Press Release
Montrouge, France, July 31, 2023

DBV Technologies Receives Feedback from FDA on Design Elements for Viaskin Peanut Safety Studies and Reports Second Quarter and Half-Year 2023 Financial Results

- **Received feedback from U.S. Food and Drug Administration (FDA) on DBV's two supplemental safety studies in toddlers (ages 1 – 3 years) and children (ages 4 – 7 years).**
- **The two Phase 3 pivotal safety studies will be named COMFORT Toddlers (1 – 3 years) and COMFORT Children (4 – 7 years).**
- **COMFORT Toddlers will be a 6-month safety study, consistent with agreement previously reached with FDA on the COMFORT Children safety study.**
- **The Company expects to seek final alignment with FDA on the COMFORT protocols prior to commencing the studies.**
- **DBV closes Q2 2023 with a cash balance of $174 million.**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced the receipt of Written Responses from the FDA on key study design elements for the COMFORT (Characterization of the Optimal Management of FOod Allergy Relief and Treatment) Toddlers and COMFORT Children supplemental safety studies in 1 – 3-year-olds and 4 – 7-year-olds, respectively, with a peanut allergy. The Company also reported financial results for the second quarter and the first half of 2023. The quarterly and half-year financial statements were approved by the Board of Directors on July 28, 2023.

Recent Business Developments

Viaskin™ Peanut in 1 – 3-year-olds (original square patch) and Viaskin™ Peanut in 4 – 7-year-olds (modified circular patch) are separate product candidates with independent clinical and regulatory paths supporting two distinct Biologics License Applications (BLAs).

DBV received Type C Meeting Written Responses from the FDA on the two supplemental safety studies, known as COMFORT. The COMFORT Toddlers safety study will enroll peanut allergic toddlers ages 1 – 3-years and will support the efficacy

results generated from the EPITOPE Phase 3 pivotal study. The COMFORT Children safety study will enroll peanut allergic children ages 4 – 7-years and will support the efficacy results anticipated from the ongoing VITESSE Phase 3 pivotal study.

The FDA agreed with a 6-month study duration and a 3:1 randomization (active:placebo) of approximately 400 subjects in the double-blind, placebo-controlled COMFORT Toddlers study. Both COMFORT studies will assess adhesion using the same tools and measurements that were established in VITESSE. Neither the COMFORT Toddlers study nor the COMFORT Children study will require an oral food challenge for participation.

The feedback received is consistent with FDA's position on COMFORT Children in 4 – 7-year-olds, as previously announced in December 2022.

Both COMFORT studies aim to bring the total number of subjects on active treatment to approximately 600 participants in each age group, when added to their respective Phase 3 pivotal efficacy studies (i.e., EPITOPE and VITESSE).

"*We are pleased to have received feedback from the FDA on key design elements for the COMFORT safety study protocols in 1 – 3 and 4 – 7-year-olds with peanut allergy*," said **Daniel Tassé, Chief Executive Officer, DBV Technologies**. "*This continues the positive momentum DBV received in December 2022 and April 2023 when we outlined our regulatory pathways for Viaskin Peanut in children and toddlers. We are actively enrolling subjects in the VITESSE Phase 3 study and were also honored to have our EPITOPE data published in the New England Journal of Medicine in May, with an accompanying editorial. The COMFORT Toddlers and COMFORT Children safety studies meet the FDA's request for additional safety studies in these patient populations. As we complete the final protocols, which we expect to share with FDA, we are actively progressing site selection and contracting to enable the start of the COMFORT safety studies as soon as final FDA protocol alignment is achieved.*"

Conference Call

DBV will host a conference call and live audio webcast on Monday, July 31st, at 5:00 p.m. ET to report first half 2023 financial results and provide a corporate update.

Participants may access this event 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.

Financial Highlights for the Second Quarter and the Six Months Ended June 30, 2023

The Company's interim consolidated financial statements for the six months ended June 30, 2023, are prepared in accordance with both generally accepted accounting principles in the U.S. ("U.S. GAAP") and International Financial Reporting Standards ("IFRS") as adopted by the European Union. Unless otherwise indicated, the financial figures presented in the Q2 Financial Highlights comply with both U.S. GAAP and IFRS consolidated financial statements. The financial figures are commented for the six months ended June 30, 2023, under U.S. GAAP. Differences between U.S. GAAP and IFRS consolidated financial statements are mainly due to discrepancies arising from the application of lease accounting standards.

Cash and Cash Equivalents

(in millions of USD)	U.S. GAAP		IFRS	
	Six months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Net cash & cash equivalents at the beginning of the period	**209.2**	**77.3**	**209.2**	**77.3**
Net cash flow used in operating activities	(46.4)	(11.7)	(45.4)	(8.6)
Net cash flow provided by / (used in) investing activities	(0.3)	(0.2)	(0.3)	(0.2)
Net cash flow provided by / ((used in) financing activities	7.8	195.2	6.8	192.1
Effect of exchange rate changes on cash & cash equivalents	3.7	(12.6)	3.7	(12.6)
Net cash & cash equivalents at the end of the period	**174.0**	**248.0**	**174.0**	**248.0**

Cash and cash equivalents amount to $174.0 million as of June 30, 2023, compared to $209.2 million as of December 31, 2022, which is a net decrease by $35.2 million mainly due to the following:

(1) $46.4 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 six months ended June 30, 2023, increased by $34.7 million compared to the six months ended June 30, 2022. The Company received 24.8 million euros during the six months ended June 30, 2022, for reimbursement of 2019, 2020, and 2021 French research tax credits.

(2) $7.8 million proceeds from the issuance and sale of new ordinary shares in 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 six months ended June 30, 2023, compared to the six months ended June 30, 2022. The Company issued and sold new ordinary shares in form of ADSs for a total gross amount of $15.3 million in May 2022, and completed a private placement financing ("PIPE") amounting to $194.0 million gross in June 2022.

(3) $3.7 million positive 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 six months ended June 30, 2023.

Operating Income

In millions of USD	U.S. GAAP		U.S. GAAP		IFRS	
	Three months ended June 30,		Six months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022	2023	2022
Research tax credits	2.0	1.5	3.7	3.1	3.7	3.1
Other operating income	0.3	-	0.7	1.0	0.7	1.0
Operating income	**2.3**	**1.5**	**4.4**	**4.1**	**4.4**	**4.1**

Operating income amounts to $4.4 million for the six months ended June 30, 2023, compared to $4.1 million for the six months ended June 30, 2022, which is an increase by $0.3 million due to:

(1) $0.6 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) Partially offset by a decrease by $0.3 million in other operating income that consists of revenues recognized in advance as part of the collaboration agreement with Nestlé Health Science ("NHS").

Operating Expenses

In millions of USD	U.S. GAAP		U.S. GAAP		IFRS	
	Three months ended June 30,		Six months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022	2023	2022
Research & Development	17.6	18.6	33.6	30.8	33.5	30.7
Sales & Marketing	0.5	1.0	1.0	1.5	1.0	1.5
General & Administrative	9.2	5.7	16.1	12.3	16.2	12.2
Operating expenses	**27.3**	**25.3**	**50.7**	**44.6**	**50.7**	**44.4**

Operating expenses amount to $50.7 million for the six months ended June 30, 2023, compared to $44.6 million for the six months ended June 30, 2022, which is an increase by $6.1 million mainly due to:

(1) The increase by $2.8 million in research and development expenses mainly explained by the difference in phasing of on-going clinical trials between the two compared periods, including initiation costs of the VITESSE trial with the first patient screened in March 2023.

(2) The increase by $3.8 million in general and administrative expenses mainly related to one-time costs associated with financing activities, organizational planning, market research and planning activities.

(3) Partially offset by the decrease by $0.5 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		IFRS	
	Three months ended June 30,		Six months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022	2023	2022
Net income / (loss) (in millions of USD)	(24.2)	(23.0)	(44,8)	(39.7)	(44.9)	(39.5)
Basic / diluted net income / (loss) per share (USD/share)	(0.26)	(0.35)	(0.48)	(0.66)	(0.48)	(0.65)

Net result for the six months ended June 30, 2023, is a loss amounting to $44.8 million, compared to a loss amounting to $39.7 million for the six months ended June 30, 2022.

On a per share basis, net loss (based on the weighted average number of shares outstanding over the period) is $0.48 for the six months ended June 30, 2023.

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION (unaudited)

In millions of USD	U.S. GAAP		IFRS	
	June 30, 2023	December 31, 2022	June 30, 2023	December 31, 2022
Assets	**217.5**	**246.5**	**217.5**	**246.5**
of which cash & cash equivalents	174.0	209.2	174.0	209.2

Liabilities	**53.3**	**52.0**	**53.2**	**52.0**
Shareholders' equity	**164.2**	**194.5**	**164.3**	**194.5**
of which net result	(44.8)	(96.2)	(44.9)	(96.0)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

In millions of USD	U.S. GAAP		U.S. GAAP		IFRS	
	Three months ended June 30,		Six months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022	2023	2022
Revenues	**2.3**	**1.5**	**4.5**	**4.1**	**4.5**	**4.1**
Research & Development	(17.6)	(18.6)	(33.6)	(30.8)	(33.5)	(30.7)
Sales & Marketing	(0.5)	(1.0)	(1.0)	(1.5)	(1.0)	(1.5)
General & Administrative	(9.2)	(5.7)	(16.1)	(12.3)	(16.2)	(12.2)
Operating expenses	**(27.3)**	**(25.3)**	**(50.7)**	**(44.6)**	**(50.7)**	**(44.3)**
Financial income/(expenses)	0.8	0.8	1.4	0.9	1.4	0.8
Income tax	-	-	-	-	-	-
Net loss	**(24.2)**	**(23.0)**	**(44.8)**	**(39.6)**	**(44.9)**	**(39.5)**
Basic/diluted net loss per share attributable to shareholders	(0.26)	(0.35)	(0.48)	(0.66)	(0.48)	(0.65)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW (unaudited)

In millions of USD	U.S. GAAP		IFRS	
	Six months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Net cash flows provided / (used) in operating activities	(46.4)	(11.7)	(45.4)	(8.6)
Net cash flows provided / (used) in investing activities	(0.3)	(0.2)	(0.3)	(0.2)
Net cash flows provided / (used) in financing activities	7.8	195.2	6.8	192.1
Effect of exchange rate changes on cash & cash equivalents (U.S. GAAP presentation)	3.7	(12.6)		
Net increase / (decrease) in cash & cash equivalents	**(35.2)**	**170.7**	**(38.9)**	**183.3**
Net cash & cash equivalents at the beginning of the period	209.2	77.3	209.2	77.3
Effect of exchange rate changes on cash & cash equivalents (IFRS presentation)			3.7	(12.6)
Net cash & cash equivalents at the end of the period	**174.0**	**248.0**	**174.0**	**248.0**

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, the ability of any of DBV's product candidates, if approved, to improve the lives of patients with food allergies, and the outcome of any litigation. 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, including the impact of the COVID-19 pandemic, 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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