Lisata Therapeutics Announces First Patient Treated in the Phase 2a Trial of LSTA1 in Patients with Glioblastoma Multiforme

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BASKING RIDGE, N.J., Jan. 17, 2024 (GLOBE NEWSWIRE) -- Lisata Therapeutics, Inc. (Nasdaq: LSTA) ("Lisata" or the "Company"), a clinical-stage pharmaceutical company developing innovative therapies for the treatment of advanced solid tumors and other serious diseases, today announced treatment of the first patient in a Phase 2a trial evaluating LSTA1 in patients with newly diagnosed glioblastoma multiforme ("GBM"). The trial is an investigator-initiated study by Lenne-Triin Kõrgvee, MD, PhD, principal investigator of the study. The first patient was enrolled at Tartu University Hospital in Tartu, Estonia.

The study is a Phase 2a, double-blind, placebo-controlled, randomized, proof-of-concept study evaluating LSTA1 when added to standard of care ("SoC"), temozolomide, versus SoC and placebo in subjects with newly diagnosed GBM. The study is being conducted across multiple sites in Estonia and Latvia and is targeted to enroll 30 patients with a randomization of 2:1 in favor of the LSTA1 treatment group. In addition to provisioning LSTA1, Lisata will also provide funding for this study. As previously announced by the Company, LSTA1 has been granted orphan drug designation by the U.S. FDA for malignant glioma.

"We are very pleased to announce the first patient treated in this Phase 2a study evaluating LSTA1 in patients with newly diagnosed GBM, a very aggressive brain tumor that is often fatal. We hold great hopes for the benefits of LSTA1 in this indication based on preclinical evidence that demonstrates LSTA1 enhances penetration through the limited permeability of the blood-brain barrier," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Lisata. "We appreciate the efforts of Dr. Kõrgvee and her team at Tartu University Hospital as well as those patients participating. We look forward to monitoring the results closely."

"We are excited by the opportunity to work with Lisata and study LSTA1's tumor targeting and penetrating technology in GBM," Dr. Kõrgvee stated. "GBM has, historically, been very difficult to successfully treat and we believe LSTA1 may be an important tool in improving those outcomes for patients."

About LSTA1

LSTA1 is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered (i.e., covalently bound) anti-cancer drugs to penetrate solid tumors more effectively. LSTA1 actuates this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor. LSTA1 also has the potential to modify the tumor microenvironment, with the objective of making tumors more susceptible to immunotherapies. Lisata and its collaborators have amassed significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies and RNA-based therapeutics. Additionally, LSTA1 has demonstrated favorable safety, tolerability, and activity in clinical trials to enhance delivery of SoC chemotherapy for pancreatic cancer. Lisata is exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively.

About Lisata Therapeutics

Lisata Therapeutics is a clinical-stage pharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for the treatment of advanced solid tumors and other major diseases. Lisata's lead product candidate, LSTA1, is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to target and penetrate solid tumors more effectively. Based on Lisata's CendR Platform ® Technology, Lisata has already established noteworthy commercial and R&D partnerships. The Company expects to announce numerous clinical study and business milestones over the next two years and has projected that its current business and development plan is funded with available capital through these milestones and into early 2026. For more information on the Company, please visit www.lisata.com.

Forward-Looking Statements

This communication contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses and capital, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Lisata or its management, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, the potential efficacy of LSTA-1 as a treatment for patients with glioblastoma multiforme, metastatic gastroesophageal adenocarcinoma and other solid tumors, statements relating to Lisata's continued listing on the Nasdaq Capital Market; expectations regarding the capitalization, resources and ownership structure of Lisata; the approach Lisata is taking to discover and develop novel therapeutics; the adequacy of Lisata's capital to support its future operations and its ability to successfully initiate and complete clinical trials; and the difficulty in predicting the time and cost of development of Lisata's product candidates. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: results observed from a single patient case study are not necessarily indicative of final results and one or more of the clinical outcomes may materially change following more comprehensive reviews of the data and as more patient data becomes available, including the risk that unconfirmed responses may not ultimately result in confirmed responses to treatment after follow-up evaluations; the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials; the safety and efficacy of Lisata's product candidates,

decisions of regulatory authorities and the timing thereof, the duration and impact of regulatory delays in Lisata's clinical programs, Lisata's ability to finance its operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of Lisata's scientific studies, Lisata's ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in Lisata's markets, the ability of Lisata to protect its intellectual property rights; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Lisata's Annual Report on Form 10-K filed with the SEC on March 30, 2023, and in other documents filed by Lisata with the Securities and Exchange Commission. Except as required by applicable law, Lisata undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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