

## DBV Technologies Announces First Patient Enrolled in Phase II Study of Viaskin Milk

No safety concerns observed during Part A of the MILES Study (Phase I)

Part B (Phase II) will evaluate the safety and efficacy of three doses of Viaskin Milk in children ages 2-17 with IgE-mediated cow's milk allergy

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced that it has begun enrolling cow's milk-allergic subjects in the Part B (Phase II) of the MILES Phase I/II study (Viaskin MILk Efficacy and Safety).

The Viaskin Milk patch is one of the company's product candidates based on epicutaneous immunotherapy (EPIT®), a proprietary technology platform that can deliver biologically active compounds to the immune system through intact skin without allowing compound passage into the blood. In Phase II, or Part B of the MILES study, 176 children with IgE-mediated cow's milk allergy (CMA) will be randomized 1:1:1:1 to receive one of the three doses of Viaskin® Milk (150 µg, 300 µg, 500 µg) or placebo for 12 months. Responders will be defined as subjects who meet one of the following criteria: a 10-fold or greater 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 equal or greater than 1444 mg (approximately 45 mL of milk) at the month-12 food challenge.

### About MILES Study

The MILES study 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. Recruitment of the 18 subjects in Part A (Phase I) of the MILES trial has been completed. In Part B (Phase II), approximately 176 additional subjects will be randomized for treatment at approximately 18 selected sites in the US and Canada. 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 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 eligible for participation. 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 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, and the change from baseline in quality of life assessments at months 12 and 24.



### About DBV Technologies

DBV Technologies created the Viaskin® patch, 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 while avoiding compound transfer to the blood. With this new class of self-administered and non-invasive product candidates, the company is dedicated to safely transforming the care of food allergy patients, for which there are currently no approved treatments. DBV's food allergy programs include ongoing clinical studies with Viaskin Peanut and Viaskin Milk, one experimental program with Viaskin Egg and a human proof concept clinical study in milk-induced Eosinophilic Esophagitis. DBV is also exploring platform indications in vaccines, and selected immune diseases with unmet medical needs.

DBV Technologies has global headquarters in Paris, France and New York, NY, USA. 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](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®) via Viaskin® 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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