LAVA Therapeutics Provides Business Update and Reports Third Quarter Financial Results

November 15, 2021

- *LAVA-051 Phase 1/2a trial actively enrolling in hematological malignancies on track to report initial data in H1 2022*
- *LAVA-1207 Phase 1/2a trial in metastatic castrate resistant prostate cancer on track to begin enrolling later this quarter*
- *LAVA-051 granted orphan drug designation by the U.S. FDA for the treatment of CLL*
- *Cash and investments of $142 million as of Sept. 30, 2021*

UTRECHT, The Netherlands and PHILADELPHIA, Nov. 15, 2021 (GLOBE NEWSWIRE) -- LAVA Therapeutics N.V. (Nasdaq: LVTX), a clinical-stage biotechnology company focused on developing its proprietary Gammabody™ platformof bispecific gamma delta T cell engagers (bsTCEs) to transform the treatment of cancer, today announced financial results for the third quarter ended Sept. 30, 2021 and recent corporate highlights.

"This was a transformational quarter for LAVA," said Stephen Hurly, president and chief executive officer. "With our lead Gammabody ™ program in the clinic and actively enrolling patients in hematological malignancies and our second program on track to enroll its first prostate cancer patient later this quarter, LAVA is poised for potential product and platform validating data milestones in 2022. Our progress in the clinic, along with our recent senior leadership hires and strong balance sheet, position us well to execute on our mission to unlock the value of our Gammabody™ platform to deliver transformative treatments to those suffering from cancer."

Recent Business and Pipeline Highlights

LAVA-051 Phase 1/2a Trial on Track: Enrollment is ongoing in the Phase 1/2a clinical trial (NCT04887259) evaluating LAVA-051 in hematological malignancies. The trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary antitumor activity of LAVA-051. Data from the Phase 1 dose escalation phase of the trial are expected in the first half of 2022 and top line data from the Phase 2a expansion cohorts in the second half of 2022. The trial was initiated in July 2021 in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) and multiple myeloma (MM) and will, later in the trial, also include patients with acute myeloid leukemia (AML).

LAVA-051 Granted U.S. FDA Orphan Drug Designation: On October 15, the company announced that the U.S. Food and Drug Administration (FDA) granted orphan drug designation to LAVA-051 for the treatment of CLL, a rare form of leukemia characterized by progressive accumulation of abnormal lymphocytes in the peripheral blood, bone marrow and lymphoid tissues. This orphan drug designation from the FDA qualifies LAVA for various incentives related to the development of LAVA-051, including tax credits for qualified clinical trials, exemption from user fees and the potential for seven years of U.S. market exclusivity for the treatment of CLL.

LAVA-1207 Phase 1/2a Trial Plans on Track: LAVA is on track to initiate the company's Phase 1/2a clinical trial of LAVA-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC) later in the fourth quarter. LAVA-1207 is a Gammabody™ that targets the prostate specific membrane antigen (PSMA) and has demonstrated preclinical proof-of-concept in a variety of preclinical models to support acceptance of a CTA/IND to study in humans. The open-label, multi-center, Phase 1/2a clinical trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary antitumor activity of LAVA-1207 in patients with mCRPC. The Phase 1 dose-escalation portion of the study will determine the recommended Phase 2 dose/schedule to be used in the subsequent Phase 2a expansion cohort to confirm safety and tolerability of LAVA-1207 in mCRPC patients.

Strategic Management Team Expansion with Three Key Appointments: On November 9, the company announced three strategic appointments to the management team.

- Jessica Truscello, vice president of clinical operations, brings more than 22 years of clinical trial and clinical operations experience to LAVA and most recently served six years at Immunocore where she supported first-in-human programs through pivotal and late-stage programs and the successful development of their clinical compliance program.
- Sumeet Ambarkhane, M.D., executive medical director, a clinical development physician with more than 17 years of experience with expertise in oncology, hemato-oncology and immunology. Dr. Ambarkhane was previously at MorphoSys, where he led medical and clinical strategy for its hemato-oncology clinical development program.
- Wouter van Hunnik, vice president of human resources, joins the company from Philips with more than 15 years of experience in building excellence and taking innovative approaches to human resources (HR) recruitment, culture shaping

and capability building.

Third Quarter Financial Results

- Cash, cash equivalents and investments were €122.7 million as of Sept. 30, 2021, compared to €12.9 million as of Dec. 31, 2020. The increase in cash and cash equivalents was attributable to proceeds from the Series C financing and subsequent IPO during the first quarter of 2021, partially offset by operating expenses.

- Research and license revenue increased to €1.8 million and €3.6 million for the three and nine months ended Sept. 30, 2021, respectively, compared to €0.8 million and €1.4 million for the three and nine months ended Sept. 30, 2020. Research and license revenue is solely attributable to the company's collaboration with Janssen Biotech, Inc., which was entered into in May 2020. During the three months ended Sept. 30, 2021, the company earned a €0.9 million research milestone under the agreement.

- Research and development expenses were €5.7 million and €25.5 million for the three and nine months ended Sept. 30, 2021, respectively, compared to €3.3 million and €9.3 million for the three and nine months ended Sept. 30, 2020. The increase for the three months ended Sept. 30, 2021, was primarily due to increases in headcount and costs associated with the commencement of our LAVA-051 clinical trial. The increase for the nine months ended Sept. 30, 2021 was additionally due to license fees of €12.0 million triggered by the IPO, most of which will be paid on the first and second anniversaries of the IPO and may be paid in either cash or common stock of the Company.

- General and administrative expenses were €3.2 million and €7.0 million for the three and nine months ended Sept. 30, 2021, respectively, compared to general administrative expenses of €0.7 million and €2.0 million for the three and nine months ended Sept. 30, 2020. The increase in both periods is primarily due to the increase in personnel-related costs, non-cash share-based compensation expense and additional costs associated with being a publicly traded company in the United States.

- Net loss was €7.5 million and €29.8 million, or €0.23 and €1.62 loss per share for the three and nine months ended Sept. 30, 2021, respectively, compared to €3.4 million and €10.5 million, or €8.43 and €24.38 loss per share, for the three and nine months ended Sept. 30, 2020.

About LAVA Therapeutics

LAVA Therapeutics N.V. is a clinical-stage biotechnology company utilizing its proprietary Gammabody™ platform to develop a portfolio of bispecific gamma delta T cell engagers (gamma delta bsTCEs) for the potential treatment of solid tumors and hematological malignancies. The company's innovative approach utilizes bispecific antibodies engineered to selectively kill cancer cells via the triggering of Vγ9Vδ2 T cell antitumor effector functions upon cross-linking to tumor associated antigens. A Phase 1/2a clinical study evaluating LAVA-051 in patients with certain hematological malignancies is currently enrolling (NCT04887259). The company currently anticipates data from the Phase 1 dose escalation phase of the study in the first half of 2022 with top line clinical data from the Phase 2a expansion cohorts expected in the second half of 2022. The company plans to initiate a Phase 1/2a clinical study to evaluate LAVA-1207 in patients with prostate cancer in the fourth quarter of 2021. For more information, please visit www.lavatherapeutics.com and follow us on LinkedIn and Twitter.

LAVA's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including in respect of the company's anticipated growth and clinical developments 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. In addition, 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. LAVA assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

LAVA Therapeutics N.V.
Unaudited Condensed Consolidated Interim Statements of Loss and Comprehensive Loss
EUR (000's)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue				

Research and license revenue	€ 1,781	€ 827	€ 3,599	€ 1,419
Total revenue	1,781	827	3,599	1,419
Operating expenses:				
Research and development	(5,714)	(3,292)	(25,476)	(9,302)
General and administrative	(3,213)	(660)	(6,969)	(2,013)
Total operating expenses	(8,927)	(3,952)	(32,445)	(11,315)
Operating loss	(7,146)	(3,125)	(28,846)	(9,896)
Total non-operating expenses	(278)	(235)	(890)	(611)
Loss before income tax	**(7,424)**	**(3,360)**	**(29,736)**	**(10,507)**
Income tax expense	(38)	—	(85)	—
Net loss	**€ (7,462)**	**€ (3,360)**	**€ (29,821)**	**€ (10,507)**
Foreign currency translation adjustment	1,582	(184)	1,178	(184)
Total comprehensive loss	**€ (5,880)**	**€ (3,544)**	**€ (28,643)**	**€ (10,691)**
Net loss per share				
Net loss per share, basic and diluted	€ (0.23)	€ (8.43)	€ (1.62)	€ (24.38)
Weighted average common shares outstanding, basic and diluted	25,775,538	420,563	17,730,337	438,464

LAVA Therapeutics N.V.
Condensed Consolidated Interim Statements of Financial Position
EUR (000's)

	September 30, 2021 (unaudited)	December 31, 2020 (1)
Assets		
Non-current assets	€ 2,274	€ 1,843
Other current assets	5,258	1,959
Cash, cash equivalents and investments	122,683	12,881
Total assets	**€ 130,215**	**€ 16,683**
Equity and Liabilities		
Total Equity	**€ 110,781**	**€ 6,207**
Deferred revenue	2,280	5,030
Lease liabilities	569	389
License liabilities	8,873	—
Borrowings	3,519	2,935
Trade payables and other	1,646	760
Accrued expenses and other current liabilities	2,547	1,362
Total liabilities	**19,434**	**10,476**
Total equity and liabilities	**€ 130,215**	**€ 16,683**

(1) Derived from the audited consolidated financial statements of LAVA Therapeutics N.V. for the year ended December 31, 2020, included on the Form F-1 filed with the Securities and Exchange Commission on March 29, 2021.

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