



## LAVA Therapeutics Presents Initial LAVA-051 Clinical Data at the ESMO Targeted Anticancer Therapies Congress 2022

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- LAVA-051 preliminary data shows encouraging initial clinical safety; no dose-limiting toxicity or cytokine release syndrome
- Pharmacodynamic markers indicate increasing receptor occupancy with increasing doses of LAVA-051 and activation of V $\gamma$ 9V $\delta$ 2 T cells
- Preclinical data presented on LAVA's lead Gammabody™ platform candidates, LAVA-051 and LAVA-1207

UTRECHT, The Netherlands and PHILADELPHIA, March 07, 2022 (GLOBE NEWSWIRE) -- [LAVA Therapeutics N.V. \(Nasdaq: LVTX\)](#), an immunology company focused on developing its proprietary [Gammabody™ platform](#) of bispecific gamma delta T cell engagers (bsTCEs) to transform the treatment of cancer, today announced initial data from its first clinical study with LAVA-051. LAVA chief scientific officer Hans van der Vliet, M.D., Ph.D. will deliver the presentation "Bispecific  $\gamma\delta$  T cell engagers for the treatment of cancer" during the Bispecifics and T cell Engagers session in the Channel 1 virtual room today from 14.35 – 14.55 CET at the [ESMO Targeted Anticancer Therapies Congress 2022](#). The presentation will include data from the first three cohorts of the LAVA-051 Phase 1/2a clinical trial along with preclinical data on its two lead programs, LAVA-051 and LAVA-1207, that illustrate characteristics of its Gammabody™ platform.

The first three dose-escalation cohorts showed LAVA-051 to be safe and well tolerated with no dose limiting toxicities or cytokine release syndrome (CRS) observed. Per the study protocol, the cohort three dose was 33-times that of the cohort one dose. Drug exposure and V $\gamma$ 9V $\delta$ 2 T cell receptor occupancy of LAVA-051 increased with LAVA-051 dose increases and peripheral blood V $\gamma$ 9V $\delta$ 2 T cells also expressed higher levels of activation markers after LAVA-051 dosing. One patient with chronic lymphocytic leukemia (CLL) experienced multiple enlarged tender diseased lymph nodes one week after first dosing that subsequently regressed, reminiscent of tumor flare.

"We are encouraged by these initial clinical data for LAVA-051, which showed that LAVA-051 was well tolerated early in dose escalation with on-mechanism pharmacodynamics consistent with V $\gamma$ 9V $\delta$ 2 T cell engagement," said Hans van der Vliet, M.D., Ph.D.

The Phase 1/2a clinical trial currently includes patients with relapsed or refractory CLL and multiple myeloma (MM). The first three cohorts enrolled one patient per dose escalation and future cohorts will enroll at least three patients per cohort. Acute Myeloid Leukemia (AML) patients will be included later in the study. Additional data from the dose escalation phase of the trial is expected in the second quarter of 2022 and from the disease-specific expansion cohorts in the second half of 2022.

The Phase 1/2a clinical trial for LAVA-051 is initially being conducted in Europe and LAVA expects to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), which, if accepted, will subsequently include patients in the United States. In October 2021, the FDA granted orphan drug designation for LAVA-051 for the treatment of CLL.

### About LAVA-051

LAVA-051 is a Gammabody™ designed to activate both V $\gamma$ 9V $\delta$ 2 (V $\gamma$ 9V $\delta$ 2) T cells and type 1 NKT cells to kill CD1d-expressing tumor cells. LAVA-051 consists of two humanized single domain antibodies linked via a short five amino acid glycine-serine linker. One domain antibody recognizes the V $\delta$ 2 chain of the V $\gamma$ 9V $\delta$ 2 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 gamma delta bispecific 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 V $\gamma$ 9V $\delta$ 2 (V $\gamma$ 9V $\delta$ 2) T cell antitumor effector functions upon their 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 additional data from the Phase 1 dose escalation phase of the LAVA-051 study in the second quarter of 2022 and data from the Phase 2a expansion cohorts 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 with data from the Phase 1 dose escalation phase of the trial expected in the second half of 2022 and data from the Phase 2a expansion cohort expected in the first half of 2023. For more information, please visit [www.lavatherapeutics.com](http://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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