LAVA Therapeutics Announces FDA IND Clearance for LAVA-051 for the Treatment of Hematologic Malignancies

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UTRECHT, The Netherlands and PHILADELPHIA, May 12, 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 that the U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application for LAVA-051, the Company's lead product candidate for the treatment of relapsed or refractory chronic lymphocytic leukemia (CLL), multiple myeloma (MM) and acute myeloid leukemia (AML).

"FDA clearance of our IND application for LAVA-051 marks the second IND for LAVA and enables us to expand patient enrollment into the U.S. for our ongoing Phase 1/2a clinical trial," said Stephen Hurly, president and chief executive officer of LAVA Therapeutics. "Supported by encouraging preclinical and preliminary clinical data, we believe in the potential of LAVA-051 to address unmet patient needs. We look forward to providing updates at the 2022 ASCO Annual Meeting, where we will present additional interim data from the dose-escalation phase of this trial."

The Phase 1/2a clinical trial currently includes patients with relapsed or refractory CLL and MM. AML patients will be included later in the study. In October 2021, the FDA granted Orphan Drug Designation for LAVA-051 for the treatment of CLL.

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, and that can be expressed on a wide range of hematological malignancies, including CLL, MM and AML.

About LAVA Therapeutics
LAVA Therapeutics N.V. is an 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 hematological malignancies. LAVA 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, LAVA'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. 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. 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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