launch of its Phase III trial of Viaskin Peanut in Children, suffering from peanut allergy, in close coordination with the US FDA.

The FDA granted this Breakthrough Therapy Designation after DBV reported positive Phase IIb results with Viaskin Peanut. The Viaskin® Peanut Efficacy and Safety trial, or VIPES, is a Phase IIb study demonstrating that Viaskin Peanut 250 µg improved the peanut allergy disease in children, as measured by a clinically significant endpoint. Available safety data from past and ongoing studies with Viaskin Peanut demonstrate an excellent safety profile in all age groups.

**Dr. Pierre-Henri Benhamou**, M.D., Chairman and CEO of DBV Technologies said: *“We are truly honored to be the first company to receive this FDA designation in food allergies. This is an historical event for the peanut allergy patients, caretakers and clinicians that have long awaited for a treatment for this severe disease.”* Dr. Benhamou continued, *“In addition to the Fast Track designation already granted in December 2011, we are thankful for the FDA’s decision to acknowledge the clinical relevance and importance of Viaskin Peanut. This Breakthrough designation highlights the urgent need to find a treatment for this life-threatening disease, and we are committed to bringing Viaskin Peanut to the market as quickly as possible.”*

### About Viaskin® Peanut

DBV is developing the Viaskin® technology platform, which delivers biologically active compounds, including allergens, via intact skin. Viaskin® is an electrostatic patch, based on Epicutaneous Immunotherapy, or EPIT®, 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 ≥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 Breakthrough Therapy Designation

The Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs/biological products that target serious or life-threatening conditions. A Breakthrough Therapy drug must show preliminary clinical evidence of a substantial improvement on a clinically significant endpoint over available therapies, or over placebo if there is no available therapy. The designation includes all of the Fast Track program features, as well as more intensive FDA guidance and discussion. The Breakthrough Therapy designation is distinct from both accelerated approval and priority review, which can also be granted to the same product if relevant criteria are met.

### About DBV Technologies

DBV Technologies is developing Viaskin®, 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, worldwide-patented technology for administering an allergen to intact skin while avoiding transfer to the blood, and thus considerably 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® Peanut and Viaskin® Milk. The clinical development program for Viaskin® Peanut has received Fast Track designation and Breakthrough Therapy designation from the US 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)



## Forward Looking Statements

This press release contains forward-looking statements, including statements about the potential safety and efficacy of Epicutaneous Immunotherapy (EPIT) via Viaskin® Peanut and the regulatory pathway afforded by Breakthrough Therapy designation by the FDA. It should be noted that Breakthrough Therapy designation does not change the standards for approval and is not a guarantee of success. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular it should be noted that these data are preclinical in nature and have not been demonstrated in human subjects. 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 prospectus filed with the SEC on October 22, 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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