DBV Technologies Announces Publication of Phase Ib Trial Results in the Journal of Allergy and Clinical Immunology (JACI) Supporting Safety and Tolerability of Viaskin® Peanut

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced the publication of results from a Phase Ib trial showing that Viaskin® Peanut was observed to have a favorable safety and tolerability profile. High adherence to treatment, which was documented by an overall 96% compliance rate and a 4% dropout, was also observed.

This scientific publication, authored by Dr. Stacie Jones, Professor of Pediatrics at the University of Arkansas for Medical Sciences, Chief of Allergy and Immunology and Dr. and Mrs. Leeman King Chair in Pediatric Allergy at Arkansas Children’s Hospital in Little Rock, and entitled “Safety of Epicutaneous Immunotherapy for the Treatment of Peanut Allergy: A Phase 1 Study Using Viaskin Patch” is available online in the Journal of Allergy and Clinical Immunology (JACI): www.jacionline.org/inpress

“With more than 25 years of experience in treating patients with this disease, I believe that Viaskin Peanut, if approved, will fulfill patients and caretakers’ unmet need for a safe, effective and patient-friendly treatment,” said Dr. Hugh Sampson, Chief Scientific Officer of DBV Technologies. “This publication offers a favorable view of the safety of Viaskin Peanut. Not only were participants of all ages and varying degrees of severity generally able to tolerate treatment, but the vast majority of study participants adhered to the protocol, which we believe highlights the convenience, ease of use and potential for rapid adoption of Viaskin Peanut.”

The study, Safety of Epicutaneous Immunotherapy for the Treatment of Peanut Allergy, was completed in February 2012. Following this Phase Ib trial, DBV Technologies initiated VIPES, a dose-finding, Phase IIb clinical trial of Viaskin Peanut in peanut allergic patients, which met its primary endpoint in October 2014. DBV is currently studying Viaskin Peanut in PEPITES, a randomized, double-blind, placebo-controlled pivotal registration Phase III trial in patients 4 to 11 years of age.

One hundred individuals between the ages of six and 50 were enrolled in this randomized, double-blind, placebo-controlled Phase Ib trial at five clinical sites in the United States. Peanut-allergic subjects were randomized 4:1 and treated for two weeks with Viaskin Peanut 20 µg, 100 µg 250 µg and 500 µg doses or placebo applied to intact skin at either 24 or 48 hour intervals. DSMB review occurred prior to progression of dosing at all stages.
“This publication reinforces the unique safety and tolerability profile of Viaskin Peanut among a variety of patient types, increasing our enthusiasm for its potential use as a new treatment option for the individuals who suffer from peanut allergy,” said Dr. Stacie Jones.

In the United States, approximately three million people are reported to have an allergy to peanuts. This allergy, which tends to develop in childhood, typically is lifelong, and the incidence is on the rise as studies show the number of children living with peanut allergy appears to have tripled between 1997 and 2008. ([https://www.foodallergy.org/facts-and-stats](https://www.foodallergy.org/facts-and-stats))

**Detailed Results of the Phase Ib Clinical Study**

No reports of serious adverse events (SAEs) or epinephrine use due to treatment occurred. Treatment emergent adverse events (TEAEs) were mostly mild and transient with no differences among treatment groups. No severe TEAEs were reported, and 47.5% of Viaskin Peanut treated subjects and 55% of placebo subjects reported no TEAE. The most commonly seen TEAEs were related to application site and included pruritus (itching), erythema (reddenning), edema (swelling) and urticarial (hives). In this study, application of Viaskin Peanut for 24 hours demonstrated a more favorable safety and tolerability drug profile than the 48 hour application.

The overall dropout rate was 4% (4/100). Of the four dropouts, three subjects were in the Viaskin Peanut arm and one subject was in the placebo group. More specifically:

- One adolescent treated with 500 µg Viaskin Peanut/48 hour was a consent withdrawal.
- Two active-treatment patients treated with the 48-hour application (one child, 250 µg Viaskin Peanut/48-hours; one adult, 100 µg Viaskin Peanut/48-hour).
- One adult patient, who only received placebo and experienced an anaphylactic reaction, was discontinued from the study for noncompliance upon investigator’s decision.

In this JACI publication, Dr. Jones and colleagues concluded that Epicutaneous Immunotherapy (EPIT®) administered via Viaskin was observed to have a favorable safety and tolerability profile, with high adherence by study participants.
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, 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® Peanut and Viaskin® Milk. The clinical development program for Viaskin® 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 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, 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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