LAVA Therapeutics Provides Business Update and Reports Second Quarter Results

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Enrollment continues in Phase 1/2a trial evaluating LAVA-051 in hematological malignancies

CTA accepted and IND cleared for Phase 1/2a trial evaluating LAVA-1207 in metastatic castrate resistant prostate cancer; on track to begin later this year

Collaboration with Janssen Biotech, Inc. remains on track and progressing towards potential milestones

Cash balance of $151 million expected to fund operations into the second half of 2023

UTRECHT, The Netherlands and PHILADELPHIA, Aug. 16, 2021 (GLOBE NEWSWIRE) -- LAVA Therapeutics N.V. (Nasdaq: LVTX), a clinical-stage biotechnology company focused on developing bispecific gamma-delta T cell engagers (bsTCEs) to transform the treatment of cancer, today announced financial results for the second quarter ended June 30, 2021 and recent corporate highlights.

"We continue our strong execution, meeting key milestones and progressing our two lead, first-in-class bispecific gamma-delta T cell engager clinical programs," said Stephen Hurly, chief executive officer of LAVA Therapeutics. "Building on our clinical momentum initiated with the start of our LAVA-051 trial in hematological malignancies earlier this quarter, we are excited to bring our second program, LAVA-1207 in metastatic castration resistant prostate cancer, into the clinic later this year. As we look towards the second half of the year, our expanding leadership, clinical progress and strong balance sheet position LAVA well to drive value as we work toward our mission of building transformative treatments that harness the potential of engaging gamma-delta T cells to potently and precisely fight cancer."

Recent Business and Pipeline Highlights

Dosing of the First Patient in Phase 1/2a Trial of LAVA-051: In July, LAVA announced it had initiated dosing in the Company's Phase 1/2a clinical trial evaluating LAVA-051 in patients with relapsed and/or refractory chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and acute myeloid leukemia (AML). LAVA-051 is a humanized bsTCE engineered to selectively target CD1d-expressing hematological cancers through activation of both gamma-delta T cells and type 1 natural killer T (NKT) cells. The trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity, and preliminary antitumor activity of LAVA-051. Initially conducted in Europe, the Phase 1/2a clinical trial will expand to the United States after the Investigational New Drug (IND) application has been accepted. The Company expects to report 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.

Acceptance of CTA and IND for LAVA-1207: The Company's CTA was accepted and the IND was cleared to initiate a Phase 1/2a clinical study to assess tolerability and efficacy of LAVA-1207 in patients with metastatic castration-resistant prostate cancer. LAVA-1207 is a gamma-delta bsTCE targeting the prostate-specific membrane antigen (PSMA) that demonstrated preclinical proof-of-concept. The Company anticipates that patient enrollment will begin in Europe later this year, and in the U.S. shortly thereafter.

Research and License Agreement with Janssen. Under the terms of the agreement, the Company is performing discovery and product development activities with novel bispecific antibodies to gamma-delta T cells for the treatment of cancer. The collaboration is on track and, in addition to an upfront payment, the Company is eligible to receive potential development and commercial milestones and future tiered royalties based on the development of the collaboration.

Executive Leadership Team Strengthened by Appointment of Amy Garabedian as General Counsel: Amy Garabedian was appointed as general counsel and corporate secretary in July 2021. Ms. Garabedian is a recognized leader with over 15-years of corporate and transactional expertise within the life science industry. Ms. Garabedian previously served as associate general counsel of Spark Therapeutics (Roche) where she helped drive the successful U.S. launch of the first gene therapy in a genetic disease. She also led key business development transactions enabling pre-clinical, clinical, and commercial product development.

Second Quarter Financial Results

- Cash and cash equivalents were €128.4 million as of June 30, 2021, compared to €12.9 million as of December 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 €0.9 million and €1.8 million for the three and six months ended June 30, 2021, respectively, compared to €0.6 million for the three and six months ended June 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.
- Research and development expenses were €4.5 million and €20.2 million for the three and six months ended June 30, 2021, respectively, compared to €3.1 million and €6.0 million for the three and six months ended June 30, 2020. The increase for the three months ended June 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 six months ended June 30, 2021 was additionally due to license fees of €12.1 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 €1.9 million and €3.3 million for the three and six months ended June 30, 2021, respectively, compared to general administrative expenses of €0.7 million and €1.4 million for the three and six months ended June 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 €5.8 million and €22.4 million, or €0.23 and €1.64 loss per share, for of the three and six months ended June 30, 2021, respectively, compared to €3.5 million and €7.1 million, or €7.75 and €15.97 loss per share, for the three and six months ended June 30, 2020.

About LAVA

LAVA Therapeutics N.V. is a clinical-stage biotechnology company developing a portfolio of bispecific gamma-delta T cell engagers (gamma-delta bsTCEs) for the 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 enrolling patients. 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 second half of 2021. For more information, please visit www.lavatherapeutics.com.

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," "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. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, clinical development and scope of clinical trials and the reporting of clinical data for LAVA's product candidates, and the potential use of our product candidates to treat various tumor targets. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical trials, changes in expected or existing competition, changes in the regulatory environment, failure of LAVA's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes, among others. 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.

Condensed Consolidated Interim Statements of Loss
EUR (000's) (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and license revenue	**€ 897**	**€ 592**	**€ 1,818**	**€ 592**
Operating expenses:				
Research and development	(4,506)	(3,074)	(20,245)	(6,010)
General and administrative	(1,858)	(672)	(3,273)	(1,353)
Total operating expenses	(6,364)	(3,746)	(23,518)	(7,363)
Operating loss	(5,467)	(3,154)	(21,700)	(6,771)
Total non-operating expenses	(292)	(318)	(6,110)	(376)
Loss before income tax	(5,759)	(3,472)	(22,311)	(7,147)
Income tax (expense) benefit	(25)	3	(47)	—
Net loss	**€ (5,784)**	**€ (3,469)**	**€ (22,358)**	**€ (7,147)**
Net loss per share, in Euros				

Net loss per share, basic and diluted	€ (0.23)	€ (7.75)	€ (1.64)	€ (15.97)
Weighted average common shares outstanding, basic and diluted	25,523,501	447,525	13,641,062	447,525

Condensed Consolidated Interim Statements of Financial Position
EUR (000's)

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Non-current assets	€ 1,786	€ 1,843
Other current assets	4,788	1,959
Cash and cash equivalents	128,354	12,881
Total assets	**€ 134,928**	**€ 16,683**
Equity and Liabilities		
Total Equity	**€ 115,586**	**€ 6,207**
Deferred revenue	3,212	5,030
Lease liabilities	366	389
License liabilities	9,074	—
Borrowings	3,262	2,935
Trade payables and other	1,820	760
Accrued expenses and other current liabilities	1,608	1,362
Total liabilities	**19,342**	**10,476**
Total equity and liabilities	**€ 134,928**	**€ 16,683**

Investor Contact:

Corey Davis, Ph.D.
LifeSci Advisors
cdavis@lifesciadvisors.com
212-915-2577