DBV Technologies Announces Publication of Preclinical Data in JACI Suggesting EPIT® Provides Sustained Protection Against Anaphylaxis

DBV Technologies (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced the publication of preclinical data in the Journal of Allergy and Clinical Immunology (JACI) suggesting that, independent of the route of sensitization, treatment with Epicutaneous Immunotherapy (EPIT) provides protection against food-induced anaphylaxis during therapy and after treatment discontinuation in animal models. The publication is now available at www.jacionline.org under "Articles in Press".

“For the first time, we were able to show that the epicutaneous route of delivery provided protection from food-induced anaphylaxis, and by supporting the development of gut-homing LAP+ Tregs, EPIT was observed to suppress mast cell activation leading to sustained clinical protection,” said Dr. Cecilia Berin, PhD, co-author of the publication. “These new data show that the unique immune communication between skin and gastrointestinal tract can be used to generate long-lasting protection from food allergies, and shed light on why we do not observe a sustained treatment response with other routes of immunotherapy.”

The publication, “Epicutaneous immunotherapy induces Gastrointestinal LAP + Tregs and prevents food-induced anaphylaxis,” details an independent study conducted by a team of researchers led by Dr. Cecilia Berin, PhD, Associate Professor, Pediatric & Allergy & Immunology, Icahn School of Medicine at Mount Sinai University, which compares the outcome of food allergy immunotherapy with EPIT and oral immunotherapy (OIT). Findings show that when mice were challenged after four weeks without treatment, EPIT-treated mice were still significantly protected while mice treated with OIT regained clinical reactivity, independent of the initial route of sensitization. In this study, Treg generation with OIT was impaired in allergic mice, which led to the lack of sustained protection after OIT was discontinued. In mice treated with EPIT, the skin-gut immune communication generated gut-homing, antigen-specific LAP+Foxp3-Tregs that directly suppressed systemic anaphylaxis and provided sustained protection after treatment discontinuation.

Food allergies affect approximately 15 million Americans and 17 million Europeans, with the majority of patients being young children. No approved treatment option exists for food allergic patients. Standard of care remains strict avoidance and the use of epinephrine to manage symptomatic life-threatening reactions.
Study Details

To determine the efficacy and mechanism of tolerance induced by EPIT, mice sensitized to ovalbumin (OVA) received either EPIT (100 µg) via Viaskin® patches once per week or OIT (1mg) once daily for eight weeks. Tissue and blood samples were analyzed along with symptom monitoring to assess protection. At the end of treatment, both EPIT and OIT-treated mice were protected, however when challenged again to test sustained protection after four weeks without treatment, only those which were treated with EPIT were still significantly protected. The protection against anaphylaxis was mediated via a TGF-β-dependent mechanism, which directly suppresses mast cell activation in the absence of modulation of T or B cell responses.

About DBV Technologies

DBV Technologies developed Viaskin®, a proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT®, DBV’s method of delivering biologically active compounds to the immune system through intact skin. With this new class of self-administered and non-invasive product candidates, the company is dedicated to safely transforming the care of food allergic patients, for whom there are no approved treatments. DBV’s food allergies programs include ongoing clinical trials of Viaskin Peanut and Viaskin Milk, and preclinical development of Viaskin Egg. DBV is also pursuing a human proof concept clinical study of Viaskin Milk for the treatment of Eosinophilic Esophagitis, and exploring potential applications of its platform in vaccines and other immune diseases.

DBV Technologies has global headquarters in Montrouge, France and New York, NY. Company shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and traded on the Nasdaq Global Select 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 Epicutaneous Immunotherapy (EPIT®) via Viaskin®. These forward-looking statements that 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, 2015 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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