LAVA Therapeutics Announces Treatment of First Patient in Phase 1/2a Clinical Trial of LAVA-051 for Multiple Hematological Malignancies

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LAVA's first-in-class gamma-delta bsTCE to be evaluated as a treatment for chronic lymphocytic leukemia, multiple myeloma and acute myeloid leukemia

UTRECHT, The Netherlands and PHILADELPHIA, July 13, 2021 (GLOBE NEWSWIRE) -- LAVA Therapeutics N.V. (Nasdaq: LVTX), a biotechnology company focused on developing bispecific gamma-delta T cell engagers (bsTCEs) to transform the treatment of cancer, today announced dosing of the first patient in the company's Phase 1/2a clinical trial of LAVA-051 in patients with relapsed and/or refractory chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and acute myeloid leukemia (AML). LAVA-051, LAVA's lead product candidate, 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 dosing of the first patient with LAVA-051 is an important step towards harnessing the therapeutic potential of the Vγ9Vδ2 subset of gamma-delta T cells in the clinic," said Benjamin Winograd, M.D., Ph.D., chief medical officer of LAVA. "Our preclinical data demonstrate that LAVA-051 targets CD1d-expressing tumors by activating both Vγ9Vδ2 T cells and type 1 NKT cells, leading to robust antitumor activity. These data make us confident that our dual-targeting approach may lead to important new treatment options for CD1d expressing hematological malignancies like CLL, MM and AML, which are devastating, difficult to treat cancers, for which novel treatments are needed."

The open-label, multi-center, Phase 1/2a clinical trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary antitumor activity of LAVA-051. The Phase 1 dose-escalation portion will determine an optimal Phase 2 dose of LAVA-051. Once a recommended Phase 2 dose has been established, the trial will expand into the Phase 2a portion, which will enroll patients in three disease specific cohorts for relapsed and/or refractory CLL, MM and AML, to confirm safety and evaluate preliminary antitumor activity in each disease cohort.

The Phase 1/2a clinical trial for LAVA-051 will initially be conducted in Europe, where the Company has already received regulatory approval for its Clinical Trial Application (CTA). LAVA expects to file an Investigational New Drug application (IND) with the U.S. Food and Drug Administration, which if accepted, will subsequently expand the trial to include patients in the United States.

Stephen Hurly, president and chief executive officer of LAVA, added, "This important milestone marks LAVA's transition to a clinical stage company. LAVA-051, the most advanced product candidate from our off-the-shelf antibody platform, is designed to utilize bi-specifics to unlock the full anti-cancer potential of a patient's own gamma-delta T cells. We believe our approach overcomes the limitations of first-generation T cell engagers, reducing the risk of off-target toxicity, regulatory T-cell activation and cytokine release syndrome, while also amplifying efficacy through innate and adaptive immune responses. Adding to our momentum in the clinic, our second clinical program, LAVA-1207 in metastatic prostate cancer, is expected to enter the clinic before year end. We look forward to generating important clinical data to support our approach in both hematological malignancies and solid tumors."

About LAVA-051
LAVA-051 is a humanized gamma-delta bsTCE that activates both Vγ9Vδ2 T cells and type 1 NKT cells to kill tumor cells while leveraging their natural ability to distinguish tumor from healthy cells. LAVA-051 consists of two VHH domain antibodies linked via a short, five amino acid glycine-serine linker. One domain recognizes the Vd2 chain of the Vγ9Vδ2 T cell receptor and the other domain is specific for CD1d, a glycoprotein involved in the presentation of lipid antigens to distinct T cell populations including type 1 NKT cells, that are expressed on a wide range of hematological malignancies, including CLL, MM and AML. CD1d is also be expressed by several solid tumors, including prostate, cervical, breast, renal cell and colorectal cancers.

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 estimates to have 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.

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