Press Release
Châtillon, France, October 22, 2024

DBV Announces Positive Regulatory Updates for the Viaskin® Peanut Patch in the United States and Europe

- **DBV to pursue an Accelerated Approval pathway for toddlers ages 1 – 3 years-old**
- **BLA submission under Accelerated Approval is subject to completion of a six-month supplemental safety study in toddlers to be initiated in Q2 2025**
- **VITESSE Phase 3 study evaluating the Viaskin Peanut patch in children ages 4 – 7 years-old exceeded enrollment goals; Topline results on track for 4Q 2025**
- **European Medicines Agency (EMA) scientific advice confirms registration path for a Marketing Authorization Application (MAA) with the modified Viaskin peanut patch for a 1 – 7 year-old indication in Europe**
- **Company to host investor conference call at 5:00pm ET today**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced positive regulatory updates for the Viaskin Peanut patch in the United States and Europe. DBV has agreed to guidance provided by the U.S. Food and Drug Administration (FDA) on a pathway under the Accelerated Approval Program for the Viaskin Peanut patch in toddlers ages 1 – 3 years-old and has also received scientific advice from the EMA on a 1 – 7 year-old indication in Europe. DBV intends to formalize the Accelerated Approval guidance provided by the FDA via submission of a meeting request.

"Our agreement with FDA guidance on a path towards Accelerated Approval for the Viaskin Peanut patch in 1 – 3 year-olds represents a significant step forward in getting this novel treatment to patients," said Daniel Tasse, Chief Executive Officer, DBV Technologies. "*I am pleased that the FDA recognizes the urgent unmet medical need that exists for this young patient population. We are also very pleased with the scientific advice received from EMA – one patch in peanut allergic children in 1 – 7 year-olds, subject to a safety study with our modified patch in toddlers 1 – 3 years-old.*"

Viaskin Peanut Patch in Toddlers 1 – 3 Years

Accelerated Approval Pathway

FDA guidance for Accelerated Approval include three qualifying criteria: 1) that the product treats a serious condition, 2) that the product candidate generally provides a meaningful advantage over available therapies, and 3) that the product candidate demonstrates an effect on an intermediate clinical endpoint that is reasonably likely to predict clinical benefit.

FDA confirmed that DBV has met criterion 1 and 2. Regarding criterion 3, FDA has provided guidance and suggestion regarding the intermediate clinical endpoint, which DBV has agreed to in informal discussions with the FDA. DBV intends to formalize the Accelerated Approval guidance provided by FDA via submission of a meeting request to confirm the general elements of the two study components: the COMFORT Toddlers safety study, to be completed before BLA submission, and the confirmatory effectiveness study, including the third Accelerated Approval criterion regarding the intermediate clinical endpoint. DBV expects that the confirmatory study will be initiated by the time of BLA submission and would run in parallel to commercialization in the United States, if Viaskin Peanut is approved.

COMFORT Toddlers

DBV is pleased to have aligned with FDA on a wear time collection methodology in COMFORT Toddlers that provides a practical approach for subjects and families, is intended to generate sufficient data to support a BLA submission, and places wear time into an acceptable clinical hierarchy relative to other study endpoints. DBV has initiated study start-up activities and plans to screen the first subject in the second quarter of 2025. The company anticipates enrolling approximately 300 - 350 subjects on active treatment into the safety study, which would bring the total Viaskin Peanut patch safety database in toddlers to approximately 600 subjects, consistent with prior FDA guidance.

With this path forward, the BLA submission for Viaskin Peanut patch in 1 – 3 year-olds under the Accelerated Approval program is anticipated to be supported by:

i. Positive efficacy and safety data from DBV's previously completed EPITOPE Phase 3 Study; and
ii. Additional safety data generated in COMFORT Toddlers supplemental safety study to be initiated in 2Q 2025.

"DBV's Viaskin Peanut patch has the potential to significantly improve the lives of peanut allergic toddlers and their caregivers," stated Dr. David Fleischer, FAAAAI, FACAAI, Professor of Pediatrics at Children's Hospital Colorado. *"With few approved treatment options for this patient population – the age range in which most young people are initially diagnosed with peanut allergy – the Viaskin Peanut patch has the potential to be a game changer in the food allergy community, and I look forward to having the opportunity to incorporate it into my own practice, if approved."*

Post-Marketing Confirmatory Study

DBV and FDA are in general agreement that the confirmatory study will need to demonstrate the effectiveness of the Viaskin Peanut patch and will need to be initiated at the time that the BLA is submitted. DBV will prioritize initiation of the COMFORT Toddlers safety study to enable the BLA submission.

"*We are encouraged to learn that FDA has heard the voices of the food allergy community*," said Sung Poblete, PhD, RN, CEO of FARE (Food Allergy Research and Education). "*This hopeful advancement in the treatment of peanut allergic toddlers has the potential to make a positive impact on the millions of families that are urgently awaiting innovative treatment options, and the confirmatory study will certainly add to the rich data that has been compiled in this important disease space. We stand by DBV in their efforts to advance Viaskin and look forward to representing the patient perspective."*

Regulatory History of the Viaskin Peanut Patch in Toddlers 1 – 3

DBV and the FDA have been engaged in ongoing dialogue regarding the COMFORT Toddlers supplemental safety study in 1 – 3 year-olds with a peanut allergy. The focus of continued exchanges has been on patch adhesion, specifically:

- The hierarchy of an adhesion assessment within the COMFORT Toddlers study (FDA requesting that it be a study objective vs. exploratory assessment);
- The sufficiency of adhesion data collected during the EPITOPE study to fully characterize daily patch adhesion duration (wear time) given the EPITOPE adhesion data collection methodology, and, conversely, the collection methodology required to generate sufficient adhesion data to inform the Viaskin label in future studies; and
- The clinical relevance and regulatory use of adhesion data collected in a study that does not include an efficacy assessment.

DBV's proposed labeling solution, submitted to the FDA on June 28, 2024, became critical in exploring with the FDA, practical solutions to linking adhesion, efficacy and safety to best inform the label. These fruitful discussions have led to what DBV believes to be an actionable regulatory pathway.

Viaskin Peanut Patch in Children 4 – 7

In September 2024, DBV announced that patient screening had been completed for the Phase 3 efficacy trial of the Viaskin Peanut patch in peanut allergic children ages 4 – 7 years-old (VITESSE). A total of 654 subjects were enrolled, and DBV anticipates topline data in the fourth quarter of 2025.

The COMFORT Children safety study is expected to be initiated in the second quarter of 2025. This study plans to enroll approximately 250 subjects to raise the total number of 4 – 7 year-olds on active treatment across the development program to approximately 600, consistent with prior FDA guidance. These two studies will constitute the core studies for a BLA submission in 4 – 7 year-olds.

EMA Regulatory Update

DBV sought scientific advice from the EMA regarding the components of a MAA for the Viaskin Peanut patch. Previous advice obtained from two local country regulatory health authorities indicated a potential path for a 1 – 7 year-old registration with one patch, the modified patch. The EMA recently confirmed through scientific advice that the completed EPITOPE study in 1 – 3 year-olds, and a positive VITESSE study in 4 – 7 year-olds, could constitute an MAA submission for a 1 – 7 year-old indication for peanut allergy patients using the modified patch, along with a new safety study in 1 – 3 year-olds with the modified patch. Timing for the initiation of this new safety study to satisfy the important EU market is currently being planned.

The most recent European Academy of Allergy & Clinical Immunology (EAACI) draft Guidelines on the Management of IgE-mediated Food Allergy has the following recommendation: "In children and adolescents with IgE-mediated peanut allergy, peanut epicutaneous immunotherapy is suggested to achieve desensitization, if available." This recommendation further supports the potential clinical benefit of the Viaskin Peanut Patch, if approved, in Europe and the unmet medical need.

Financial Update

Based upon preliminary estimates and information available to the Company as of the date of this announcement, DBV's cash and cash equivalents amount to $46.4 million as of September 30, 2024, compared to $66.2 million as of June 30, 2024, a net decrease by $19.8 million comprising :

- $22.5 million of net cash flow used in operating activities, mainly external clinical-related expenses notably progress on patient enrollment in VITESSE Phase 3 clinical trial, Regulatory and Medical activities as well as Manufacturing Operations.
- Partially offset by Research Tax Credit complementary refund for years 2020 to 2022 of $3.0 million.

These preliminary financial results reflect the Company's estimates and are based on currently available information. The Company's actual financial results for the quarter ended September 30, 2024 have not yet been finalized by management or reviewed by the Company's independent auditors. This preliminary financial information is not a comprehensive statement of all financial results for the quarter ended September 30, 2024. Accordingly, undue reliance should not be placed on these preliminary financial results.

The Company has incurred operating losses and negative cash flows from operations since inception. As of the date of this announcement, the Company's available cash and cash equivalents is not projected to be sufficient to support its operating plan for at least the next 12 months. As such, there is substantial doubt regarding the Company's ability to continue as a going concern. Based on current operations, plans and assumptions, the Company expects that its balance of cash and cash equivalents will be sufficient to fund its operations into 1Q 2025 and intends to seek additional capital as it continues research and development efforts and prepares for the launch of Viaskin Peanut, if approved.

Investor Conference Call and Webcast

DBV management will host an investor conference call and webcast today, October 22nd, at 5:00pm EST, to discuss these regulatory updates. This call is accessible via the below teleconferencing numbers and requesting the DBV Technologies call.

- United States: +1-877-346-6112
- International: +1-848-280-6350

A live webcast of the call will be available on the Investors & Media section of the Company's website: https://www.dbv-technologies.com/investor-relations/. A replay of the presentation will also be available on DBV's website after the event.

About DBV Technologies

DBV Technologies is a clinical-stage biopharmaceutical company developing treatment options for food allergies and other immunologic conditions with significant unmet medical need. DBV is currently focused on investigating the use of its proprietary Viaskin® patch technology to address food allergies, which are caused by a hypersensitive immune reaction and characterized by a range of symptoms varying in severity from mild to life-threatening anaphylaxis. Millions of people live with food allergies, including young children. Through epicutaneous immunotherapy (EPIT™), the Viaskin® patch is designed to introduce microgram amounts of a biologically active compound to the immune system through intact skin. EPIT is a new class of non-invasive treatment that seeks to modify an individual's underlying allergy by re-educating the immune system to become desensitized to allergen by leveraging the skin's immune tolerizing properties. DBV is committed to transforming the care of food allergic people. The Company's food allergy programs include ongoing clinical trials of Viaskin Peanut in peanut allergic toddlers (1 through 3 years of age) and children (4 through 7 years of age).

DBV Technologies is headquartered in Châtillon, France, with North American operations in Warren, NJ. The Company's ordinary shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345) and the Company's ADSs (each representing one ordinary share) are traded on the Nasdaq Capital Select Market (Ticker: DBVT).

For more information, please visit www.dbv-technologies.com and engage with us on X (formerly Twitter) and LinkedIn.

Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding DBV's financial condition (including certain preliminary financial results), forecast of its cash runway, the therapeutic potential of Viaskin® Peanut patch and EPIT™, designs of DBV's anticipated clinical trials, DBV's planned regulatory and clinical efforts including timing and results of communications with regulatory agencies, plans to formalize the Accelerated Approval guidance provided by the FDA via submission of a meeting request, expectations regarding initiation of the confirmatory study, plans and expectations with respect to COMFORT Toddlers (including DBV's plan to prioritize initiation of this study), anticipated support for the BLA submission, DBV's expectations with respect to an actionable regulatory pathway, and the ability of any of DBV's product candidates, if approved, to improve the lives of patients with food allergies. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and

uncertainties. At this stage, DBV's product candidates have not been authorized for sale in any country. 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, and DBV's ability to successfully execute on its budget discipline measures. A further list and description of risks and uncertainties that could cause actual results to differ materially from those set forth in the forward-looking statements in this press release can be found in DBV's regulatory filings with the French Autorité des Marchés Financiers ("AMF"), DBV's filings and reports with the U.S. Securities and Exchange Commission ("SEC"), including in DBV's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 7, 2024, and future filings and reports made with the AMF and SEC by DBV. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release.

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