# Lisata Therapeutics Announces First Patient Treated in the BOLSTER Trial of LSTA1, a Novel Tumor-Targeting and Penetrating Peptide, in Patients with Advanced Solid Tumors

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*Phase 2a double-blind, placebo-controlled, multi-center, randomized study evaluating LSTA1 in combination with standards of care versus standards of care alone in subjects with advanced solid tumors including cholangiocarcinoma, head and neck squamous cell carcinoma, or esophageal squamous cell carcinoma*

*First patient treated in the head and neck squamous cell carcinoma cohort*

BASKING RIDGE, N.J., Sept. 12, 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 treatment of the first patient in the head and neck squamous cell carcinoma cohort of the BOLSTER trial, by Dr. Alexander N. Starodub, a principal investigator of the study, at The Christ Hospital in Cincinnati, Ohio.

The BOLSTER trial is a Phase 2a, double-blind, placebo-controlled, multi-center, randomized study evaluating LSTA1 when added to standard-of-care ("SOC") versus SOC alone in patients with either advanced second-line head and neck squamous cell carcinoma, second-line esophageal squamous cell carcinoma, or first-line cholangiocarcinoma. The BOLSTER trial is a basket trial being conducted at approximately 40 sites in North America, Europe, and Asia-Pacific. Total trial enrollment of 120 patients is expected to be completed in the second half of 2024. A "basket" trial is a trial in which a product (e.g., LSTA1) is tested in multiple indications sharing a similar trait or challenge (e.g., dense stroma in solid tumors) in separate arms of the study. The individual arms are enrolled and analyzed independently but share operational synergies such that the study is more efficient to execute than would be for conducting independent studies for each indication. Each arm of BOLSTER will enroll 40 patients: 20 randomized to LSTA1 in combination with SOC, 20 randomized to placebo in combination with SOC.

"We are excited to announce treatment of the first patient in the second-line head and neck squamous cell carcinoma cohort of the BOLSTER trial. Head and neck squamous cell carcinoma, which usually begins in the mucosal surfaces of the mouth, throat or voice box, is a rare and aggressive form of solid tumor cancer that is diagnosed in roughly 67,000 patients a year in the U.S. Most head and neck cancers eventually spread to the lymph nodes nearest to the affected area and can become incurable or uncontrollable resulting in advanced or terminal stage disease. The BOLSTER trial gives us the opportunity to evaluate the potential of LSTA1 in a variety of solid tumor settings in combination with corresponding standards-of-care and will provide direction on potential next steps in development," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Lisata. "Now that the first patient in BOLSTER has been treated, we expect an uptake in enrollment in the coming quarters. We remain committed to developing groundbreaking therapies that can transform the outcomes of individuals facing these life-threatening conditions."

For more information on the BOLSTER Trial, please visit https://clinicaltrials.gov/study/NCT05712356.

**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, 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.

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