LAVA Therapeutics Announces Initial Data from the Ongoing Phase 1/2a Clinical Trial of LAVA-1207 in Therapy Refractory mCRPC at the 2023 ASCO GU Symposium

February 16, 2023

- ***Favorable safety profile to date, with no occurrence of high-grade (>2) cytokine release syndrome or dose-limiting toxicities***
- ***Preliminary signs of anti-tumor activity were observed, with iRECIST stable disease (iSD) in 8 out of 14 evaluable patients at week 8 and PSA levels stabilizing or decreasing in heavily pre-treated patients***
- ***Dose escalation is ongoing***

UTRECHT, The Netherlands and PHILADELPHIA, Feb. 16, 2023 (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 initial clinical data from its ongoing Phase 1/2a study of LAVA-1207 in patients with therapy refractory metastatic castration resistant prostate cancer (mCRPC). The data are presented in a poster presentation at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) taking place in San Francisco from February 16-18, 2023.

"These early data from the first five cohorts of our Phase 1/2a study indicate LAVA-1207 to have a favorable safety profile in patients with therapy refractory metastatic castration resistant prostate cancer. Importantly, preliminary signs of clinical activity were observed with disease stabilization and PSA reduction during dose escalation in these heavily pretreated patients," said Niven Mehra, M.D., Ph.D., medical oncologist at the Radboud University Medical Center in Nijmegen, The Netherlands. "We are encouraged by the progress of this trial and will continue to enroll patients for additional cohorts."

LAVA-1207 is an Fc-containing humanized bispecific antibody that directly engages prostate-specific membrane antigen (PSMA) and the Vδ2-T cell receptor chain of Vγ9Vδ2-T cells to mediate potent killing of PSMA-expressing prostate cancer cells. The objectives of the Phase 1/2a study (EudraCT 2021-001789-39; NCT05369000) are to investigate safety and tolerability, evaluate pharmacokinetic and pharmacodynamic effects, immunogenicity and preliminary antitumor activity of LAVA-1207. LAVA-1207 is administered via intravenous infusion every two weeks.

The data presented to date show that a total of 20 patients have been treated with doses ranging from 1.5 to 120 micrograms of LAVA-1207, with treatment duration ranging from 4 to 38 weeks. The safety profile is favorable to date, without occurrence of high grade (>2) cytokine release syndrome or dose-limiting toxicities. LAVA-1207 showed predictable and linear pharmacokinetics and on-mechanism pharmacodynamics including Vγ9Vδ2-T cell activation. Preliminary signs of anti-tumor activity were observed at week 8, with iRECIST stable disease (iSD) in 8 out of 14 evaluable patients and PSA levels stabilizing or decreasing. The largest overall decrease in PSA was 61% (46% vs baseline). The patient improved clinically with improvement in pain and fatigue. Dose escalation is continuing both in Europe and the U.S.

"We are encouraged by these initial data for LAVA-1207," said Stephen Hurly, president and chief executive officer of LAVA Therapeutics. "At LAVA Therapeutics, we are committed to transforming cancer therapy. I am thrilled to see our second clinical asset continuing to move forward, and an emerging safety profile with the potential for differentiation from prior generation PSMA directed bispecific T-cell engagers."

Details of the poster presentation are as follows:

Abstract #: 153
Abstract Title: *Early dose escalation of LAVA-1207, a novel bispecific gamma-delta T cell engager (Gammabody™), in metastatic castration-resistant prostate cancer (mCRPC) patients*
Session Title: Poster Session A: Prostate Cancer
Poster Board #: E13
Session Date: Thursday, February 16, 2023
Session Time: 11:30 AM-1:00 PM PT; 5:45 PM-6:45 PM PT
Presenter: Niven Mehra, MD, PhD, Department of Medical Oncology, Radboud University Medical Center, Nijmegen, The Netherlands

LAVA-1207
LAVA-1207 is a Gammabody™ that conditionally activates Vγ9Vδ2 (Vgamma9 Vdelta2) T cells upon crosslinking to prostate-specific membrane antigen (PSMA) to trigger the potent and preferential killing of PSMA-positive tumor cells, including metastatic castration-resistant prostate cancer (mCRPC).

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 (EudraCT 2020-004583-26; NCT04887259). A Phase 1/2a clinical study to evaluate LAVA-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC) is also enrolling (EudraCT 2021-001789-39; 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 in respect to the company's anticipated growth and clinical developments plans, and 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 & clinical 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

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