LAVA Therapeutics Provides Business Update and Reports First Quarter Financial Results

May 17, 2022

- *LAVA-051 updated interim clinical data from Phase 1/2a clinical trial in patients with relapsed or refractory chronic lymphocytic leukemia and multiple myeloma to be presented at 2022 ASCO Annual Meeting*
- *LAVA-1207 Phase 1/2a trial in metastatic castration-resistant prostate cancer dosed the first patients and is on track to report initial data in H2 2022*
- *Cash and investments of $124.2 million as of March 31, 2022*

UTRECHT, The Netherlands and PHILADELPHIA, May 17, 2022 (GLOBE NEWSWIRE) -- LAVA Therapeutics N.V. (Nasdaq: LVTX), a clinical stage immuno-oncology company focused on developing its proprietary Gammabody™ platform of bispecific gamma delta T cell engagers to transform the treatment of cancer, today announced recent corporate highlights and financial results for the first quarter ended March 31, 2022.

"We are pleased with the clinical development progress of our lead product candidates. We continue to enroll patients in our LAVA-051 trial focused on hematologic malignancies, and we look forward to presenting updated interim data from the dose escalation phase of this trial at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in June," said Stephen Hurly, president and chief executive officer of LAVA Therapeutics. "We are also excited about the continued progress of our lead solid tumor program, LAVA-1207, as we recently dosed the first metastatic castration-resistant prostate cancer patients in our Phase 1/2a clinical trial. We will continue to enroll patients in this dose escalation trial and announce initial data later this year."

Recent Pipeline and Business Highlights

LAVA-051
Gammabody that targets CD1d-expressing tumors, including multiple myeloma, chronic lymphocytic leukemia and acute myeloid leukemia (AML)

- Announced the presentation of data at the 2022 ASCO Annual Meeting, being held June 3-7 in Chicago and virtually. Benjamin Winograd, M.D., Ph.D., chief medical officer of LAVA Therapeutics, will present abstract # 2577, "Phase I dose escalation of LAVA-051, a novel bispecific gamma delta T-cell engager (Gammabody™), in relapsed/refractory hematological malignancies," and a short video in the session, "Developmental Therapeutics — Immunotherapy," on Sunday, June 5, 2022, at 8–11 a.m. CDT/9 a.m.–12 p.m. EDT. The Company will also present at the European Hematology Association (EHA) 2022 Congress, being held in Vienna, Austria and virtually.
- Presented initial data from the Company's first clinical study with LAVA-051 at the European Society for Medical Oncology Targeted Anticancer Therapies (ESMO-TAT) Congress 2022 demonstrating that the first three dose-escalation cohorts showed LAVA-051 to be safe and well tolerated with no dose limiting toxicities or cytokine release syndrome observed. The Company also presented preclinical data illustrating the potential of its Gammabody platform.
- Received clearance from the U.S. Food and Drug Administration (FDA) to enroll patients in the U.S in the Phase 1/2a clinical trial.
- Additional clinical data are expected in the second half of 2022, and initial Phase 2a expansion cohort data are expected in the first half of 2023.

LAVA-1207
Gammabody that targets the prostate-specific membrane antigen (PSMA) to trigger the potent and preferential killing of PSMA-positive tumor cells, including metastatic castration-resistant prostate cancer (mCRPC)

- Dosed the first patient and continues enrollment in the open-label, multi-center Phase 1/2a clinical trial evaluating the tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary antitumor activity of LAVA-1207 in patients with mCRPC. The Phase 1 dose-escalation portion will determine the optimal Phase 2 dose to be used in the subsequent Phase 2a expansion cohort. The Phase 1/2a clinical trial for LAVA-1207 was initiated in Europe.

- Presented preclinical data showing LAVA-1207 can activate Vγ9Vδ2 (Vgamma9 Vdelta2) T cells to exert cytotoxicity toward PSMA-expressing tumor cells at picomolar concentrations, demonstrating potent and precise killing of PSMA-expressing tumor cells, including those obtained from patients.
- A Phase 1 data readout is expected in the second half of 2022, and initial Phase 2a expansion cohort data are expected in the first half of 2023.

Early-Stage Gammabody Pipeline Development

LAVA-1223, a Gammabody directed at the epidermal growth factor receptor (EGFR) for the treatment of solid tumors

- A clinical trial application (CTA) and/or IND is planned for late 2022.

LAVA-1266, a CD123 Gammabody for the treatment of hematologic malignancies

- Announced the addition of this drug candidate to LAVA's early-stage development program. CD123 is overexpressed in a wide range of hematologic malignancies, including AML, B-cell acute lymphoblastic leukemia, hairy cell leukemia, Hodgkin lymphoma, blastic plasmacytoid dendritic cell neoplasm, B-cell chronic lymphoproliferative disorders and myelodysplastic syndrome.
- A CTA and/or IND is planned for late 2023.

Business Update

- Ed Smith, chief financial officer of LAVA Therapeutics, has resigned to pursue other interests, effective as of May 17, 2022. He may serve in a consulting capacity to support the Company's transition. The Company has commenced a search for Mr. Smith's permanent replacement.

First Quarter Financial Results

- As of March 31, 2022, LAVA had cash, cash equivalents and investments totaling $124.2 million compared to cash and cash equivalents of $133.2 million as of December 31, 2021.
- Research and license revenue was solely attributable to the company’s collaboration with Janssen Biotech, Inc. which was entered into in May 2020.
- Research and development expenses were $7.6 million for the quarter ended March 31, 2022, compared to $18.7 million for the quarter ended March 31, 2021. The decrease was primarily due to the VUmc license fees incurred in 2021 at the time of our IPO of $14.3, offset by increases in clinical trial, headcount and other costs incurred in connection with advancing our lead Gammabody clinical candidates, LAVA-051 and LAVA-1207, into human clinical trials.
- General and administrative expenses were $4.3 million for the quarter ended March 31, 2022, compared to $1.7 million for the quarter ended March 31, 2021. The increase for the quarter was primarily due to increases in non-cash share-based compensation expense of $0.9 million and other personnel-related costs as well as costs associated with being a publicly-traded company in the United States, including additional insurance costs, professional fees and consulting fees.
- Net losses were $10.6 and $19.7 million, or $0.41 and $12.14 loss per share for the quarters ended March 31, 2022 and 2021, respectively.

LAVA Therapeutics N.V.
Condensed Consolidated Statements of Loss (unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
Research and license revenue	$ 1,000	$ 1,000
Total revenue	**1,000**	**1,000**
Operating expenses:		
Research and development	(7,601)	(18,712)
General and administrative	(4,298)	(1,727)
Total operating expenses	**(11,899)**	**(20,439)**
Operating loss	**(10,899)**	**(19,439)**
Total non-operating expenses	403	(279)
Loss before income tax	**(10,496)**	**(19,718)**
Income tax expense	(59)	(24)

Loss for the year	**$ (10,555)**	**$ (19,742)**
Foreign currency translation adjustment	(2,216)	(1,076)
Total comprehensive loss	**$ (12,771)**	**$ (20,818)**
Loss per share:		
Loss per share, basic and diluted	$ (0.41)	$ (12.14)
Weighted average common shares outstanding, basic and diluted	25,775,538	1,626,598

Condensed Consolidated Statements of Financial Position (unaudited)
(in thousands)

	March 31, 2022	December 31, 2021
Assets:		
Non-current assets	$ 2,818	$ 2,742
Other current assets	2,534	3,302
Cash, cash equivalents and investments	124,156	133,203
Total assets	**$ 129,508**	**$ 139,247**
Equity and Liabilities:		
Total Equity	**$ 108,409**	**$ 118,367**
Deferred revenue	485	1,527
Lease liabilities	587	581
License liabilities	9,870	10,056
Borrowings	4,509	4,284
Trade payables and other	2,656	2,553
Accrued expenses and other current liabilities	2,992	1,879
Total liabilities	**21,099**	**21,880**
Total equity and liabilities	**$ 129,508**	**$ 139,247**

About LAVA Therapeutics
LAVA Therapeutics N.V. is a clinical stage immuno-oncology company utilizing its proprietary Gammabody™ platform to develop a portfolio of bispecific gamma delta T cell engagers for the potential treatment of solid and hematological malignancies. The Company utilizes bispecific antibodies engineered to selectively kill cancer cells by triggering Vγ9Vδ2 (Vgamma9 Vdelta2) T cell antitumor effector functions upon cross-linking to tumor-associated antigens. LAVA-051, the Company's lead candidate for the treatment of multiple myeloma, chronic lymphocytic leukemia and acute myeloid leukemia, is enrolling patients in a Phase 1/2a clinical study (NCT04887259). A Phase 1/2a clinical study to evaluate LAVA-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC) is also enrolling (NCT05369000). For more information, please visit www.lavatherapeutics.com, and follow us on LinkedIn, Twitter and YouTube.

LAVA's Cautionary Note on Forward-Looking Statements
This press release contains forward-looking statements, including with respect to the company's anticipated growth and clinical development plans, including the timing of clinical trials. Words such as "anticipate," "believe," "could," "will," "may," "expect," "should," "plan," "intend," "estimate," "potential" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on LAVA's expectations and assumptions as of the date of this press release and are subject to various risks and uncertainties that may cause actual results to differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the preclinical data, clinical development and scope of clinical trials, and the potential use of our product candidates to treat various tumor targets. Many factors, risks and uncertainties may cause differences between current expectations and actual results including, among other things, the timing and results of our research and development programs and preclinical and clinical trials, our ability to obtain regulatory approval for and commercialize our product candidates, our ability to leverage our initial programs to develop additional product candidates using our Gammabody™ platform, and the failure of LAVA's collaborators to support or advance collaborations or our product candidates. The COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity. In addition, there may be adverse effects on our business condition and results from general economic and market conditions and overall fluctuations in the United States and international equity markets, including deteriorating market conditions due to investor concerns regarding inflation and hostilities between Russia and Ukraine. LAVA assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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