LAVA Doses First Patient in Phase 1 LAVA-1266 Study in Hematological Cancers

January 10, 2025

- LAVA-1266 is a potent and selective bispecific anti-CD123 Gammabody®
- First-in-human study enrolling adult patients with CD123-expressing AML or MDS
- Initial Phase 1 data read-out expected by year-end 2025

UTRECHT, The Netherlands and PHILADELPHIA, Jan. 10, 2025 (GLOBE NEWSWIRE) -- LAVA Therapeutics N.V. (NASDAQ: LVTX, "LAVA," "the Company"), a clinical-stage immuno-oncology company focused on developing its proprietary Gammabody® platform of bispecific gamma delta T cell engagers, announced dosing of the first patient in the Phase 1, first-in-human study of the CD123-targeted Gammabody®, LAVA-1266, an investigational agent in development for the treatment of hematologic cancers including acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS).

"We are pleased to announce the dosing of the first patient with LAVA-1266, a potent and selective CD123-targeted Gammabody®. Based on the positive results of preclinical models showing tumor cell lysis with limited off-target effects, we believe that LAVA-1266's preclinical safety and efficacy profile supports its potential as a treatment for AML and MDS," said **Stephen Hurly, President and Chief Executive Officer** of LAVA Therapeutics. "We are eager to evaluate the safety, pharmacokinetics and pharmacodynamic properties and potential activity of LAVA-1266 and provide initial results from the dose escalation study by the end of the year."

"CD123 is well-recognized as a potential therapeutic target for AML. However, the opportunity for earlier generations of CD123-targeted therapies has been limited by on-target, off-tumor toxicity, cytokine release syndrome and capillary leak syndrome," said **Charles Morris, MD, Chief Medical Officer** of LAVA Therapeutics. "We are enthusiastic about LAVA-1266 based on its strong preclinical profile, and we look forward to working with our clinical study sites in Australia."

About LAVA-1266

LAVA-1266 is a potent bi-specific, T cell engager (bsTCE) that targets CD123+ tumor cells with Vγ9Vδ2-T cells using LAVA's Gammabody® platform. The bsTCE was designed to lyse CD123+ tumor cells with high potency and a wide therapeutic window.

Preclinical studies confirmed target cell expression by showing CD123+ expression and the presence of Vγ9Vδ2-T cells in AML patient samples. In preclinical studies, LAVA showed that LAVA-1266 preferentially targets and kills CD123 cells and induces Vγ9Vδ2-T cell activation. Furthermore, in preclinical studies, LAVA demonstrated that treatment with LAVA-1266 produces high levels of specific tumor cell lysis, with substantially less cytokine release, compared to CD3-based T cell engagers, and increased survival in an AML xenograft model, without the co-activation of immunosuppressive regulatory T cells.

About the Phase 1 First-in-human Study of LAVA-1266 (ACTRN12624001214527)

The open-label, multi-center Phase 1, first-in-human study of LAVA-1266 is currently being conducted in Australia. The study will include a dose escalation and dose expansion segment to evaluate LAVA-1266 in approximately 50 adults with CD123+ relapsed/refractory acute myeloid leukemia (AML) and certain grades of myelodysplastic syndrome (intermediate risk, high risk or extremely high risk). Patients will be dosed every two weeks (Q2W), with an initial target dose of 100 µg for the first cohort.

The study will evaluate safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), immunogenicity and preliminary anti-tumor activity.

About LAVA Therapeutics

LAVA Therapeutics N.V. is a clinical-stage immuno-oncology company focused on advancing its proprietary Gammabody® platform to develop a portfolio of bispecific gamma-delta T cell engagers for the potential treatment of solid tumors and hematologic malignancies. The Company utilizes bispecific antibodies engineered to selectively kill cancer cells by triggering Vγ9Vδ2 (Vgamma9 Vdelta2) T cell anti-tumor effector functions upon cross-linking to tumor-associated antigens.

LAVA's pipeline includes three internal and partnered clinical-stage bispecific gamma-delta T cell engagers for the treatment of solid tumor and hematological cancers including LAVA 1266, targeting CD123+ cancers (ACTRN12624001214527); PF-08046052, targeting EGFR (NCT05983133); and JNJ-89853413, targeting hematological cancers (NCT06618001). The pipeline also includes preclinical programs. For more information on LAVA, please visit our website at www.lavatherapeutics.com, or follow us on LinkedIn, X, and YouTube.

Gammabody® is a registered trademark of LAVA Therapeutics N.V.

LAVA's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipate", "believe", "could", "will", "may", "expect", "should", "plan", "intend", "estimate", "potential", "suggests", 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 relating to the therapeutic potential, development strategy and potential uses of LAVA's product candidates, including LAVA-1266, the timing of initiation of clinical trials and achievement of clinical milestones, LAVA's cash runway and the sufficiency of resources to pursue development activities, progress and data from clinical trials, and the ability of LAVA's product candidates to treat various tumor targets and improve patient outcomes. Many factors, risks and uncertainties may cause differences between current expectations and actual results, including, among other things, the Company's ability to leverage its initial programs to develop additional product candidates using its Gammabody® platform, the failure of LAVA's collaborators to support or advance collaborations or LAVA's product candidates, the timing and results of LAVA's research and development programs and preclinical and clinical trials, the possibility that clinical trials may fail to establish sufficient efficacy, the risk that adverse events or safety signals may occur in clinical trials, the risk that results obtained in preclinical studies or clinical trials to date may not be indicative of results obtained in ongoing or future trials, the risk that adverse regulatory actions or other setbacks could occur in clinical trials even after promising results in earlier clinical trials or preclinical studies, the Company's ability to obtain regulatory approval for and commercialize its product candidates, and the risk that setbacks in development could occur as a result of the difficulty and uncertainty of pharmaceutical product development and other factors. There may be adverse effects on the Company's business condition and results from general economic and market conditions and overall fluctuations in the United States and international equity markets, including as a result of inflation, heightened interest rates, recent and potential future pandemics and other health crises, and hostilities, including between Russia and escalating tension in the Middle East. These and other risks are described in greater detail under the caption "Risk Factors" in LAVA's most recent Annual Report on Form 20-F and other filings the Company makes with the Securities and Exchange Commission. LAVA assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

CONTACTS

Investor Relations
ir@lavatherapeutics.com

LifeSci Advisors (IR/Media)
Joyce Allaire
Jallaire@lifesciadvisors.com