



LAVA Therapeutics to Present Initial Phase 1/2a Clinical Trial Dose Escalation Data of LAVA-051 in Chronic Lymphocytic Leukemia and Multiple Myeloma Patients at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting

June 1, 2022

LAVA Therapeutics to host clinical results conference call and webcast on June 16 at 8:00 a.m. EDT/2:00 p.m. CEST

UTRECHT, The Netherlands and PHILADELPHIA, June 01, 2022 (GLOBE NEWSWIRE) -- [LAVA Therapeutics N.V. \(Nasdaq: LVTX\)](https://www.lavatherapeutics.com), 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 the presentation of initial dose-escalation data from the Phase 1/2a clinical trial of LAVA-051 in patients with chronic lymphocytic leukemia (CLL) and multiple myeloma (MM) at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting taking place in Chicago and virtually June 3-7, 2022.

"These dose-escalation data from the first four cohorts of our Phase 1/2a clinical trial demonstrate a favorable safety profile to date and early encouraging signs of potential anti-tumor activity of LAVA-051, as well as a desirable pharmacokinetic and pharmacodynamic profile, in patients with chronic lymphocytic leukemia and multiple myeloma. Importantly, while reaching 100 times the starting dose, LAVA-051 was well-tolerated without observing dose-limiting toxicity and without incurring any cytokine release syndrome, a 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, LAVA-051 clinical trial investigator and lead author of the ASCO abstract. "We are pleased with these initial data as we continue to enroll patients for additional cohorts in our trial."

In the Phase 1/2a clinical study of LAVA-051 in patients with CLL and MM, the primary objectives are to investigate safety and tolerability and determine the recommended Phase 2 dose, while the secondary objectives are to evaluate pharmacokinetics, pharmacodynamics, immunogenicity, and preliminary anti-tumor activity. Acute myeloid leukemia (AML) patients will be included later in the study.

In addition to the favorable safety profile demonstrated to date, LAVA-051 showed predictable and linear pharmacokinetics and on-mechanism pharmacodynamic parameters consistent with Vγ9Vδ2-T cell engagement, including increasing occupancy of LAVA-051 on patient Vγ9Vδ2-T cells and consistent increases in the expression of T-cell activation markers. In these initial data, potential signs of clinical anti-tumor activity were also observed: a CLL patient experienced early enlargement and tenderness of several CLL-affected lymph nodes followed by a regression of those lymph nodes, resulting in a stable disease assessment after 12 weeks of therapy in combination with a reduction in the peripheral blood leukemic cell count over five cycles of LAVA-051; a MM patient showed a 23% reduction in myeloma cell-produced M-protein levels in the blood.

"These clinical data from the LAVA-051 study in patients with therapy-refractory CLL and MM, supported by comprehensive preclinical data, strengthen our expectation that targeting Vγ9Vδ2 T cells using our Gammabody™ platform has the potential to trigger anti-tumor responses in patients within a favorable safety profile," said Stephen Hurlly, president and chief executive officer of LAVA Therapeutics. "We are also encouraged by the potential signs of anti-tumor activity occurring this early during the dose escalation. We anticipate the release of additional clinical data in 2022 and initial Phase 2a expansion cohort data in the first half 2023."

Details for the ASCO 2022 presentation are as follows:

Poster #: 2577

Poster Title: *Phase I dose escalation of LAVA-051, a novel bispecific gamma delta T-cell engager (Gammabody™), in relapsed/refractory hematological malignancies*

Session Title: Developmental Therapeutics — Immunotherapy

Session Date: Sunday, June 5, 2022

Session Time: 9 a.m.–12 p.m. EDT/8–11 a.m. CEST

Presenter: Arnon Kater, M.D., Ph.D.

Conference Call Information

LAVA Therapeutics management will host a conference call to review and discuss data presented at ASCO on June 16 at 8:00 a.m. EDT/2:00 p.m. CEST. Analysts and investors are invited to participate in the conference call by dialing 1-877-270-2148 from the U.S. and Canada or 1-412-902-6510 internationally and asking to be joined into the LAVA Therapeutics call. The live webcast can be accessed under the "Events" tab on the investor relations section of the LAVA Therapeutics website at: <https://ir.lavatherapeutics.com/news-events/events>. A replay of the webcast will be available on

LAVA's website approximately two hours after the completion of the event and will be archived for at least 30 days.

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 is 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.

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