

DBV Technologies Announces Positive Topline Results from Phase 3 VITESSE Trial of VIASKIN® Peanut Patch in Peanut Allergic Children Aged 4-7 Years

- **VITESSE met its primary endpoint: the lower bound of the 95% confidence interval (CI) of the difference between treatment arms was 24.5%, exceeding the prespecified threshold of 15%**
- **46.6% of children treated with the VIASKIN® Peanut patch met response criteria at 12 months, compared to 14.8% of children in the placebo arm**
- **Safety results were consistent with the safety profile observed in the VIASKIN Peanut clinical program to date**
- **BLA submission in 4-7-year-olds on track for the first half of 2026**
- **Achievement of primary endpoint triggers an acceleration of the exercise period of certain warrants issued pursuant to DBV's March 2025 financing**
- **DBV to host a conference call today at 5:00 p.m. ET to discuss the VITESSE topline results and path forward**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT – CUSIP: 23306J309), a late-stage biopharmaceutical company, today announced that VITESSE, its pivotal Phase 3 study assessing the safety and efficacy of VIASKIN® Peanut patch for the treatment of peanut-allergic children aged 4 to 7 years, met its primary endpoint.

VIASKIN Peanut demonstrated a statistically significant treatment effect ($p < 0.001$)*, with 46.6% of children in the VIASKIN Peanut arm meeting the treatment responder criteria after 12 months, as compared to 14.8% of children in the placebo arm (difference in response rates = 31.8%; 95% CI = (24.5, 39.0%)), exceeding the lower bound prespecified threshold of 15%.

* $p = 1 \times 10^{-17}$



Responders were defined as children with a baseline eliciting dose (ED) ≤ 30 mg who achieved an ED ≥ 300 mg of peanut protein at month 12, or a child with a baseline ED = 100 mg who achieved an ED ≥ 600 mg of peanut protein at month 12, as measured by a double-blind, placebo-controlled food challenge (DBPCFC). The ED is the amount of peanut protein that induced an allergic reaction. The month 12 responder rates for each ED subgroup performed as expected based on the Company's statistical projections.

"Peanut allergy places a considerable burden on children and their families that is insufficiently addressed by current treatment options or strict avoidance," stated David Fleischer M.D., Professor of Pediatrics at Children's Hospital Colorado and Global Principal Investigator of the VITESSE study. "I'm thrilled by these topline results which show a statistically significant treatment effect in children treated with the VIASKIN Peanut patch. The levels of desensitization achieved in this study after one year on treatment are highly clinically meaningful and represent substantial progress towards a well-tolerated, non-invasive potential option that I believe would be welcomed into pediatric care. As a practicing allergist, I look forward to what that may mean for families managing peanut allergy every day and hope to be able to implement this treatment in my clinic, if approved."

VITESSE enrolled 654 children, exceeding its original enrollment target of 600, of which 438 and 216 were randomized to the active and placebo arms, respectively. Enrollment was balanced for age and baseline disease characteristics between the active and placebo treatment arms. Rates of enrollment in the VITESSE open-label extension were in line with previous VIASKIN Phase 3 studies.

Safety results were consistent with the safety profile of the VIASKIN Peanut clinical program to date. The most common treatment-emergent adverse events (TEAEs) observed during the VITESSE study were mild-to-moderate local skin reactions at the patch application site. Discontinuations due to TEAEs were low at 3.2% in the treatment arm compared to 0.5% of in the placebo arm. Notably, there were no reports of treatment-related serious



adverse events and treatment-related anaphylaxis was low at 0.5% (n=2) – both children continued treatment. The data from the exploratory adhesion assessments were in line with the Company's expectations. Overall, compliance was high at 96.2%, consistent with what has been observed in other Phase 3 VIASKIN Peanut studies.

"We saw tremendous enthusiasm around EPIT and the VIASKIN Peanut patch development program at ACAAI's annual scientific meeting last month" said allergist Cherie Zachary M.D., President of the American College of Allergy, Asthma and Immunology. "I am excited to see what's possible with this innovative treatment in 4-7-year-old patients, if approved. I look forward to open-label results in the future to fully understand the potential impact VIASKIN Peanut can have in this age group."

DBV is moving forward with plans for a Biologics License Application (BLA) submission in the United States in the first half of 2026.

"VITESSE is the largest immunotherapy clinical trial ever conducted in food allergy and we are thrilled that the resulting clinical evidence supporting the VIASKIN Peanut patch is robust. With these data in hand, I am looking forward to submitting the BLA to the FDA, as planned, in the first half of 2026," stated Daniel Tassé, Chief Executive Officer of DBV Technologies. "I would again like to express my gratitude to the FDA for a constructive dialogue that enabled us to reach alignment on a [path forward](#) for this important program, as well as our clinical investigators and their staff. Most importantly, we must acknowledge the tremendous belief, dedication, and investment made by patients and all those who participated in the study—without whom the efficient execution of the study would not have been possible. Thanks to the food allergy community, we are one step closer to delivering on our mission to transform the lives of children and families living with peanut allergy."

The FDA previously granted Breakthrough Therapy Designation for VIASKIN Peanut patch, and the Company expects the BLA may be eligible for priority review.



Investor Conference Call and Webcast

DBV management will host an investor conference call and webcast today, Tuesday, December 16th, at 5:00pm ET, to discuss the VITESSE results and next steps for the program. 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.

Business Updates

These positive results represent a major milestone for DBV Technologies. In connection with this announcement and the notice to investors posted to the Company's website, in March 2025 DBV [announced a financing](#) of up to €284.5 million, including gross proceeds of €116.3 million received upon closing and an aggregate of up to €168.2 million in gross proceeds subject to the full exercise of the warrants attached to the new ordinary shares (the "ABSA Warrants") and the warrants attached to the first pre-funded warrants (the "BS Warrants") issued by the Company on April 7, 2025. The terms of the financing provided that the exercise period of the ABSA Warrants and BS Warrants is accelerated upon the announcement of positive VITESSE topline results. As a result of this announcement of positive VITESSE topline results, the ABSA Warrants and BS Warrants are exercisable through January 15, 2026, which is 30 days following the publication of this announcement (the "Exercise Period"). The Company will publish a comprehensive press release following the end of the Exercise Period (or following the date on which all ABSA Warrants and BS Warrants have been exercised, as the case may be).

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 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](#).

About the VITESSE Study

VITESSE ([NCT05741476](https://clinicaltrials.gov/ct2/show/study/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.

DBV plans to present the full VITESSE results at future medical congresses as well as submit them for publication in a peer-reviewed journal.

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 and expectations with respect to the submission of BLAs to FDA, expectations around the BLA's potential for priority review, the exercisability of warrants issued in connection with the financing announced on March 27, 2025, 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, 2024, filed with the SEC on April 11, 2025, as amended by Amendment No. 1 on Form 10-K/A filed with the SEC on April 28, 2025, and as amended further by Amendment No. 2 on Form 10-K/A filed with the SEC on May 14, 2025 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, filed with the SEC on



October 28, 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 of DBV Technologies.

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