

Press Release

Bagneux, France, June 8, 2015

## DBV Technologies Presents Clinical and Scientific Data at the EAACI Congress

Data presented on VIPES continues to show strong treatment effect and clear dose response

New Preclinical research data characterizes additional mechanistic features of Epicutaneous Immunotherapy (EPIT®)

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced that it has presented and will present clinical and scientific data on EPIT® for the treatment of food allergies at the 2015 European Academy of Allergy & Clinical Immunology (EAACI) Congress in Barcelona, Spain, that is being held from June 6-10. Specifically, investigators conducting the company's VIPES study presented additional post-hoc results from this Phase IIb trial for the treatment of peanut allergy, which showed that increasing the stringency of the responder definition led to a clear treatment dose-response versus placebo in both the study's population and in the children's subgroup. New scientific data also supports the use of EPIT® in the treatment of food allergies versus oral (OIT) and sublingual (SLIT) immunotherapy. The company remains on track to start its Phase III trial in peanut allergic children, the PEPITES (Peanut EPIT Efficacy and Safety study) study, in late 2015.

*"We strive to better understand and characterize EPIT®'s unique mechanism of action while building a robust research and development program. Last October, we reported positive efficacy and safety results in the largest peanut allergy trial ever conducted and we continue to show promising preclinical data supporting the use of EPIT® in food allergies" said Dr. Pierre-Henri Benhamou, Chairman & CEO of DBV Technologies. He continued, "Food allergy is an area of high unmet need, and we continue to make progress towards finding a treatment that can improve patients' ability to manage their disease."*

### Clinical Data Highlights

Dr. Christophe Dupont from Necker hospital, Paris, France, and Dr. Hugh Sampson from the Mount Sinai Hospital in New York, NY, USA presented results that continue to support the efficacy and safety profile of Viaskin® Peanut for the treatment of peanut allergy. Results of the company's Phase IIb trial in peanut allergic patients, the VIPES study, were previously presented at the 2015 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting. In VIPES, 221 patients were randomized to Viaskin® Peanut doses of 50 µg, 100 µg, or 250 µg, or to placebo. The primary efficacy endpoint, measured after 12 months of treatment, was the proportion of responders with a peanut eliciting dose 10-fold greater than baseline or achievement of a post-treatment eliciting dose of at

least 1,000 mg peanut protein. The primary efficacy endpoint was met at a dose of 250 µg, with 50.0% responders vs 25.0% with placebo,  $p=0.0108$ . Children in this arm (6-11 years) exhibited statistically significant efficacy with 53.6% responders vs 19.4% for placebo,  $p=0.0076$ .

New data presented by Drs. Dupont and Sampson also emphasized Viaskin® Peanut's clinical relevance and magnitude of treatment effect, which was observed in VIPES. A post-hoc analysis showed that increasing the stringency of the responder definition lead to a clear treatment dose-response versus placebo in both the study's population and in the children's subgroup. Using the more stringent definition, results show that 50% of children were able to achieve a post-treatment eliciting dose of at least 300 mg of peanut protein after 12 months of treatment versus 12.9% in the placebo arm ( $p=0.0039$ ). According to Dr. Dupont, in patients reacting to very low amount of peanut at baseline, the threshold dose of 300 mg peanut protein is clinically relevant as reaching this level significantly reduces the risk of allergic reactions against potential peanut traces in commercial processed foods.

## Scientific Presentations Highlights

Dr. Lucie Mondoulet, DBV's Deputy Chief Scientific Officer, presented data on EPIT®'s scientific profile. During an oral presentation, Dr. Mondoulet demonstrated that early treatment with EPIT® prevents sensitization and anaphylaxis to additional allergens via a Tregs-mediated mechanism, with EPIT®-induced Foxp3+ Tregs playing a key role in conferring this protection. The iterative sensitization mice model presented by Dr. Mondoulet, which mimics the 'allergic march', supports the company's belief that early treatment with Viaskin® may prevent the development of subsequent allergic diseases. Dr. Mondoulet also highlighted that the prolonged and continuous skin exposure to an allergen through EPIT® leads to sustained epigenetic modifications of the DNA expression of Th2 (down regulation) and Treg (up regulation) transcription factors. This trait of EPIT®-induced immunomodulation may explain the tolerance induction due to Viaskin® that has been observed in previous preclinical models.

In a poster titled "*Larger homing receptor expression on Tregs suggests increased efficacy of epicutaneous compared to oral or sublingual immunotherapy for the treatment of food allergy*," Dr. Vincent Dioszeghy, Researcher at DBV, showed that EPIT® induced more Tregs than OIT or SLIT, as well as inducing a larger repertoire of gut homing receptors. The increase in gut homing receptor CCR9 and in Th2 homing receptor CCR8 in these EPIT®-induced Tregs suggests a wider range of action for EPIT® over SLIT and OIT during food allergy desensitization.

## Summary of Corporate Satellite Symposium

In addition to data presented during the EAACI congress, DBV hosted its first Corporate Satellite Symposium chaired by Drs. Dupont and Sampson. During this meeting, the chairmen presented the key features and data of EPIT®. In addition, Dr. Spergel of the Children Hospital of Philadelphia, presented an anticipated a proof of concept clinical trial in children suffering from milk-induced Eosinophilic Esophagitis (EoE) who will be treated with Viaskin® Milk, which is scheduled to start before the end of 2015. The symposium was webcasted live, and a replay is available on DBV's website.



## 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)

## Forward Looking Statements

This press release contains forward-looking statements, including statements about the potential safety and efficacy of Epicutaneous Immunotherapy (EPIT<sup>®</sup>) via Viaskin<sup>®</sup> Peanut and the regulatory pathway afforded by Breakthrough Therapy designation by the U.S. Food and Drug Administration, which 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. 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.

## DBV Technologies Contacts

### Nathalie Donne

Director, Corporate Communication & Business Development

Tél. : +33(0)1 55 42 78 72

[nathalie.donne@dbv-technologies.com](mailto:nathalie.donne@dbv-technologies.com)

### Susanna Mesa

VP Finance, US Investor Relations & Strategy

Tél. : +1 917-346-3447

[susanna.mesa@dbv-technologies.com](mailto:susanna.mesa@dbv-technologies.com)

## DBV Technologies Media Contacts

### Marion Janic

Rooney & Associates

Tél. : +1-212-223-4017

[mjanic@rooneyco.com](mailto:mjanic@rooneyco.com)