LAVA Therapeutics Provides Business Update and Reports Second Quarter Financial Results

September 13, 2022

- *Initial Phase 1/2a clinical findings for LAVA-051 in patients with chronic lymphocytic leukemia and multiple myeloma patients demonstrated encouraging anti-tumor activity and safety profile; on track to report additional clinical data in fourth quarter 2022*
- *Enrollment continuing in LAVA-1207 Phase 1/2a trial in metastatic castration-resistant prostate cancer*
- *Cash and investments of $110.7 million as of June 30, 2022, providing approximately two years of cash runway*
- *Appointed James Noble and Jay Backstrom, M.D., M.P.H., as non-executive directors to the Company's board of directors*

UTRECHT, The Netherlands and PHILADELPHIA, Sept. 13, 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 second quarter ended June 30, 2022.

"In the second quarter, we continued to enroll patients in our two clinical programs, LAVA-051 and LAVA-1207," said Stephen Hurly, president and chief executive officer of LAVA Therapeutics. "Notably, at ASCO and EHA, we presented encouraging initial dose escalation data from the Phase 1/2a clinical trial of LAVA-051. While still early, we are pleased with LAVA-051's attractive safety profile and signs of potential anti-tumor activity and are excited about its potential as a therapy that can overcome challenges with current T cell approaches."

Recent Pipeline and Business Highlights

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

- Presented initial dose escalation data from the Phase 1/2a clinical trial of LAVA-051 in patients with CLL and MM at the 2022 ASCO Annual Meeting, held June 3-7, 2022, and at the EHA 2022 Congress, held June 9-12, 2022. In addition to demonstrating a favorable safety profile and signs of potential clinical anti-tumor activity, LAVA-051 showed predictable and linear pharmacokinetics and on-mechanism pharmacodynamic parameters consistent with Vγ9Vδ2-T cell engagement, including increasing occupancy of LAVA-051 on patient Vγ9Vδ2-T cells and consistent increases in the expression of T cell activation markers.
- Received clearance from the U.S. Food and Drug Administration to enroll patients in the U.S. in the Phase 1/2a clinical trial for the treatment of relapsed or refractory CLL, MM and AML.
- Hosted a clinical update call featuring Arnon Kater, M.D., Ph.D., chairman of the Dutch/Belgium HOVON CLL working group and professor of translational hematology at the Amsterdam University Medical Center, and LAVA-051 clinical trial investigator. The call summarized initial Phase 1/2a clinical trial data presented at the 2022 ASCO and EHA meetings and can be accessed on demand at this link.
- Additional clinical data are expected in the fourth quarter of 2022.

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)

- Enrollment continues in Europe and the U.S. 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.
- Initial Phase 1 data readout is expected in the fourth quarter of 2022.

Early-Stage Gammabody Pipeline Development
LAVA-1223, a Gammabody directed at the epidermal growth factor receptor (EGFR) for the treatment of solid tumors which induces tumor cell lysis independent of EGFR downstream signaling mutations (e.g. KRAS/BRAF)

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

Remarked Benjamin Winograd, M.D., Ph.D., chief medical officer of LAVA Therapeutics, “We are optimistic about LAVA-1223, a Gammabody directed at the epidermal growth factor receptor (EGFR), our second program in solid tumors. EGFR is a well-validated target in a broad range of malignancies. LAVA-1223 has demonstrated the potential to overcome certain limitations of other anti-EGFR drugs, and specifically, our LAVA-1223 Gammabody ‘uses’ the EGFR receptor predominantly for homing purposes. As with other Gammabodies, we have observed a tumor preferential effect which may avoid some of the on-target, off tumor adverse effects seen with other anti-EGFR drugs.”

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

- A CTA and/or IND is planned for late 2023.

Second Quarter Financial Results

The financial information provided below reflects changes made to previously issued condensed consolidated interim financial statements to revise immaterial prior period misstatements. Further information regarding the revision is included in our condensed consolidated interim financial statements, "Note 11 — Revision of Immaterial Misstatements," included as Exhibit 99.1 to this current report on Form 6-K.

- As of June 30, 2022, LAVA had cash, cash equivalents, and investments totaling $110.7 million compared to cash and cash equivalents of $133.2 million as of December 31, 2021, which we expect to be sufficient to fund the Company for approximately two years.
- 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 $8.3 million and $15.9 million for the three and six months ended June 30, 2022, respectively, compared to $4.9 million and $23.6 million for the three and six months ended June 30, 2021. The increase for the three months ended June 30, 2022 was primarily driven by increases in clinical trial costs, headcount and other costs incurred in connection with advancing our lead Gammabody clinical candidates, LAVA-051 and LAVA-1207, into human clinical trials. For the six months ended June 30, 2022, the decrease was driven by the $14.3 million VUmc license fees incurred in the first quarter of 2021, partially offset by increases in clinical trial costs, 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 $3.0 million and $7.3 million for the three and six months ended June 30, 2022, respectively, compared to $2.8 million and $4.5 million for the three and six months ended June 30, 2021. The increase for both periods was primarily due to costs associated with being a publicly-traded company in the United States, including increases in personnel-related costs and additional insurance, severance and professional and consultant fees. For the three months that ended June 30, 2022, the increases were partially offset by the reversal of stock-based compensation expense for unvested forfeited stock options.
- Net losses were $7.9 million and $17.8 million, or $0.31 and $0.69 loss per share, for the three and six months ended June 30, 2022, respectively.

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

	Three Months Ended June, 30		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Research and license revenue	$ 468	$ 1,080	$ 1,490	$ 2,189
Total revenue	**468**	**1,080**	**1,490**	**2,189**
Operating expenses:				

Research and development	(8,342)	(4,896)	(15,944)	(23,607)
General and administrative	(3,016)	(2,764)	(7,314)	(4,491)
Total operating expenses	**(11,358)**	**(7,659)**	**(23,258)**	**(28,098)**
Operating loss	**(10,890)**	**(6,579)**	**(21,768)**	**(25,909)**
Interest expense, net	(90)	(187)	(253)	(316)
Foreign currency exchange gain (loss), net	3,136	(1,239)	4,248	(922)
Total non-operating income (expenses)	**3,046**	**(1,426)**	**3,995**	**(1,238)**
Loss before income tax	**(7,844)**	**(8,005)**	**(17,773)**	**(27,147)**
Income tax expense	(76)	(32)	(135)	(55)
Loss for the year	**$ (7,920)**	**$ (8,037)**	**$ (17,908)**	**$ (27,202)**
Foreign currency translation adjustment	(6,659)	1,648	(8,862)	569
Total comprehensive loss	**$ (14,579)**	**$ (6,389)**	**$ (26,770)**	**$ (26,633)**
Loss per share:				
Loss per share, basic and diluted	$ (0.31)	$ (0.31)	$ (0.69)	$ (1.99)
Weighted-average common shares outstanding, basic and diluted	25,780,811	25,523,501	25,778,190	13,641,062

LAVA Therapeutics N.V.
Condensed Consolidated Interim Statements of Financial Position
(in thousands) (unaudited)

	June 30, 2022	December 31, 2021
Assets:		
Non-current assets	$ 2,515	$ 2,742
Other current assets	2,077	3,302
Cash, cash equivalents, and investments	110,714	133,203
Total assets	**$ 115,306**	**$ 139,247**
Equity and Liabilities:		
Total Equity	**$ 94,038**	**$ 118,367**
Deferred revenue	—	1,527
Lease liabilities	501	581
License liabilities	9,251	10,056
Borrowings	4,329	4,284
Trade payables and other	2,930	2,553
Accrued expenses and other current liabilities	4,257	1,879
Total liabilities	**21,268**	**20,880**
Total equity and liabilities	**$ 115,306**	**$ 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 hematologic 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 the timing and results 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.

CONTACTS

Investor Relations
ir@lavatherapeutics.com

Argot Partners (IR/Media)
212-600-1902
lava@argotpartners.com