

DBV Technologies Announces Submission of Biologics License Application to U.S. FDA for the VIASKIN® Peanut Patch in Children Aged 4-7 Years

- The BLA is supported by the results from the successful Phase 3 VITESSE trial – the largest immunotherapy clinical trial to date for this population.
- DBV has requested Priority Review of the BLA.

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a late-stage biopharmaceutical company, today announced that the Company has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the VIASKIN® Peanut Patch in children with peanut allergy aged 4 through 7 years.

DBV has requested Priority Review of the BLA. The FDA previously granted Breakthrough Therapy Designation to the VIASKIN® Peanut Patch.

“The submission of our BLA brings VIASKIN® Peanut Patch, a non-invasive, practical treatment option, one step closer to being available for children ages 4 through 7 living with peanut allergy, and marks a significant milestone in DBV’s transformation into a commercial organization,” said Daniel Tassé, Chief Executive Officer of DBV Technologies. “This BLA reflects years of rigorous clinical development, meaningful contributions from the entire food allergy community, and ongoing collaboration with the FDA. We are grateful for the Agency’s constructive engagement over the last few months and look forward to working closely with them during the review process.”

The VIASKIN® Patch uses epicutaneous immunotherapy (EPIT), an innovative, non-oral, non-injection approach to food allergy treatment that delivers small amounts of an allergen protein through the skin. By using the immune properties of the skin, the VIASKIN® Peanut Patch is designed to progressively desensitize children to peanut allergy.

The BLA is supported by the [positive results from the VITESSE Phase 3 clinical trial](#) of the VIASKIN® Peanut Patch in 654 children ages 4 through 7 years with peanut allergy. VITESSE is the largest immunotherapy clinical trial to date for this population.



About the VITESSE Study

VITESSE (NCT05741476) is a global Phase 3, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of the VIASKIN® Peanut patch (250 µg) in children ages 4-7 years with peanut allergy. The study enrolled 654 children randomized 2:1 to receive either VIASKIN® Peanut Patch or placebo. Conducted at 86 sites across the United States, Canada, United Kingdom, Europe, and Australia, VITESSE represents the largest immunotherapy clinical trial for this patient population. The primary endpoint is the difference between the percentage of treatment responders in the active versus placebo group after 12 months of treatment. Following the 12-month double-blind period, children were given the option to continue into an open-label extension where all participants receive VIASKIN® Peanut Patch for up to a total of three years on treatment.

About DBV Technologies

DBV Technologies is a late-stage biopharmaceutical company developing treatment options for food allergies and other immunologic conditions with significant unmet medical need. DBV Technologies 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® Peanut 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 Technologies is committed to transforming the care of people with food allergies. The Company's food allergy programs include ongoing clinical trials of VIASKIN® Peanut Patch in toddlers (1 through 3 years of age) and children (4 through 7 years of age) with peanut allergy.

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 (DBV, ISIN code: FR0010417345) and the Company's ADSs (each representing five ordinary shares) are traded on the Nasdaq Capital Market (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, results of DBV's clinical trials, DBV's planned regulatory and clinical efforts including timing and results of communications with regulatory agencies, plans, timing and expectations with respect to priority review of the BLA for VIASKIN® Peanut Patch for children ages 4 through 7, 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, 2025, filed with the SEC on March 26, 2026, as amended by Amendment No. 1 on Form 10-K/A filed with the SEC on April 30, 2026, DBV Technologies' Quarterly Reports on Form 10-Q for the quarters ended March 31, 2026 and June 30, 2026 filed with the SEC on April 30, 2026 and July 16, 2026, respectively, 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 of DBV Technologies.

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