Lisata Therapeutics Announces U.S. FDA Orphan Drug Designation Granted to LSTA1 for the Treatment of Malignant Glioma

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BASKING RIDGE, N.J., Aug. 08, 2023 (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 the U.S. Food and Drug Administration ("FDA") has granted Orphan Drug Designation to LSTA1, the Company's lead product candidate, for the treatment of malignant glioma.

"Malignant glioma is one of the most aggressive and deadly malignancies," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Lisata. "This Orphan Drug Designation acknowledges the high unmet medical need of this patient population as well as the potential of LSTA1 to benefit patients in this setting."

Orphan Drug Designation is granted by the FDA to drugs or biologics intended to treat a rare disease or condition, defined as one that affects fewer than 200,000 people in the United States. Orphan Drug Designation provides certain financial incentives to support clinical development as well as a seven-year period of U.S. market exclusivity if the product receives FDA approval for such indication.

Currently, LSTA1 is the subject of multiple ongoing or planned Phase 1b/2a and 2b clinical studies being conducted globally in a variety of solid tumor types in combination with a variety of anti-cancer regimens. In the coming months, the Company, in collaboration with investigators from the University of Tartu in Estonia, plans to initiate a clinical study evaluating LSTA1 in previously untreated glioblastoma multiforme ("GBM"). The study will be the first step in the clinical exploration of the impact of LSTA1 added to standard-of-care ("SoC") for the treatment of GBM and is designed as a Phase 2a double-blind, placebo-controlled, randomized, proof-of-concept study evaluating LSTA1 when added to SoC temozolomide versus temozolomide alone and matching LSTA1 placebo in subjects with newly diagnosed GBM. It will be conducted at several sites in Estonia and Latvia and is targeted to enroll 30 patients with a randomization of 2:1 LSTA1 + SoC versus placebo + SoC. The Company expects that the first patient will be treated in the fourth quarter of 2023.

About LSTA1

LSTA1 is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered 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, 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 standard-of-care 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, 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: 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.

Contact:

Investors and Media:

Lisata Therapeutics, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: 908-842-0084
Email: jmenditto@lisata.com