LAVA Therapeutics Announces Updated Data from the Phase 1/2a Clinical Trial of LAVA-051 at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition

December 10, 2022

Poster presentation to include initial data from subcutaneous administration and updates on intravenous dosing-cohorts

UTRECHT, The Netherlands and PHILADELPHIA, Pa., Dec. 10, 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 a poster presentation highlighting updated data, including safety, pharmacodynamics (PD) and pharmacokinetics (PK) from the ongoing Phase 1/2a clinical trial of LAVA-051 in patients with relapsing/refractory (R/R) chronic lymphocytic leukemia (CLL) and multiple myeloma (MM) at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition, taking place in New Orleans, Louisiana and virtually December 10–13, 2022. The presentation includes initial data from patients receiving LAVA-051 subcutaneously, along with updates on the intravenous dosing-cohorts.

"To date, the Phase 1 data, as presented, showed that dose escalation of LAVA-051 up to 200 µg could be achieved in patients with R/R MM and CLL without evidence of dose-limiting toxicity and cytokine release syndrome (CRS). Often, such toxicities are a significant safety challenge for T-cell engager therapies," said 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. "I am pleased that this first clinical study with a gamma delta T-cell engager has progressed into more relevant dose levels." In the phase 1/2a study of LAVA-051 in patients with relapsed/ refractory (R/R) CLL, MM and AML (NCT04887259), the primary objectives are to investigate safety and tolerability of LAVA-051 and determine the recommended Phase 2 dose (RP2D) of LAVA-051. The secondary objectives include evaluation of PK, PD, immunogenicity, and preliminary anti-tumor activity.

In addition to the favorable safety profile demonstrated as of the data cutoff (November 11, 2022), LAVA-051 showed predictable and linear pharmacokinetics and on-mechanism pharmacodynamic parameters consistent with Vγ9Vδ2-T cell engagement, including increasing occupancy of patient Vγ9Vδ2-T cells with LAVA-051 and consistent increases in the expression of T-cell activation markers. Moreover, potential signs of clinical activity of LAVA-051 were seen.

"The LAVA Therapeutics team is committed to transforming treatment for people living with cancer," said Stephen Hurly, president and chief executive officer of LAVA Therapeutics. "We are pleased with the encouraging findings so far from this clinical trial and dose escalation is continuing in the US and EU. I am excited about the potential of LAVA-051 as a novel therapy that may overcome the challenges associated with current T cell-engager approaches."

Details of the poster presentation session are as follows:

Abstract #: 2014
Abstract Title: *LAVA-051, a Novel Bispecific Gamma-Delta T-Cell Engager (Gammabody™), in Relapsed/Refractory MM and CLL: Pharmacodynamic and Early Clinical Data*
Session Name: Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster I
Session #: 704
Session Date: Saturday, December 10, 2022
Session Time: 5:30 p.m.–7:30 p.m. CT
Presenter: Arnon P. 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

A PDF copy of the presentation is available here.

About LAVA-051
LAVA-051 is a humanized Gammabody™ designed to activate both Vγ9Vδ2 (Vgamma9 Vdelta2) T cells and type 1 NKT cells to kill CD1d-expressing tumor cells. LAVA-051 consists of two single domain antibodies linked via a short five amino acid glycine-serine linker. One domain antibody recognizes the Vδ2 chain of the Vγ9Vδ2 T cell receptor, and the other domain antibody is specific for CD1d, a glycoprotein involved in the presentation of (glyco)lipid antigens to distinct T cell populations including type 1 NKT cells, that can be expressed on a wide range of hematologic malignancies, including chronic lymphocytic leukemia, multiple myeloma, and acute myeloid leukemia.

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, 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.

CONTACTS

Investor Relations
ir@lavatherapeutics.com

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