

Press Release

Bagneux, France, February 24, 2015

## Viaskin® Data Presented at AAAAI Meeting Show Safety and Efficacy in the Treatment of Food Allergies

VIPES Phase IIb data supports Viaskin® Peanut safety and efficacy in the treatment of peanut allergy

Preclinical data highlighted the unique and long-lasting therapeutic profile of Epicutaneous Immunotherapy (EPIT®)

DBV will provide development milestones for the Viaskin® Platform during an Analyst & Investor briefing

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced that further clinical and preclinical data supporting the use of DBV's proprietary technology, Viaskin® for EPIT®, in the potential treatment of food allergies were presented at the 2015 Annual Meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) in Houston, Texas, February 20-24. During a separate analyst and investor briefing, DBV will also provide a strategic update delineating development milestones for Viaskin® in food allergies, allergic diseases, immunology, and vaccines.

**Dr Pierre-Henri Benhamou**, Chairman & CEO of DBV Technologies, said: *"We are excited to be at the verge of revolutionizing the field of allergy, and our strong presence at AAAAI highlights Viaskin's role in changing the way we think about these diseases. Food allergic patients, especially children, have long awaited for a safe and effective treatment, and we are close to meeting their medical needs."* Dr. Benhamou continued: *"In addition to the data on Viaskin Peanut's clinical trial, which is the largest peanut allergy immunotherapy study that has ever been conducted, our other presentations and posters continue to characterize the uniqueness of EPIT's mechanism of action, which we believe could target all food allergies safely and effectively with a long lasting effect."*

**Pr. Hugh A. Sampson**, MD, FAAAAI, Director of the Jaffe Food Allergy Institute at the Kravis Children's Hospital at Mount Sinai and first author of the late-breaking abstract commented: *"EPIT appears safe, well tolerated and effective. That's good news for families who suffer from food allergies"* Sampson said.

DBV's data presentations at AAAAI included three oral presentations and three poster sessions highlighting EPIT's role in the treatment of food allergies.

## Clinical Presentations Highlights

In an oral presentation titled *"Epicutaneous Immunotherapy (EPIT®) Is Effective and Safe to Treat Peanut Allergy: A Multi-National Double-Blind Placebo-Controlled Randomized Phase IIb Trial"*, Dr. Hugh Sampson from Mount Sinai Hospital (New York) concluded that in VIPES, Viaskin Peanut appeared to be safe and effective in treating peanut allergy patients. In this clinical trial, 221 subjects (6–55 years) reacting to less or at 300 mg peanut protein during a Double-Blind Placebo Controlled Food Challenge (DBPCF) 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 achieving a post-treatment eliciting dose of at least 1,000 mg. Cumulative reacting dose (CRD) of peanut protein consumed by subjects was also measured. Immunological markers were studied at entry, 3, 6 and 12 months.

The primary efficacy endpoint was met with Viaskin 250 µg, with 50.0% responders vs 25.0% with placebo,  $p=0.0108$ . Children in this arm (6-11 years) exhibited 53.6% responders vs 19.4% for placebo,  $p=0.0076$ . In children, the mean CRD showed a Viaskin Peanut dose-dependent response, with a change from Baseline of +61 mg, +471 mg, +570 mg and +1121 mg for the placebo, 50 µg, 100 µg, and 250 µg arms, respectively. Children's immunological responses were deemed to be robust. In the Viaskin 250µg arm, peanut-specific IgE exhibited a median increase  $\geq 50$  kUA/L at 3 months and decreased back to baseline at 12 months; median peanut-specific IgG4 at 12 months increased in a dose-dependent fashion: 1.3, 5.5-, 7.2- and 19.1-fold for each dose arm, respectively. Viaskin Peanut was observed to be safe in all patient populations, with a high adherence to treatment reported. The compliance rate was more than 95% across all cohorts, dropout for related adverse events less than 1%, and there were no serious adverse events related to treatment. The top-line results for VIPES were previously announced by DBV Technologies.

*"Phenotypic Analysis of Peanut-Responsive T Cells at Baseline in Subjects Enrolled in CoFAR6, a Randomized Placebo-Controlled Epicutaneous Immunotherapy (EPIT) Trial for the Treatment of Peanut Allergy"*, which was presented independently by investigators from the Consortium of Food Allergy Research (CoFAR), a NIH/NIAID/DAIT sponsored research organization, provided baseline peanut-responsive T cells levels for subjects enrolled in the CoFAR6 peanut allergy trial (n=75), which is currently ongoing.

## Scientific Presentations Highlights

Preclinical data presented at the meeting focused on characterizing EPIT's mechanism of action. In a poster titled, *"Epicutaneous Immunotherapy Prevents from Induction of Anaphylaxis to Further Allergen,"* Dr. Lucie Mondoulet, Director of Research at DBV, demonstrated in a mice model that T cells (Tregs) induced via EPIT play an important role in protecting against multiple allergen sensitization. Dr. Mondoulet suggests that early treatment with Viaskin® may prevent the development of subsequent allergic diseases.

Other presentations highlighted EPIT's ability to induce a larger repertoire of homing receptors on Tregs versus other specific immunotherapies. In *"Larger and Stronger Expression of Tregs Gut Homing Receptors with EPIT than with Sublingual or Oral Immunotherapy"* and *"Epicutaneous but Not Oral Immunotherapy Induces Antigen-Specific Gastrointestinal Tregs and Protects Against Food-Induced Anaphylaxis"* EPIT - and not oral immunotherapy - induced antigen-specific gastrointestinal Tregs and provided protection against food-induced anaphylaxis, independent of the initial route of sensitization.

Epigenetic mechanisms modulated during EPIT were also described in *"Epigenetic changes following epicutaneous immunotherapy in peanut sensitized mice"*. The poster concluded that epigenetic modifications of the DNA methylation of Th2 and Treg transcription factor appear to be a major trait of EPIT-induced immunomodulation, which may explain the long-lasting therapeutic and preventive effect that was observed in mice that were treated with EPIT versus Sham.

### Summary of Analyst & Investor Briefing

In addition to data presented at AAAAI, DBV will host an analyst and investor briefing, where it will provide development objectives for the Viaskin® Platform, including:

- Building on Viaskin Peanut's positive phase IIb data, DBV will aim to become the leader in the discovery, development and commercialization of food allergy products by launching a new product every two years. DBV will start deploying commercial platforms in order to maximize penetration of its food allergy products in North America and Europe. With this focused pipeline development & commercialisation strategy, DBV has identified Hen's Egg as its third food allergy target. Viaskin Egg development will commence in the first half 2015.
- Leveraging EPIT's unique mechanism of action, which has a Treg-oriented immune response, DBV will focus on advancing pipeline development in immunology indications and vaccines. Dedicated in-house therapeutic teams bolstered by industry and scientific experts' partnerships will aim to bring three to five immunology and/or vaccine products into clinical stage by 2020. Based on EPIT's scientific profile, DBV will explore development in areas of high unmet medical need where Viaskin® can have a transformational effect on the available treatment options.
- The event will also highlight the VIPES results, and in particular, the therapeutic effect that was observed in children. In a post-hoc analysis, VIPES shows that 32.1%, 26.9% and 17.9% of children subjects in the Viaskin 250 ug, 100 ug and 50 ug arms, respectively, ingested both 10 times more peanut protein compared to baseline and at least 1,000 mg of peanut protein at month 12, compared to 0% in the placebo arm. This analysis confirms data presented by Dr. Sampson, which demonstrated both strong treatment and clear dose effect across the trial.



### 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, 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<sup>®</sup> Peanut and Viaskin<sup>®</sup> Milk. The clinical development program for Viaskin<sup>®</sup> Peanut has received Fast Track 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 safety and efficacy of Epicutaneous Immunotherapy (EPIT) via Viaskin, including the potential to prevent sensitizations in other allergens, the potential to induce a sustained protection effect and the potential to influence the natural history of allergy. 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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