



DBV Technologies Initiates Phase I/II Clinical Trial with Viaskin® Milk for the Treatment of Children with Cow's Milk Allergy

BAGNEUX, France, November 20, 2014 - DBV Technologies, (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, announced today it has begun enrolling cow's milk-allergic subjects in a Phase I/II clinical study to evaluate the safety and efficacy of Viaskin® Milk, an epicutaneous patch for the treatment of children with IgE-mediated cow's milk allergy (CMA).

Pierre-Henri Benhamou, M.D., Chairman and CEO of DBV Technologies said: *"Milk allergy is a life-threatening condition for which there are no approved treatments. As part of our commitment to improve the quality of life of food allergic patients, we have continued to advance our pipeline, and the initiation of this trial marks an important milestone for our patients, their caretakers and our Company. We believe Viaskin has the potential to reshape the future of food allergies immunotherapy."*

The Viaskin **MILK** Efficacy and Safety Phase I/II study, or MILES study, is a multi-center, double-blind, placebo-controlled, randomized study designed to evaluate the safety and efficacy of Viaskin® Milk used to treat subjects on a daily basis by Epicutaneous Immunotherapy (EPIT®). Eligible subjects are those with elevated cow's milk-specific Immunoglobulin E levels and who show clear objective signs or symptoms to an eliciting dose of cow's milk proteins ≤ 300 mg (approximately 9.4 mL of cow's milk).

The MILES study is composed of 2 parts. Part A, or Phase I, will evaluate the safety of three escalating doses of Viaskin® Milk (150 μ g, 300 μ g and 500 μ g cow's milk protein) versus placebo over three weeks. Part B, or Phase II, will evaluate the efficacy and safety of up to 12 months of EPIT with two selected doses of Viaskin® Milk from Part A. Approximately 150 subjects (18 subjects in Part A and 132 subjects in Part B) from 2 to 17 years of age will be randomized in the study, at selected North American sites, specialized in the management of food allergic subjects.

The primary efficacy endpoint is the percentage of treatment responders after 12 months of EPIT. Responders are subjects who meet one of the following criteria: a ≥ 10 -fold increase in the cumulative reactive dose (CRD) of cow's milk proteins at the Month 12 food challenge as compared to the baseline value and reaching at least 144 mg of cow's milk proteins (approximately 4.5 mL of milk); or a CRD of cow's milk proteins ≥ 1444 mg (approximately 45 mL of milk) at the Month 12 food challenge.

Bpifrance will be providing €3 million in the form of an interest free loan (PTZI: Prêt à Taux Zero pour l'innovation) to DBV for the clinical development of Viaskin® Milk. This funding demonstrates Bpifrance's continued support for DBV's development programs. The interest-free loan provided by Bpifrance has a first date of payment as of June 30, 2017. After this initial payment, 19 linear quarterly payments will follow until March 31, 2022.



About Viaskin® Milk

Viaskin Milk for the treatment of pediatric CMA is DBV's second most advanced product in development. CMA is the first allergy to appear during early childhood and the most common food allergy in infants and young children, affecting 2% to 3% of the general population. CMA is often missed in the primary care setting and can be a significant cause of infant distress when left undiagnosed. Symptoms can include gastrointestinal problems including vomiting and diarrhea, skin rash, angioedema or rapid swelling of the skin, and anaphylaxis. The only option available for CMA management is the avoidance of cow's milk, which can lead to issues of dietary imbalance, failure to thrive and poor quality of life.

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, 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® Peanut and Viaskin® Milk. The clinical development program for Viaskin® Peanut has received Fast Track designation from the US Food and Drug Administration.

DBV Technologies shares are traded on segment C 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

About Bpifrance

Formed by the law of the 31st December 2012, Bpifrance (a public sector investment bank) is the outcome of the merger between OSEO, the FSI, CDC Entreprises and FSI Régions. Its two shareholders are the French state and the Caisse des Dépôts bank. Bpifrance finances businesses from the seed phase to transfer to stock exchange listing, through loans, guarantees and equity. Bpifrance also provides enhanced support and backing for innovation, export, and external growth. With its 42 regional offices, it is a one-stop shop for entrepreneurs in each region for all their finance and investment needs. Bpifrance also participates in the management of several European funding programs. www.bpifrance.fr - Follow us on Twitter: @bpifrance

Forward Looking Statements

This press release contains forward-looking statements, including statements about the safety and efficacy of DBV Technologies' product, our ability to successfully complete the clinical trial, our ability to obtain regulatory approval for and commercialize Viaskin® Milk, and our ability to obtain funding from Bpifrance. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. 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 clinical trial results may not be predictive of future trial results, whether Viaskin® Milk will be successfully marketed if approved, and subsequent changes in the agreement with Bpifrance. 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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