



Press Release

Châtillon, France, January 8th, 2025

DBV Technologies Announces Positive 3-Year Results from EPITOPE Phase 3 Open-Label Extension Study

- **EPITOPE OLE data demonstrates continued improvement in treatment benefit of VIASKIN® Peanut patch in toddlers 1 – 3 years through 36 months**
- **68.2% of subjects completed the oral food challenge (~12-14 peanut kernels) without meeting stopping criteria, compared to 30.7% at month 12**
- **No treatment-related anaphylaxis or serious treatment-related Treatment-Emergent Adverse Events (TEAEs) occurred in year three of EPITOPE OLE**
- **DBV also announced daily patch wear time data from EPITOPE that is supportive of the Company's proposed labeling approach shared with FDA**
- **DBV to highlight these data in multiple abstract presentations at the Eastern Food Allergy & Comorbidity Conference, January 9-12, in Palm Beach, Florida**
- **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 positive twenty-four month results from its Open-Label Extension (OLE) Study of EPITOPE (Phase 3 trial of VIASKIN® peanut 250 µg [VP250] in toddlers ages 1 to 3 years). The data provide support that continued treatment with VIASKIN Peanut showed further improvement through 36 months of treatment across all efficacy parameters.

DBV also announced today new Viaskin Peanut Patch efficacy and safety data based on average daily wear time from the EPITOPE study that is supportive of the Company's VIASKIN peanut labeling strategy, [proposed to FDA in June 2024](#). This post-hoc analysis identified subjects on Viaskin Peanut with low or high day-to-day variability in daily wear time during the first 90 days on treatment – a highly predictive marker of the average daily wear time (ADWT) during the course of the 12-month study. Subjects with



low day-to-day variability in daily wear time had higher ADWT which correlated with a more robust efficacy response at 12 months.

These data are being presented in multiple poster presentations at the Eastern Food Allergy & Comorbidity Conference, which is being held January 9th through 12th, 2025, in Palm Beach, Florida.

Twenty-Four Month EPITOPE OLE Results

After completing participation (12 months) in [the EPITOPE study](#), eligible subjects could enroll in the OLE to receive a total of 36 months of VIASKIN peanut treatment. Double-blind placebo-controlled food challenges (DBPCFC) were conducted at the end of each year of treatment with safety assessed throughout the entire OLE. Importantly, all subjects remained blinded to their treatment assignment in EPITOPE until every patient completed EPITOPE and the database was locked; therefore, the decision to enter the OLE was not biased by the unblinding of the randomized treatment.

In the EPITOPE OLE, VIASKIN Peanut data suggests further improvement through 36 months of treatment across all efficacy parameters. Key data highlights include:

- 266 EPITOPE participants enrolled in the OLE; 211 underwent the Month 36 DBPCFC (n=149 VP250; n=62 placebo).
 - After three years of VP250, 83.5% of participants reached an eliciting dose (ED) of ≥ 1000 mg, an increase from 64.2% at month 12 (the EPITOPE study).
 - A similar increase was observed for participants reaching an ED of ≥ 2000 mg (72.7% at month 36; 37.0% at month 12;).
 - Those completing the DBPCFC without meeting stopping criteria increased to 68.2% at month 36 from 30.7% at month 12.
- Continued reductions in DBPCFC reaction severity occurred, with 66.5% having no/mild symptoms at month 36 vs 40.2% at month 12.
- No treatment-related anaphylaxis or serious treatment-related TEAEs occurred in Year 3.



- Local application-site reactions occurred less frequently in Year 3 vs Years 1 and 2.
- In placebo-treated EPITOPE participants, outcomes after 24 months of VP250 in the OLE were consistent with 24-month results in EPITOPE VP250 participants.

“The compelling results from 36 months of Viaskin Peanut treatment demonstrate a continuation of the very positive efficacy and safety trends that have been previously observed in this study,” said Pharis Mohideen, Chief Medical Officer, DBV Technologies. “Notably, the data indicates that continued treatment with VIASKIN Peanut resulted in further improvement across all efficacy parameters in the second year of the OLE with no new safety signals. The data show that more than two-thirds of subjects completed the food challenge without meeting pre-defined stopping criteria, consuming the equivalent of 12-14 peanut kernels, and more than 83% reached an ED of $\geq 1,000$ mg, or the equivalent of 3-4 peanut kernels. Recall that this is a patient population that can experience devastating consequences from accidental exposure to just fractions of a peanut kernel. As we prepare to initiate the COMFORT Toddlers supplemental safety study, one of the final steps to support a BLA submission, these results remind us of the tremendous potential of VIASKIN Peanut as a game changer for the peanut allergy community.”

Shared decision making for best response based on patch wear experience.

DBV also announced today new data from the Phase 3 EPITOPE study that supports the labeling approach that was proposed to FDA in [June 2024](#). Patch wear time assessed daily by caregivers was averaged (i.e., average daily wear time or ADWT) for each subject for the first 90 days of treatment (excluding treatment initiation Days 1-28) and over the 12-month EPITOPE study.

Baseline markers of atopic disease severity such as peanut-specific IgE, skin prick test wheal size, SCORAD scores (measure of atopic dermatitis) and eliciting dose were similar between subjects with ADWT ≥ 20 hours/day and < 20 hours/day. The incidence rates and severity of local application site reactions and use of corticosteroids were also similar between groups, but the participants with ADWT < 20 hours reported markedly more scratching as a reason for patch detachments. This strongly suggests that these



participants experienced lower tolerability (i.e., higher degree of “itchiness”) to peanut-induced local skin immune responses.

Data suggests that subjects with low day-to-day wear time variability (≥ 20 hours/day ADWT) had a more robust efficacy response relative to the high day-to-day variability (<20 hour/day ADWT) subjects.

Efficacy and safety data were compared for VP250 participants according to ADWT.

Key data highlights include:

- 167/244 (68.4%) VP250 participants had an ADWT ≥ 20 hours, with median ADWT (22.9 hours) similar to placebo (23.7 hours).
- 77/244 (31.6%) participants had an ADWT <20 hours (median: 16.7 hours).
- ADWT during the first 90 days on treatment was highly predictive of ADWT over the 12-month treatment period ($r=0.81$).
- Participants with ADWT ≥ 20 vs <20 hours during the first 90 days showed greater month 12 efficacy, according to EPITOPE responder criteria (75.7% vs 47.3%).
- Rates of key safety outcomes of interest were numerically lower in participants with ADWT ≥ 20 vs <20 hours, based on treatment-related: epinephrine use (0.6% vs 2.6%), anaphylaxis (0.6% vs 3.9%), and permanent discontinuations (9.6% vs 19.5%).
- As a point of reference, overall clinical response in EPITOPE was 67.0% for patients on active, and 33.5% for patients on placebo.

“Average daily wear time is something that can easily be reported by my caregivers and patients and can be a very useful tool for me to guide shared decision making. Knowing that the ADWT during the first 90 days on treatment is highly predictive of ADWT over a full year and that these data further suggest that ADWT greater than 20 hours show a strong correlation with clinical efficacy response at 12 months will help to guide optimal use of VIASKIN peanut, if approved.”, stated Dr. Edwin Kim, Division Chief, Pediatric Allergy & Immunology, University of North Carolina School of Medicine, and presenting author.



Eastern Food Allergy and Comorbidity Conference - Poster Presentations

January 9-12, 2025, Palm Beach, FL

All posters will be displayed from 3:00pm ET on Thursday, January 9th through 11:45am ET on Saturday, January 11th.

“EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: Results After 3 Years of Treatment”

- Presenter: Matthew Greenhawt, MD

“VP250 Average Daily Wear Time: Impact on Efficacy and Safety in the Phase 3 EPITOPE Study”

- Presenter: Edwin H. Kim, MD

“Changes in Biomarkers During Epicutaneous Immunotherapy for Peanut Allergy in Toddlers”

- Presenter: Edwin H. Kim, MD

“We are very pleased with the progress that DBV continues to make advancing this novel therapy through its remaining regulatory steps, and believe that, if approved, it has the potential to revolutionize the treatment of peanut allergy,” stated Eleanor Garrow-Holding, CEO, Food Allergy and Anaphylaxis Connection Team. “It is encouraging to see new data that further inform the real-world use of VIASKIN Peanut, and we are hopeful that it will soon be an available treatment option for peanut allergic patients and their caregivers.”

Investor Conference Call and Webcast

DBV management will host an investor conference call and webcast today, January 8th, at 5:00pm EST, to discuss these clinical 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.

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

Investor Contact

Katie Matthews
DBV Technologies

katie.matthews@dbv-technologies.com

Media Contact

Angela Marcucci
DBV Technologies

angela.marcucci@dbv-technologies.com