Press Release
Montrouge, France, October 31, 2023

DBV Technologies Receives Requested Feedback from FDA on Protocol Design Elements for COMFORT Safety Studies and Reports Third Quarter 2023 Financial Results

- DBV has received written feedback from the U.S. Food and Drug Administration (FDA) clarifying design elements for both the COMFORT Toddlers and COMFORT Children supplemental safety studies.
- Both supplemental safety studies will have harmonized, simplified protocol language on how the product should be used.
- The COMFORT Toddlers study will apply the same eligibility criteria as EPITOPE, DBV's successful Phase 3 efficacy study in toddlers 1-3 years.
- DBV will submit the final protocol for COMFORT Toddlers to FDA expeditiously and anticipates the first subject enrolled in Q1 2024.
- DBV closes Q3 2023 with a cash balance of $149 million.
- The Company will host a conference call and live audio webcast on Tuesday, October 31st at 5:00pm.

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced the receipt of written feedback from the U.S. Food and Drug Administration (FDA) regarding the remaining study design elements for the COMFORT (**C**haracterization of the **O**ptimal **M**anagement of **FO**od Allergy **R**elief and **T**reatment) supplemental safety studies. The Company also reported financial results for the third quarter of 2023. The quarterly financial statements were approved by the Board of Directors on October 31, 2023.

Recent Business Developments

Following DBV's request for clarification after receipt of Type C Meeting feedback in July 2023, the FDA provided Written Responses on protocol design elements for the COMFORT supplemental safety studies. Both COMFORT Toddlers and COMFORT Children protocol will have harmonized language guiding how the product will be used in the trials, such as, "Each DBV712 250 µg epicutaneous system is intended to

be worn for a full day (24 hours)." These instructions are simpler and more concise relative to previously used protocol language.

Further to this approach, both supplemental safety studies will seek to enroll populations that are closely aligned with their respective Phase 3 efficacy studies, as is feasible. For COMFORT Toddlers, eligibility criteria will be the same as in EPITOPE (Phase 3 efficacy study in 1-3-year-olds) as reliance on peanut specific-IgE and skin prick test alone does not ensure a Regulatory-level of assurance of peanut allergy or a similar peanut allergic patient population relative to EPITOPE. Thus, COMFORT Toddlers will include a double-blind, placebo-controlled food challenge (DBPCFC) as part of the Inclusion criteria.

For COMFORT Children, key inclusion criteria will remain peanut specific-IgE and skin prick test as these criteria are well established from previously conducted DBV studies (PEPITES and REALISE), as well as from the medical literature, and are expected to support enrollment of a similar study population relative to VITESSE (Phase 3 efficacy study in 4-7-year-olds). Therefore, a DBPCFC will not be required for COMFORT Children.

The size and duration of both supplemental safety studies remains unchanged from previous communications. These protocol design elements ensure closer alignment between the supplemental safety studies and their respective efficacy studies, which should ultimately support a more robust future BLA submission package for each indication.

"We are very pleased with the engagement and clarity of the feedback received from the FDA," stated Pharis Mohideen, Chief Medical Officer of DBV Technologies. *"With a clear regulatory path forward, we will submit to FDA the final protocols for the COMFORT studies. We remain confident that this work will support a Biologics License Application (BLA) in both age groups and potentially bring this novel, much needed therapy to a vulnerable patient population."*

DBV will implement the FDA's feedback and expects to submit the final COMFORT Toddlers protocol design to the Agency in the coming weeks. DBV anticipates the first subject will be enrolled in Q1 2024. The initiation of COMFORT Children is expected after the start of COMFORT Toddlers and in alignment with VITESSE recruitment.

Financial Highlights for the Third Quarter and the Nine Months Ended September 30, 2023

The Company's interim consolidated financial statements for the nine months ended September 30, 2023, are prepared in accordance with accounting principles in the U.S. ("U.S. GAAP"). Unless otherwise indicated, the financial figures presented in the Q3 Financial Highlights comply with U.S. GAAP consolidated financial statements. The financial figures are commented for the nine months ended September 30, 2023, under U.S. GAAP.

Cash and Cash Equivalents

(in millions of USD)	U.S. GAAP	
	Nine months ended September 30	
	2023	2022
Net cash & cash equivalents at the beginning of the period	**209.2**	**77.3**
Net cash flow used in operating activities	(66.0)	(31.8)
Net cash flow provided by / (used in) investing activities	(0.6)	(0.1)
Net cash flow provided by / (used in) financing activities	7.0	194.4
Effect of exchange rate changes on cash & cash equivalents	(0.4)	(27.2)
Net cash & cash equivalents at the end of the period	**149.1**	**212.7**

Cash and cash equivalents amount to $149.1 million as of September 30, 2023, compared to $209.2 million as of December 31, 2022, which is a net decrease by $60.1 million mainly due to the following:

(1) $66.0 million of cash used for operations, mainly driven by the initiation of the VITESSE trial with the first patient screened in March 2023.

Cash used for operations in the nine months ended September 30, 2023, increased by $34.2 million compared to the nine months ended September 30, 2022. The Company received 24.8 million euros (corresponding to $28.1 million on the basis of 2021 closing exchange rate) during the nine months

ended September 30, 2022, for reimbursement of 2019, 2020, and 2021 French research tax credits.

(2) $7.0 million net proceeds from the issuance and sale of new ordinary shares in the form of American Depositary Shares ("ADSs") on June 16, 2023, and pursuant to the At-The-Market ("ATM") program established in May 2022.

Cash provided by financing activities decreased by $187.4 million in the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. The Company issued and sold new ordinary shares in the form of ADSs for a total gross amount of $7.8 million in June 2023 compared to $15.3 million in May 2022, and completed a private placement financing ("PIPE") amounting to a total gross amount of $194.0 million in June 2022.

(3) $0.4 million negative impact of changes in exchange rates. The Company's treasury position, stated in U.S. Dollars, has been impacted by an appreciation of Euro against U.S. Dollar during the nine months ended September 30, 2023.

Operating Income

In millions of USD	U.S. GAAP		U.S. GAAP	
	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research tax credits	1.2	1.4	5.0	4.5
Other operating income	1.1	0.7	1.9	1.7
Operating income	**2.4**	**2.1**	**6.9**	**6.1**

Operating income amounts to $6.9 million for the nine months ended September 30, 2023, compared to $6.1 million for the nine months ended September 30, 2022, which is an increase by $0.8 million due to:

(1) $0.5 million increase in research tax credit estimate as costs eligible to the French tax credit increased to support research and development activities

(a) after the initiation of VITESSE with the first patient screened in March 2023, and (b) as part of the new safety study for toddlers after the FDA confirmed in April 2023 additional safety data is required for BLA submission.

(2) $0.2 million increase in other operating income that consists of revenues recognized in advance as part of the Development, Collaboration, and Licensing Agreement ("the Agreement") with Nestlé Health Science.

On October 30th, 2023, Nestle Health Science and the Company agreed to terminate, as of the effective date of signature, the Development, Collaboration and License Agreement, which set out the terms for the development of a standardized atopy patch test tool for the diagnosis of Cow's Milk Protein Allergy (non-IgE-mediated) in infants and children. Additionally, the parties agreed to end the APTITUDE study conducted as part of the collaboration due to enrollment difficulties and not as a result of any safety issues.

Operating Expenses

In millions of USD	U.S. GAAP		U.S. GAAP	
	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research & Development	13.8	15.1	47.4	45.9
Sales & Marketing	0.7	0.2	1.6	1.7
General & Administrative	6.2	4.8	22.3	17.2
Operating expenses	**20.6**	**20.1**	**71.4**	**64.8**

Operating expenses amount to $71.4 million for the nine months ended September 30, 2023, compared to $64.8 million for the nine months ended September 30, 2022, which is an increase by $6.6 million mainly due to:

(1) The increase by $1.5 million in research and development expenses is driven by clinical - related expenses mainly to support (i) the VITESSE trial with the first patient screened in March 2023, and (ii) the new safety study for toddlers after the FDA confirmed additional safety data is required for BLA.

(2) The increase by $5.1 million in general and administrative expenses related to:
   a. one-time costs associated with financing activities, organizational planning, market research, and planning activities;
   b. recruitments to support general and administrative activities with a nine-month impact at end of September 2023 compared to a one or few months impact at end of September 2022; and
   c. a provision of costs to be incurred if the Montrouge office lease agreement is not renewed at its July 2024 term expiration.

(3) Slightly offset by the decrease by $0.1 million in sales and marketing expenses due to a decrease of external professional services and employee-related costs.

Net Loss and Net Loss Per Share

	U.S. GAAP		U.S. GAAP	
	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Net income / (loss) (in millions of USD)	(16.7)	(17.3)	(61.5)	(57.0)
Basic / diluted net income / (loss) per share (USD/share)	(0.17)	(0.18)	(0.65)	(0.79)

Net result for the nine months ended September 30, 2023, is a loss amounting to $61.5 million, compared to a loss amounting to $57.0 million for the nine months ended September 30, 2022.

On a per share basis, net loss (based on the weighted average number of shares outstanding over the period) is $0.65 for the nine months ended September 30, 2023.

Conference Call Information

DBV will host a conference call and live audio webcast on Tuesday, October 31st, at 5:00 p.m. ET to report third quarter 2023 financial results and provide a business update.

Participants may access this call via the below teleconferencing numbers and asking to join the DBV Technologies call:

- United States: 1-844-481-2866
- International: 1-412-317-1859

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.

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION (unaudited)

In millions of USD	U.S. GAAP	
	September 30, 2023	December 31, 2022
Assets	**189.8**	**246.5**
of which cash & cash equivalents	149.1	209.2
Liabilities	**45.8**	**52.1**
Shareholders' equity	**144.0**	**194.5**
of which net result	(61.5)	(96.3)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

In millions of USD	U.S. GAAP		U.S. GAAP	
	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenues	**2.4**	**2.1**	**6.9**	**6.1**
Research & Development	(13.8)	(15.1)	(47.4)	(45.9)

Sales & Marketing	(0.7)	(0.2)	(1.6)	(1.7)
General & Administrative	(6.2)	(4.8)	(22.3)	(17.2)
Operating expenses	**(20.6)**	**(20.1)**	**(71.4)**	**(64.8)**
Financial income/(expenses)	1.5	0.7	3.0	1.7
Income tax	-	-	0.0	(0.1)
Net loss	**(16.7)**	**(17.3)**	**(61.5)**	**(57.0)**
Basic/diluted net loss per share attributable to shareholders	(0.17)	(0.18)	(0.65)	(0.79)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW (unaudited)

In millions of USD	U.S. GAAP	
	Nine months ended September 30,	
	2023	2022
Net cash flows provided / (used) in operating activities	(66.0)	(32.0)
Net cash flows provided / (used) in investing activities	(0.6)	(0.1)
Net cash flows provided / (used) in financing activities	7.0	194.4
Effect of exchange rate changes on cash & cash equivalents (U.S. GAAP presentation)	(0.4)	(27.2)
Net increase / (decrease) in cash & cash equivalents	**(60.1)**	**135.4**
Net cash & cash equivalents at the beginning of the period	209.2	77.3
Net cash & cash equivalents at the end of the period	**149.1**	**212.7**

About DBV Technologies

DBV Technologies is developing Viaskin™, an investigational proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on

epicutaneous immunotherapy, or EPIT™, and is DBV Technologies' method of delivering biologically active compounds to the immune system through intact skin. With this new class of non-invasive product candidates, the Company is dedicated to safely transforming the care of food allergic patients. DBV Technologies' food allergies programs include ongoing clinical trials of Viaskin Peanut. DBV Technologies has global headquarters in Montrouge, France, and North American operations in Basking Ridge, 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 one-half of one ordinary share) are traded on the Nasdaq Global Select Market (Ticker: DBVT).

Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding DBV's forecast of its cash runway, 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-K for the year ended December 31, 2022, filed with the SEC on March 2, 2023, 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.

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