

DBV Technologies Announces First Subject Screened in COMFORT Toddlers Supplemental Safety Study in Peanut Allergic Toddlers 1 – 3 Years Old

- **First subject screened at the Respiratory Medicine Research Institute of Michigan with Dr. Jeffrey Leflein acting as Principal Investigator**
- **Additional sites, including Allergy and Asthma Center of Minnesota and Hamilton Allergy and Immunology Clinic of Ontario, Canada have been activated and are scheduling screenings**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Market: DBVT), a clinical-stage biopharmaceutical company, today provided an update on the progress on the Company's COMFORT Toddlers supplemental safety study using the Viaskin® Peanut patch 250 µg in peanut-allergic children ages 1 – 3 years old.

COMFORT Toddlers will enroll approximately 480 subjects at approximately 80 – 90 study centers across the U.S., Canada, Australia, UK and Europe. Principal Investigator, Jeffrey Leflein, MD, FAAAAI, FAAAAI from the Respiratory Medicine Research Institute of Michigan, in Ann Arbor, Michigan screened the first subject in the study. Additionally, Dr. Doug McMahon, MD, Allergy and Asthma Center in Maplewood, Minnesota and Dr. Jason Ohayon, MD, Hamilton Allergy and Immunology Clinic in Ontario, Canada have been activated and are currently open to recruitment.

"I am thrilled that our talented team of clinicians was the first to screen a subject for the COMFORT Toddlers supplemental safety study and we have several other potential subjects scheduled for screening," said Dr. Leflein. "The initiation of subject enrollment in COMFORT Toddlers reinforces our commitment to peanut-allergic children and their families and is an important step in generating the data needed to potentially advance the Viaskin Peanut patch to market."

COMFORT Toddlers is a Phase 3 double-blind, placebo-controlled (DBPC) safety study designed to supplement the safety and efficacy data from the completed Phase 3 EPIPOPE study in the same population. The study duration will be six months followed by an optional 18-month open-label treatment phase, to generate



up to 24 or 18 months of active treatment with the Viaskin Peanut patch for participants randomized to the active or placebo groups, respectively.

"I am very pleased subject screening has commenced in COMFORT Toddlers and look forward to working with my fellow investigators on the efficient enrollment and execution of this important study," stated **Julie Wang, MD**, FAAAAI, FACAAI, Professor of Pediatrics, Jaffe Food Allergy Institute, the Icahn School of Medicine at Mount Sinai and Global Principal Investigator for the COMFORT Toddlers study. *"The interest we've seen to date further reinforces the significant unmet need that exists for this specific subject cohort."*

"Screening our first subject marks a crucial step forward in our mission to develop this potential groundbreaking therapy for food allergic patients, as we are now well underway with both of our core clinical programs," said **Daniel Tassé** CEO, DBV Technologies. *"We believe the data generated through the COMFORT Toddlers study will complete the data set necessary for a Biologics License Application submission to the FDA. DBV is committed to advancing the development of Viaskin Peanut. Our patients and their families are counting on us."*

The data generated from COMFORT Toddlers will support the submission of a BLA anticipated in 2H 2026 under the Accelerated Approval Pathway, [as previously agreed to with FDA](#).

Investor Conference Call and Webcast

DBV management will host an investor conference call and webcast today, Wednesday, June 25th, at 5:00pm EDT, to discuss these updates. This call is accessible via the teleconferencing numbers below 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, 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-Q for the year ended March 31, 2025, filed with the SEC on April 30, 2025, 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.

Viaskin is a registered trademark and EPIT is a trademark of DBV Technologies.

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