Press Release

Châtillon, France, December 11th, 2024

DBV Confirms Alignment with U.S. FDA on Accelerated Approval Pathway for the Viaskin® Peanut Patch in Toddlers 1 – 3 Years-Old

- **DBV and FDA aligned on key study design elements for the COMFORT Toddlers study in 1 – 3 year-olds, including study size and wear time collection methodology and analysis**
- **COMFORT Toddlers study on-track to initiate in 2Q 2025**
- **Viaskin Peanut patch BLA submission for the Toddlers indication anticipated for 2H 2026**
- **FDA confirmed criteria for post-marketing confirmatory study in toddlers 1 – 3 years-old**
- **Company to host investor webcast today at 5:00pm ET**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced the successful outcome of recent written and oral communication with the U.S. Food and Drug Administration (FDA) that provides a clear and well-defined regulatory pathway for the Viaskin Peanut patch program in toddlers 1 – 3-years-old. The FDA has formalized guidance on an Accelerated Approval for the Viaskin Peanut patch in toddlers 1 – 3-years-old. DBV and FDA have agreed on the key design elements for a post-marketing confirmatory study.

"DBV is pleased to have received, what we believe to be, a clear and reasonable pathway towards an Accelerated Approval for the Viaskin Peanut patch in toddlers 1 – 3-years-old. This comes on the heels of our October 22nd press release announcing details in support of our separate Viaskin Peanut programs in 4 – 7 year-olds and in 1 – 7 year-olds in Europe," said Daniel Tassé, Chief Executive Officer, DBV Technologies. *"We believe we have decreased the regulatory pathway risk of our programs. DBV can now fully focus on executing the remaining studies that will support two distinct BLAs across age groups and an MAA in Europe. We are grateful to the Agency for its attentive collaboration as we continue to work towards introducing this novel therapy to caregivers and patients as expeditiously as possible."*

Accelerated Approval Pathway

The FDA recently issued written communication confirming an Accelerated Approval pathway for the Viaskin Peanut patch in toddlers 1 – 3-years-old. As a reminder, current FDA guidance for Accelerated Approval includes three qualifying criteria:

1. That the product candidate treats a serious condition
2. That the product candidate generally provides a meaningful advantage over available therapies
3. That the product candidate demonstrates an effect or an intermediate clinical endpoint that is reasonably likely to predict clinical benefit

As DBV previously announced, FDA confirmed via written communication that the Viaskin Peanut patch already met criteria one and two.

FDA and DBV have been engaged in ongoing dialogue throughout Q4 of this year regarding the intermediate clinical endpoint necessary to meet the third criterion. In the recent written communication, the FDA confirmed the efficacy data from the Company's Phase 3 EPITOPE study can serve as an intermediate clinical endpoint. The FDA has agreed that the endpoint is reasonably likely to predict clinical benefit and will therefore fulfill the requirement for Accelerated Approval.

In preparation for commercialization, DBV made slight modifications to the Viaskin Peanut patch used in EPITOPE to increase the simplicity of application for the caregiver and provide product identification on each patch. No changes, including patch shape or size, were made to the device components that are in contact with the patient's skin. Further, to increase the volume of patch production for future commercialization, changes needed to be made to the manufacturing process and location.

Although the intended commercial Viaskin Peanut patch is currently being used (N=304) in the ongoing 3-year Open Label Extension to EPITOPE, the collective changes to the commercial Viaskin Peanut patch were viewed by the FDA as constituting a different product relative to the clinical patch used in the EPITOPE study. The Company intends to use the commercial Viaskin Peanut patch in both the COMFORT Toddlers study and the post-marketing confirmatory study.

Post-Marketing Confirmatory Study

In the recent written communication, FDA confirmed criteria for a post-marketing confirmatory study in toddlers 1 – 3-years-old. DBV and FDA agreed that the confirmatory study will assess the effectiveness of the intended commercial Viaskin Peanut patch and will need to be initiated at the time that the BLA is submitted.

To date, the commercial patch has been used in 304 subjects with over 234,695 patient-days of therapy in the placebo crossover and the EPITOPE Open Label Extension, with no clinically relevant differences in efficacy or safety vs. the clinical patch used in the EPITOPE Phase 3 trial.

The confirmatory study will include a double-blind, placebo-controlled food challenge (DBPCFC) and will use the same statistical criteria for success (i.e., lower bound of the 95% CI $\geq$ 15%) as used in the EPITOPE Phase 3 efficacy study. Adhesion data for the post-marketing confirmatory study will be collected in a similar manner relative to the COMFORT Toddlers study. The Company expects these data will further support the importance of average daily wear time in the use of the Viaskin Peanut patch as it relates to efficacy and labeling.

"When it comes to food allergy management, what works for one family, might not work for another. That is why having varied treatment options available is so incredibly important to our community," said Sung Poblete, PhD, RN, CEO of FARE (Food Allergy Research & Education). *"I'm pleased to learn that DBV's constructive dialogue with the FDA has resulted in this Accelerated Approval guidance outlining remaining developmental steps for the Viaskin Peanut patch in toddlers with a peanut allergy. At FARE, we look forward to the possibility that one day, if approved, caregivers and families will have this exciting new treatment as an option to consider."*

COMFORT Toddlers Supplemental Safety Study

COMFORT Toddlers is a Phase 3 double-blind, placebo-controlled (DBPC) study designed to generate additional safety (primary endpoint) and adhesion data of the Viaskin Peanut patch in peanut allergic toddlers 1 – 3-years old. DBV is pleased to announce that Dr. Julie Wang, MD, Professor of Pediatrics, Jaffe Food Allergy Institute, the Icahn school of Medicine at Mount Sinai, will act as the Global Principal Investigator for the COMFORT Toddlers study.

"I am thrilled to assume the role of Global Principal Investigator of the COMFORT Toddlers study," stated Dr. Julie Wang, Professor of Pediatrics, Jaffe Food Allergy

Institute, Icahn school of Medicine at Mount Sinai in New York. *"Viaskin Peanut, if approved, would offer a much-needed alternative treatment option for patients and caregivers. I look forward to working with the DBV team to advance this important clinical trial."*

The Company anticipates that COMFORT Toddlers will enroll approximately 480 subjects randomized 3:1 (active: placebo) at approximately 80 – 90 study centers across the U.S., Canada, Australia, and Europe. COMFORT Toddlers will be a six-month study followed by an optional 18-month open-label treatment phase, to provide 24 or 18 months of treatment with the Viaskin Peanut patch for participants randomized to the active or placebo groups, respectively. Thus, the COMFORT Toddlers study will increase the total subjects exposed to the Viaskin Peanut patch for at least six-months in a controlled study to 600, as required by FDA. In total, there will be approximately 240 subjects with the clinical patch in EPITOPE and 360 with the commercial patch in COMFORT Toddlers.

As previously disclosed, DBV and FDA have aligned on a patch wear time collection methodology, analysis and study objective hierarchy in the COMFORT Toddlers study. The agreed-upon adhesion data collection methodology provides a practical approach for subjects, families, and investigators. The methodology is intended to generate sufficient data to support a BLA submission under the Accelerated Approval pathway (i.e., collecting patch adhesion data with a focus on daily wear time at relevant time points). We believe there are three positive outcomes coming out of the productive discussions with FDA:

1. FDA agreed that adhesion would not be a co-objective of a safety study and would be an exploratory endpoint.
2. Next, adhesion should be assessed in the overall totality of benefit to risk (i.e., in the context of efficacy and safety).
3. The third success is that we have aligned on what DBV believes is a very feasible approach to collecting adhesion data.

DBV has initiated study start-up activities and plans to screen the first subject in the second quarter of 2025.

Biologic License Application Submission in 1 – 3 Year-Olds

There will be two Phase 3 studies in 1 – 3-year-olds using the Viaskin Peanut patch. The data generated from the studies will be used to inform a BLA submission:

1. Twelve months of DBPC efficacy and safety data from the previously completed Phase 3 EPITOPE study (published in the *New England Journal of Medicine* in May 2023), and 36 months of open-label extension data.
2. Six months of DBPC data generated in COMFORT Toddlers supplemental safety study.

DBV anticipates that the BLA for the Viaskin Peanut patch in toddlers 1 – 3 years-old under the Accelerated Approval program will be submitted in 2H 2026.

Investor Conference Call and Webcast

DBV management will host an investor conference call and webcast today, Wednesday, December 11th, 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 five ordinary shares) are traded on the Nasdaq Capital Market (Ticker: DBVT; CUSIP: 23306J309).

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 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 and expectations regarding initiation of the confirmatory study, plans and expectations with respect to COMFORT Toddlers and COMFORT Children, plans and expectations with respect to the submission of BLAs to FDA, anticipated support for the BLA submission, DBV's expectations with respect to the Accelerated Approval pathway and any other 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.

Investor Contact

Katie Matthews
DBV Technologies

katie.matthews@dbv-technologies.com

Media Contact
Angela Marcucci
DBV Technologies
angela.marcucci@dbv-technologies.com