Press Release
Châtillon, France, March 24, 2025

DBV Technologies Secures Agreement with FDA on Safety Exposure Data Required for Biologics License Application (BLA) for Viaskin® Peanut Patch in 4 – 7-year-olds, Accelerating the Timeline for a BLA Filing Submission to 1H 2026, and Reports 2024 Unaudited Financial Results[1]

- **COMFORT Children supplemental safety study in children 4 – 7-years-old no longer required**
- **FDA confirms safety exposure data generated from VITESSE Phase 3 clinical study and VITESSE Open-Label Extension (OLE) are sufficient to support a Biologics License Application (BLA) for Viaskin peanut patch in children 4 – 7-years-old**
- **VITESSE topline results on-track for the fourth quarter of 2025**
- **BLA submission for Viaskin peanut patch in children 4 – 7-years-old is now expected in the first half of 2026; DBV anticipates this path may accelerate potential launch, if approved by the FDA, by approximately one year**
- **DBV also reports unaudited financial results[1] for the full year 2024, including cash and cash equivalents**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT, the "Company"), a clinical-stage biopharmaceutical company, today announced that in a Written Responses Only to the Company's Type D IND meeting request, the U.S. Food and Drug Administration (FDA) agreed with the Company's proposal that the safety exposure data from the VITESSE Phase 3 study for Viaskin peanut patch in 4 – 7-year-olds will be sufficient to support a Biologics License Application (BLA) filing in this age group. As a result, the COMFORT Children supplemental safety study will no longer be required, which accelerates the timeline for a BLA submission of Viaskin® peanut patch in 4 – 7-year-olds with a

[1] The financial information published in this press release shall be considered as "*données financières estimées*" or "estimated financial data", according to AMF Position-Recommendation DOC-2016-05.

peanut allergy. The Company also reported unaudited financial results[1] for the full year 2024, including cash and cash equivalents.

FDA Update

Based on the Written Responses Only received, DBV will no longer conduct the COMFORT Children 6-month supplemental safety study. The Company will utilize the safety data from the VITESSE participants randomized to active treatment as well as placebo-crossover participants in the VITESSE Open Label Extension (OLE), expediting the BLA submission for the Viaskin peanut patch from the previously anticipated timeline. Accordingly, the Company plans to submit a BLA in the first half of 2026 and anticipates potentially accelerating the product launch by approximately one year, subject to FDA approval.

"*DBV's alignment with FDA represents a tremendous achievement for food allergy families, clinicians, researchers, and countless external partners that have been working for many years to advance the Viaskin peanut patch in children living with peanut allergy*," said Daniel Tassé, Chief Executive Officer, DBV Technologies. "*I thank the FDA and the Review Team for their collaboration and constructive approach during the Type D meeting process, which enabled us to gain clarity expeditiously. DBV is commencing preparations for a BLA submission in the first half of 2026 to be supported by the Phase 3 VITESSE study, which is on-track for readout of topline results in the fourth quarter of 2025. We believe that the Viaskin peanut patch has the potential to change the lives of millions of children living with peanut allergy. This mission drives DBV every day. We will continue to work hard to bring this innovative treatment option to market.*"

FDA has agreed with DBV's proposal to support potential licensure of the Viaskin peanut patch in children 4 – 7-years-old with the efficacy, safety and patch wear time data generated from VITESSE, which enrolled 654 participants, making it the largest Phase 3 clinical trial for peanut allergy ever conducted in this age group. This will include safety data from study participants on active treatment for 12-months and the additional crossover study participants on active treatment in the VITESSE OLE. At the time of BLA submission, the safety database will be comprised of more than 500 study participants on Viaskin peanut patch active treatment.

"*I am extremely pleased to see that FDA agrees that the VITESSE safety exposure data being generated is sufficiently robust to support a BLA in this age group*," said Dr. David Fleischer, FAAAAI, FACAAI, Global Principal Investigator, VITESSE,

Professor of Pediatrics at Children's Hospital Colorado. "*This is the largest, most rigorous study ever conducted in peanut allergic children between 4 and 7 years of age. The insights that we will gain from this work are invaluable to the disease space as a whole. Clinicians want to see additional FDA approved treatment options in food allergy so that we may conduct thoughtful conversations with our patients about which option is best for them and their lifestyle. I look forward to the day when the Viaskin peanut patch may be part of those conversations.*"

As previously communicated, DBV also plans to pursue an Accelerated Approval pathway for the Viaskin peanut patch in toddlers 1 – 3-years-old with a peanut allergy. The COMFORT Toddlers 6-month supplemental safety study is on-track to initiate in the second quarter of 2025 and will recruit approximately 480 study participants. The BLA submission for the 1 – 3-year-old indication is expected in the second half of 2026, subject to the successful completion of the COMFORT Toddlers study.

"*On behalf of our 6,500 members in the United States and globally, we are pleased to support potential new innovations in food allergy, including the Viaskin peanut patch, that could add to the toolbox allergist-immunologists consider when treating patients*," said Dr. James Tracy, DO, FACAAI, President, American College of Allergy, Asthma, and Immunology (ACAAI). "*The ACAAI advocates for the best treatment outcomes for our patients under the care of their clinician. We are encouraged by the robust dataset being generated by the VITESSE Phase 3 study, in which many of our members are currently serving as investigators. We continue to support DBV's development of the Viaskin peanut program in this 4 – 7-year-old age group. Our community encourages as many treatment options as possible to reach those who are eagerly awaiting.*"

Unaudited Financial Results[1] for Full Year 2024

These unaudited financial results[1] have been examined by the Board of Directors of the Company on March 23, 2025, and the audited final financial statements are expected to be approved by the Board of Directors on March 28, 2025.

The audit procedures by the statutory auditors of the Company on the 2024 consolidated full year financial statements are in progress.

Financial results are presented under both U.S. generally accepted accounting principles ("US GAAP") and the International Financial Reporting Standards ("IFRS")

as adopted by the European Union. Financial statement comments refer to U.S. GAAP financial statements. Differences between US GAAP and IFRS as adopted by the European Union consolidated financial statements result mainly from the discrepancies arising from the application of lease accounting standards.

In order to finance its activities, the Company needs to raise additional funds and is actively reviewing potential financing and strategic options with its financial advisors.

Cash and Cash Equivalents

Cash and cash equivalents amounted to $32.5 million as of December 31, 2024, compared to $141.4 million as of December 31, 2023, a net cash consumption of $108.9 million, mainly driven by external clinical trial-related expenses, in particular those related to subject enrollment in the Company's ongoing VITESSE Phase 3 clinical trial, with topline results expected by the fourth quarter of 2025 as previously communicated, as well as regulatory and manufacturing activities to support ongoing clinical trials.

The Company has incurred operating losses and negative cash flows from operations since inception. As of the date of this press release, the Company's available cash and cash equivalents will not be sufficient to support its operating plan for the next 12 months. Based on its current operations, plans and assumptions, the Company expects that its cash and cash equivalents will be sufficient to fund its operations only into April 2025.

As such, there is substantial doubt regarding its ability to continue as a going concern.

The Company intends to seek additional capital as it continues research and development efforts and prepares for the filing of the BLA and launch of Viaskin® Peanut patch, if approved.

The Company cannot guarantee that it will successfully obtain the necessary financing to meet its needs or to obtain funds at attractive terms and conditions. If the Company is not successful in its financing objectives, the Company could have to scale back its operations, notably by delaying or reducing the scope of its research and development efforts or obtain financing through arrangements with collaborators or others that may require the Company to relinquish rights to its

product candidates that the Company might otherwise seek to develop or commercialize independently or discontinue all or part of its operations.

In millions of USD *(unaudited)*	U.S. GAAP Year ended December 31,		IFRS Year ended December 31,	
	2024	**2023**	2024	2023
Net cash & cash equivalents at the beginning of the period	**141.4**	**209.2**	**141.4**	**209.2**
Net cash flow used in operating activities	(104.5)	(79.7)	(102.7)	(77.6)
Net cash flow provided by / (used in) investing activities	(0.8)	(0.8)	(0.6)	(0.8)
Net cash flow provided by / (used in) financing activities	0.6	6.8	(0.7)	4.8
Effect of exchange rate changes on cash & cash equivalents	(4.3)	5.9	(5.3)	5.9
Net cash & cash equivalents at the end of the period	**32.5**	**141.1**	**32.1**	**141.4**

Operating Income

Operating income amounted to $4.2 million for the year ended December 31, 2024, compared with $15.7 million for the same period in 2023. This decrease by $11.5 million is composed of (1) $7.0 million following the mutual termination of the Development, Collaboration, and License Agreement with with Societé des Produits Nestlé S.A (formerly NESTEC S.A.) ("**NESTEC**"), and (2) a lower Research Tax Credit ("**CIR**"). This decrease is due to a corrective CIR filed in 2023 by the Company for $2.9 million for fiscal years 2020, 2021 and 2022 and a greater proportion of study activities carried out in North America in 2024 as compared to 2023, which are not eligible to the CIR.

In millions of USD *(unaudited)*	U.S. GAAP Year ended December 31,		IFRS Year ended December 31,	
	2024	**2023**	**2024**	**2023**
Research tax credits	4.1	8.8	4.1	8.8
Other operating income	0.0	7.0	0.0	7.0
Operating income	**4.2**	**15.7**	**4.2**	**15.7**

Operating Expenses

Operating expenses amounted to $120.7 million for the year ended December 31, 2024, compared with $92.2 million for the year ended December 31, 2023, an increase of $28.5 million. This increase is primarily driven by research & development costs of $29.1 million resulting from (1) subject enrollment in the Company's ongoing VITESSE Phase 3 clinical trial, (2) preparatory activities for the Company's COMFORT supplemental safety studies in anticipation of initiation after FDA alignment, and (3) regulatory and manufacturing activities to support ongoing clinical trials.

General and administrative expenses decreased by $0.8 million during the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily due to the positive impact of office moves in France and the U.S.

In millions of USD *(unaudited)*	U.S. GAAP Year ended December 31,		IFRS Year ended December 31,	
	2024	2023	**2024**	2023
Research & Development	(89.3)	(60.2)	(89.2)	(60.1)
Sales & Marketing	(2.7)	(2.4)	(2.7)	(2.4)
General & Administrative	(28.7)	(29.5)	(28.8)	(29.5)
Operating expenses	**(120.7)**	**(92.2)**	**(120.6)**	**(92.0)**

Net Loss Per Share

The Company recorded a net loss of $113.9 million for the year ended December 31, 2024, compared to a net loss of $72.7 million for the year ended December 31, 2023. On a per share basis, net loss (based on the weighted average number of shares outstanding over the period) was $(1.17) for the year ended December 31, 2024.

(unaudited)	U.S. GAAP		IFRS	
	Year ended December 31,		Year ended December 31,	
	2024	2023	**2024**	2023
Net income / (loss) (in millions of USD)	(113.9)	(72.7)	(114.1)	(72.7)
Basic / diluted net income / (loss) per share (USD/share)	(1.17)	(0.76)	(1.18)	(0.76)

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION (unaudited)

In millions of USD *(unaudited)*	U.S. GAAP		IFRS	
	Year ended December 31,		Year ended December 31,	
	2024	2023	**2024**	2023
Assets	65.7	183.0	65.5	183.0
of which cash & cash equivalents	32.5	141.4	32.5	141.4
Liabilities	**38.3**	**42.8**	**38.2**	**42.7**
Shareholders' equity	**27.4**	**140.2**	**27.4**	**140.3**

CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

In millions of USD (unaudited)	U.S. GAAP Year ended December 31,		IFRS Year ended December 31,	
	2024	2023	**2024**	2023
Operating income	**4.2**	**15.7**	**4.2**	**15.7**
Research & Development	(89.3)	(60.2)	(89.2)	(60.1)
Sales & Marketing	(2.7)	(2.4)	(2.7)	(2.4)
General & Administrative	(28.7)	(29.5)	(28.8)	(29.5)
Operating expenses	**(120.7)**	**(92.2)**	**(120.6)**	**(92.0)**
Financial income/(expenses)	2.7	3.7	2.4	3.6
Income tax	(0.1)	(0.0)	(0.1)	(0.0)
Net loss	**(113.9)**	**(72.7)**	**(114.1)**	**(72.7)**
Basic/diluted net loss per share attributable to shareholders	(1.17)	(0.76)	(1.18)	(0.76)

CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

In millions of USD (unaudited)	U.S. GAAP Year ended December 31,		IFRS Year ended December 31,	
	2024	2023	**2024**	2023
Net cash flows provided / (used) in operating activities	(104.5)	(79.7)	(102.7)	(77.6)
Net cash flows provided / (used) in investing activities	(0.8)	(0.8)	(0.6)	(0.8)
Net cash flows provided / (used) in financing activities	0.6	6.8	(0.7)	4.8
Effect of exchange rate changes on cash & cash equivalents (U.S. GAAP presentation)	(4.3)	5.9	(5.3)	5.9
Net increase / (decrease) in cash & cash equivalents	**(108.9)**	**(67.8)**	**(109.3)**	**(67.8)**
Net cash & cash equivalents at the beginning of the period	141.4	209.2	141.4	209.2
Net cash & cash equivalents at the end of the period	**32.5**	**141.4**	**32.1**	**141.4**

Disclaimer

The unaudited financial results as of and for the year ended December 31, 2024 included in

this press release have been examined by the Board of Directors of the Company on March 23, 2025 and remain subject to any adjustments, and other developments arising between now and the time such financial results are finalized. The Company's independent auditors have not yet audited nor have they expressed any opinion or any other form of assurance on these unaudited financial results, in particular DBV has not yet obtained assurance from its auditors that the financial statements will be certified without qualification. The audit procedures by the statutory auditors of the Company are in progress.

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 Company's financial condition, forecast of its cash runway, financing plans, 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 the submission of BLAs to FDA, anticipated support for the BLA submission, 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, the Company'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 DBV's ability to obtain necessary financing, uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, and the Company's ability to successfully execute on its budget discipline measures. The review of potential financial and strategic options may not result in any particular action or transaction being pursued, entered into or consummated, and there is no assurance as to the timing, sequence or outcome of any action or transaction or series of actions or transactions. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its financial statements, and it is likely that investors will lose all or part of their investment. 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 the Company's regulatory filings with the French Autorité des Marchés Financiers ("AMF"), the Company's filings and reports with the U.S. Securities and Exchange Commission ("SEC"), including future filings and reports made with the AMF and SEC by the Company. 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, the Company undertakes no obligation to update or revise the information contained in this press release.

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