



LAVA Announces Clinical Development Milestone Achieved by Pfizer for PF-08046052 (formerly SGN-EGFRd2/LAVA-1223)

March 5, 2024

Milestone triggered by clinical progress in Phase 1 study, initiated in Q4 2023

UTRECHT, The Netherlands and PHILADELPHIA, March 05, 2024 (GLOBE NEWSWIRE) -- [LAVA Therapeutics N.V.](#) (NASDAQ: LVTX, "LAVA"), a clinical-stage immuno-oncology company focused on developing its proprietary Gammabody® platform of bispecific gamma delta T cell engagers, today announced that Pfizer has achieved a clinical development milestone for PF-08046052 (formerly SGN-EGFRd2 /LAVA-1223), prompting the first milestone payment of \$7 Million to LAVA. LAVA granted Seagen (acquired by Pfizer in December 2023) a worldwide, exclusive license to PF-08046052 in September 2022.

"We are very pleased with the initiation of clinical development by Pfizer of PF-08046052, formerly SGN-EGFRd2/LAVA-1223. We have always viewed this molecule with excitement about its potential in oncology. Achievement of this milestone is another important step in realizing the potential of LAVA's Gammabody® platform. As the Phase 1 study advances, we look forward to continued clinical progress and future data readouts," said Stephen Hurly, President and Chief Executive Officer of LAVA.

"The initiation of the Phase 1 study for PF-08046052 marks the third asset utilizing LAVA's Gammabody® platform to enter the clinic and will add further information on safety, clinical pharmacology and potential anti-tumor activity to the growing database for this novel class of molecules," commented Charles Morris, M.D., Chief Medical Officer, LAVA. "We are especially encouraged by the ongoing progress for PF-08046052 and PSMA-directed LAVA-1207, currently in a Phase 1/2a study. Both programs direct Vy9Vδ2 T cells to validated targets and have the potential to provide important proof-of-concept for LAVA's Gammabody® platform."

About PF-08046052 (formerly LAVA-1223)

PF-08046052 is a potential first-in-class asset utilizing the Gammabody® platform designed to conditionally activate Vy9Vδ2 (Vgamma9 Vdelta2) T cells, upon crosslinking to epidermal growth factor receptor (EGFR), to trigger the potent and preferential killing of EGFR-positive tumor cells. EGFR is a well-validated target that is over-expressed in multiple solid tumor types, including colorectal cancer (CRC), non-small cell lung cancer (NSCLC), head and neck squamous cell cancer (HNSCC) and pancreatic ductal adenocarcinoma (PDAC). PF-08046052 is being evaluated in an ongoing Phase 1 study ([NCT05983133](#)) by Pfizer under an exclusive worldwide license agreement. In accordance with the agreement, LAVA received a \$50 million upfront payment and is eligible to receive milestones of up to approximately \$650 million upon achievement of development, regulatory and commercial milestones as well as royalties on potential sales.

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 Vy9Vδ2 (Vgamma9 Vdelta2) T cell antitumor effector functions upon cross-linking to tumor-associated antigens.

A Phase 1/2a dose escalation study ([NCT05369000](#)) to evaluate the lead program, LAVA-1207, in patients with metastatic castration-resistant prostate cancer (mCRPC) is actively enrolling in Europe and the United States in a study evaluating monotherapy and combination treatment with interleukin-2 (IL-2). The Company is also planning to expand the Phase 1/2a study to include a combination arm with KEYTRUDA® (pembrolizumab), through a clinical collaboration with Merck & Co., Inc., Rahway, NJ, USA. The Company licensed PF-08046052 (formerly SGN-EGFRd2/LAVA-1223) to Pfizer for clinical development and commercialization. For more information, please visit www.lavatherapeutics.com, and follow us on [LinkedIn](#), [X](#), and [YouTube](#).

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co. LLC, Rahway, NJ, USA

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 and results of clinical trials. 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 and potential uses of LAVA's product candidates, the timing of initiation of clinical trials, including the expansion phase of the Phase 1/2a trial to evaluate LAVA-1207 in combination with KEYTRUDA®, availability of information regarding clinical development plans, progress and data from clinical trials, the potential uses of LAVA's product candidates to treat various tumor targets, including CRC, NSCLC, PDAC and HNSCC, and improve patient outcomes and the sufficiency of resources to pursue development activities. 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 our Gammabody® platform, and 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 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 an commercialize its product candidates, the risk that setbacks in development could occur in clinical trials even after promising results in earlier trials or preclinical studies; 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, hostilities between Russia and Ukraine or Israel and Hamas, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures. These and other risks are described in greater detail under the caption "Risk Factors" and included in LAVA's filings 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.

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