



LAVA Therapeutics Presents Preclinical Data on its Gammabody™ T Cell Engager Platform at the 21st Annual PepTalk Conference

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The collective data indicate that LAVA's approach to recruit gamma delta T cells with its bispecific antibody platform results in potent anti-tumor activity while avoiding off-tumor toxicity and cytokine release syndrome (CRS), potentially translating in a superior therapeutic index compared to CD3-based T cell engagers

New non-human primate data support the safety and tolerability profile of LAVA's lead solid tumor Gammabody™ programs

Recruitment is underway for the phase 1/2a clinical trial of LAVA-1207 for metastatic castration-resistant prostate cancer (mCRPC)

UTRECHT, The Netherlands and PHILADELPHIA, Jan. 18, 2022 (GLOBE NEWSWIRE) -- [LAVA Therapeutics N.V. \(Nasdaq: LVTX\)](#), a clinical-stage biotechnology company focused on developing its proprietary [Gammabody™ platform](#) of bispecific gamma delta T cell engagers (gamma delta bsTCEs) to transform the treatment of cancer, today announced it will present preclinical data on its Gammabody™ platform and data on its lead solid tumor Gammabody™ LAVA-1207. The presentation will also include new non-human primate data with a fully cross-reactive gamma delta bsTCE utilizing a surrogate Fc-containing Gammabody™ format to assess the safety of its most advanced solid tumor programs, LAVA-1207 and LAVA-1223. Paul W.H.I. Parren, Ph.D., executive vice president, head of research and development, will present these data at the [21st Annual PepTalk Conference](#) today, [Tuesday, Jan. 18, 2022 from 5:00 – 5:30 p.m. PST in the Sapphire Session Room](#) in San Diego. The presentation will be available on the conference website for viewing during and after the meeting.

In preclinical experiments, LAVA-1207 has shown the ability to activate Vγ9Vδ2 (Vgamma9 Vdelta2) T cells to exert cytotoxicity toward PSMA (prostate specific membrane antigen)-expressing tumor cells at picomolar concentrations. Using prostate cancer patient samples, LAVA-1207 activated autologous Vγ9Vδ2 T cells and triggered lysis of tumor cells, while sparing normal prostate tissue. The mechanism of preferential tumor cell killing may be due to a demonstrated overexpression of a range of Vγ9Vδ2 T cell ligands on tumor cells. A first-in-human Phase 1/2a open-label trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, immunogenicity and antitumor activity of LAVA-1207 in patients with therapy refractory metastatic castration-resistant prostate cancer (mCRPC) is currently recruiting.

"We are grateful for the opportunity to discuss both our Gammabody™ technology and our first clinical-stage solid tumor program, LAVA-1207, at the PepTalk Conference," said Dr. Parren. "We believe our preclinical dataset for LAVA-1207 is highly encouraging; showing potent and precise killing of PSMA-expressing tumor cells, most importantly including those obtained from patients."

In addition, data from the non-human primate study showed an EGFR (epidermal growth factor receptor)-targeted surrogate Gammabody™ to be safe and well-tolerated in non-human primates. The EGFR Gammabody™ was administered at doses up to 23 mg/kg leading to high sustained plasma levels and dose-dependent accumulation in relevant tissues with no safety-related effects and no signs of cytokine release syndrome (CRS). LAVA's clinical stage PSMA Gammabody™, LAVA-1207, is an Fc-containing Gammabody™ for which pre-clinical data from *in vitro*, *ex vivo* and *in vivo* models will also be presented.

"Solid tumors have proven an especially difficult challenge for CD3-based T cell engagers. First generation T cell engagers have shown a relatively high risk for CRS-related toxicities," said Dr. Parren. "Our Gammabody™ platform continues to show data supporting a larger therapeutic window with potent anti-tumor activity and a low risk of CRS and on-target/off-tumor toxicity – meaning a greater potential for achieving optimal dosing."

In the non-human primate study, animals were administered weekly intravenous doses of 1, 5 or 23 mg/kg of an EGFR gamma delta bsTCE that is fully cross-reactive with EGFR and Vγ9 T cells in non-human primates. At all doses, the EGFR gamma delta bsTCE only induced minimal levels of cytokines such as IL-2, IL-6 and IFN-gamma and there were no signs of CRS. No changes in general health parameters, clinical chemistry, hematology or histopathology were observed. The compound was pharmacologically active in the animals, with Vγ9-positive T cells expressing markers indicating activation (CD25 and CD69). Presence of the injected compound in EGFR-expressing tissues, such as skin, muscle and colon, was demonstrated using immune-histochemistry. The elimination half-life was similar to the half-life of regular human IgG and ranged between 84.7 and 127.4 hours.

About LAVA Therapeutics

[LAVA Therapeutics N.V.](#) is a clinical-stage biotechnology company utilizing its proprietary [Gammabody™ platform](#) to develop a portfolio of bispecific gamma delta T cell engagers (gamma delta 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 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](https://clinicaltrials.gov/ct2/show/study/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 prostate cancer 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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