



LAVA Therapeutics Announces Treatment of First Patient in Phase 1/2a Clinical Trial of LAVA-1207 for Metastatic Castration-Resistant Prostate Cancer

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LAVA's Lead Solid Tumor Program and Second Gammabody™ T cell Engager Enters the Clinic

UTRECHT, The Netherlands and PHILADELPHIA, Feb. 01, 2022 (GLOBE NEWSWIRE) -- [LAVA Therapeutics N.V.](#) (Nasdaq: LVTX), an immuno-oncology company focused on developing its proprietary [Gammabody™ platform](#) of 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-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC). LAVA-1207 is a Gammabody™ that targets the prostate-specific membrane antigen (PSMA) and has demonstrated preclinical proof-of-concept driving antitumor responses in a variety of prostate cancer models.

"The dosing of the first patient with LAVA-1207 is an important step toward unlocking the therapeutic potential of our Gammabody™ platform that pairs potent and selective tumor cell killing with an anticipated low risk for on-target/off-tumor toxicity and cytokine release syndrome. This can potentially translate into improved anti-cancer therapeutics with a wider therapeutic window. Our off-the-shelf Gammabody™, LAVA-1207, has preclinically demonstrated dose dependent, potent and selective anti-cancer activity against PSMA-expressing tumors through the triggering of gamma delta T cell-mediated immunity," said Benjamin Winograd, M.D., Ph.D., chief medical officer, LAVA Therapeutics. "Despite current treatment options for prostate cancer, there is an unmet need for the many patients who experience relapse or become refractory to existing therapies."

"Bispecific gamma delta T cell engaging therapies have the potential to bring novel immunotherapy approaches to those tumors that have not benefitted from the advancement of other immunotherapies. We are thrilled to work with LAVA and initiate a trial of LAVA-1207 for mCRPC," said Martijn Lolkema, M.D., Ph.D., medical oncologist, Erasmus MC Cancer Institute, Rotterdam, The Netherlands and one of the study's principal investigators. "I am delighted the Erasmus MC Cancer Institute is participating in this important study and to have the first patient treated."

The open-label, multi-center, Phase 1/2a clinical trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and preliminary antitumor activity of LAVA-1207 in patients with mCRPC. The Phase 1 dose-escalation portion of the study will determine the optimal Phase 2 dose to be used in the subsequent Phase 2a expansion cohort. The Phase 1/2a clinical trial for LAVA-1207 was initiated in Europe and will subsequently expand to enroll patients in the United States.

"This is a major milestone for LAVA," said Stephen Hurly, president and chief executive officer, LAVA Therapeutics. "Solid tumors have presented a significant challenge for prior T cell engager efforts. Based on the compelling preclinical data of LAVA-1207 in prostate cancer, we believe our Gammabody™ platform has the potential to provide effective treatment options for patients with mCRPC, the second leading cause of cancer-related death among men. We are pleased to have treated the first patient and look forward to continuing to progress the trial."

About LAVA-1207

LAVA-1207 is a Gammabody™ that conditionally activates Vγ9Vδ2 (Vgamma9 Vdelta2) T cells upon crosslinking to PSMA to trigger the potent and preferential killing of PSMA positive tumor cells. LAVA-1207 is a bispecific antibody of 78 kDa, comprising two heavy chains, each consisting of a humanized VHH domain antibody and a human IgG1 modified hinge region, CH2 and CH3 domain.

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 (bsTCEs) for the potential 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 (Vgamma9 Vdelta2) 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 currently enrolling ([NCT04887259](#)). The company currently anticipates data from the Phase 1 dose escalation phase of the LAVA-051 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. A Phase 1/2a clinical study to evaluate LAVA-1207 in patients with metastatic castration-resistant prostate cancer (mCRPC) is 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 in respect of the company's anticipated growth and clinical developments 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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