

Press Release Montrouge, France, April 11, 2016

# DBV Technologies Announces Publication of Experimental Data on Targeted Regulatory T Cell Induction during Epicutaneous Immunotherapy

Publication in Cellular & Molecular Immunology Shows that Desensitization with

EPIT® Induces Tregs with Specific Homing Properties

Compared to Other Methods Studied, Scientific Data Shows that Only EPIT Retains Suppressive Ability After Treatment Discontinuation

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced the publication of experimental data in *Cellular & Molecular Immunology* characterizing the response of regulatory T cell (Tregs) to allergen-specific immunotherapy intended for the treatment of food allergies. The study characterized Tregs activity during Epicutaneous Immunotherapy (EPIT), oral immunotherapy (OIT) and sublingual immunotherapy (SLIT), and showed that all methods of treatment desensitized peanut-sensitized mice, but only EPIT-induced Tregs continued to show suppressive abilities after treatment discontinuation. DBV Technologies is developing Viaskin®, a proprietary technology that uses EPIT to deliver allergenic compounds targeting the immune system through the immune cells of intact skin, the Langerhans cells in the epidermis.

"Although EPIT, OIT and SLIT were all able to desensitize peanut-allergic mice, only EPIT-induced Tregs maintained suppressive activities after treatment was stopped," explained **Dr. Lucie Mondoulet**, Deputy Chief Scientific Officer, DBV Technologies. "Knowing that maintaining suppression ability after treatment may lead to the induction of long-term tolerance, we are now working to confirm these experimental data through our ongoing clinical trials with Viaskin."

The study, "Differences in Phenotype, homing properties and suppressive activities of Regulatory T cells induced by Epicutaneous, Oral or Sublingual Immunotherapy in Mice Sensitized to Peanut", showed that peanut desensitization with EPIT, OIT, and SLIT induce different Tregs subsets with differing homing properties, consequently inducing distinct long-term efficacy and maintenance ability *in vivo*. The three immunotherapy routes studied were all found to have a desensitization



effect, but suppressive activities after discontinuation of treatment were only observed with EPIT, and not with OIT or SLIT. Tregs observed during OIT and SLIT showed only an effector/memory cell profile, while Tregs during EPIT showed both effector/memory and naive cell profiles. These "naive" Tregs appear to induce sustained suppression after discontinuation of treatment, suggesting the induction of a longer-lasting allergen tolerance in a mice model.

The study was published in *Cellular & Molecular Immunology* and is now available via Open Access at <a href="http://www.nature.com/cmi/journal/vaop/ncurrent/full/cmi201614a.html">http://www.nature.com/cmi/journal/vaop/ncurrent/full/cmi201614a.html</a>.

Food allergies affect approximately 15 million Americans and 17 million Europeans, with the majority of patients being young children. There is currently no approved treatment other than dietary avoidance and the availability of self-injectable epinephrine.

# **Study Details**

To study efficacy and characterization of Tregs induced by the different therapies, mice sensitized with peanut protein extract (PPE) were randomly allocated to four groups of eight and treated for eight weeks: EPIT (100  $\mu$ g), OIT (1 mg the first week, 2 mg the second week, then 5 mg the following 6 weeks), SLIT (100  $\mu$ g) and a placebo group. Allergen specific responses as well as Treg phenotypes were analyzed using blood and tissue samples. To examine the transfer of protection by Tregs, mice were randomly allocated to six groups of 15 animals and treated for eight weeks: two groups treated by EPIT, two treated by SLIT and two groups treated by OIT. Following treatment, or 8 weeks after the end of treatment, one group treated with each form of immunotherapy were sacrificed for spleen cell recovery and CD4<sup>+</sup>CD25<sup>+</sup> cell sorting. Cells were then transferred into peanut-sensitized non-treated mice (n=8 per group). Three days after the transfer, mice were orally exposed to peanuts daily for 10 days. A tissue analysis of esophagus was then conducted to assess the protection conferred by passive Tregs transfer.

## **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: <u>www.dbv-technologies.com</u>

#### **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>. 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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