

Press Release

Bagneux, France, June 30, 2015

## DBV Technologies Announces Completion of Part A of the MILES Study Evaluating the Safety of Viaskin<sup>®</sup> Milk in Pediatric Cow's Milk Allergy

DSMB expressed no safety concerns and recommended that the study continue as planned

Initiation of Part B expected in the second half of 2015 pending consultation with regulatory agencies

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage, specialty biopharmaceutical company, today announced the completion of Phase I or Part A, of the Viaskin Milk Efficacy and Safety Phase I/II study (MILES). The Data Safety Monitoring Board (DSMB) for the study recommended that the study continue and expressed no safety concerns after evaluating the Part A safety data of subjects treated with a 150 µg, 300 µg and 500 µg doses of Viaskin Milk.

The MILES study is a two part, multi-center, double-blind, placebo-controlled, randomized clinical trial designed to evaluate the safety and efficacy of Viaskin<sup>®</sup> Milk in IgE-mediated cow's milk protein allergic (CMPA) patients ranging from two to 17 years of age. Part A evaluated the safety of three escalating doses of Viaskin<sup>®</sup> Milk (150 µg, 300 µg and 500 µg) versus placebo over three weeks in 18 patients.

Pending review of the Part A data by the U.S. Food & Drug Administration (FDA) and U.S. and Canadian approvals of the revised protocol described below, the Company intends to initiate Part B of the trial in the second half of 2015. Part B, or Phase II, of the MILES study is expected evaluate the efficacy and safety of all three doses of Viaskin<sup>®</sup> Milk (150 µg, 300 µg, 500 µg) versus placebo for 12 months. Approximately 176 patients between two and 17 years of age are expected to be randomized in a 1:1:1:1 ratio at selected North American sites.

### About the MILES Study

The MILES trial is a multi-center, double-blind, placebo-controlled, randomized Phase I/II trial to study the safety and efficacy of Viaskin Milk in pediatric patient populations (age two to 17) suffering from IgE-mediated cow's milk protein allergy, or CMPA, with elevated IgE levels related to cow's milk protein. The trial is being conducted in select U.S. and Canadian clinical centers. Part A of the MILES trial has been completed. Under the proposed amended MILES Part B protocol, up to 176 subjects are expected to be randomized for treatment at

approximately 18 sites. Eligible subjects with confirmed IgE-mediated CMPA will perform an initial food challenge at screening with escalating doses of cow's milk proteins. Subjects who display objective signs or symptoms of allergic response to an eliciting dose of 300 mg cow's milk proteins (approximately 9.4 mL of cow's milk) or below will be randomized in the trial. The primary efficacy endpoint will be the percentage of subjects who are treatment responders after 12 months, defined as subjects who meet at least one of the following criteria: (1) a 10-fold or greater increase in the cumulative reactive dose, or CRD, of cow's milk proteins at month 12 of the food challenge as compared to baseline value in addition to reaching tolerance to at least 144 mg of cow's milk protein (approximately 4.5 mL of milk) or (2) a CRD of cow's milk protein greater than or equal to 1,444 mg (approximately 45 mL of milk) at month 12 of the food challenge. Secondary efficacy endpoints include, among others, the percentage of subjects who are treatment responders at month 24, the mean and median CRD of cow's milk proteins at months 12 and 24 as well as the change in CRD from baseline, the change from baseline in the severity of symptoms elicited during the food challenge from baseline to months 12 and 24, and the change from baseline in quality of life assessments at months 12 and 24.

### 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: [www.dbv-technologies.com](http://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<sup>®</sup>) via Viaskin<sup>®</sup> Milk and DBV's anticipated clinical development of Viaskin Milk and other product candidates. 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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