Lisata Therapeutics Announces Completion of Enrollment in its Phase 2a BOLSTER Trial of Certepetide in First-Line Cholangiocarcinoma

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Complete enrollment achieved nearly six months ahead of plan

Top-line data now anticipated mid-2025

Addition of second-line cholangiocarcinoma arm to BOLSTER trial

BASKING RIDGE, N.J., July 16, 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, announced today the early completion of enrollment in its Phase 2a BOLSTER trial evaluating certepetide (formerly LSTA1), Lisata's investigational product, as a treatment for first-line cholangiocarcinoma ("CCA"). This key milestone comes nearly six months sooner than originally expected.

The BOLSTER trial is a Phase 2a double-blind, placebo-controlled, multi-center, randomized study evaluating certepetide in combination with standard-of-care (gemcitabine/cisplatin/durvalumab) versus standard-of-care alone in patients with first-line CCA in the United States. The rapid enrollment of this cohort underscores the urgent need for new treatment options for patients with CCA, a difficult-to-treat solid tumor with a poor prognosis. Based on this rapid enrollment rate and the pressing need to improve treatment outcomes in second-line CCA, Lisata has added an arm to the BOLSTER trial evaluating second-line CCA. The Company expects to enroll the first patient in the second-line CCA arm by the fourth quarter of 2024.

"Completing enrollment in the first-line CCA cohort of the BOLSTER trial represents a significant accomplishment for Lisata and is a critical step forward in the development of certepetide for CCA," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "This achievement underscores the dedication and enthusiasm of everyone involved in supporting the study, both internally and externally, as well as the promise of certepetide as a first-line treatment option for CCA. Top-line data from the trial is anticipated by mid-2025. These results will be instrumental in evaluating certepetide's potential as a novel therapeutic approach for CCA."

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

About Cholangiocarcinoma

Cholangiocarcinoma, also known as bile duct cancer, is a cancer that forms in the bile ducts, a network of thin tubes that play a crucial role in digestion. Cholangiocarcinoma is a rare but serious cancer. According to the American Cancer Society, approximately 8,000 people in the United States are diagnosed with CCA each year, however, the true count is likely higher due to diagnostic challenges. The five-year survival rate for CCA is under 5%, highlighting the urgent need for new and effective treatments.

About Certepetide

Certepetide (formerly 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. Certepetide 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. Certepetide has also been shown to modify the tumor microenvironment, diminishing its immunosuppressive nature and inhibiting the metastatic cascade. We and our collaborators have amassed significant non-clinical data demonstrating enhanced delivery of various emerging anti-cancer therapies, including immunotherapies and RNA-based therapeutics. To date, certepetide has also demonstrated favorable safety, tolerability, and clinical activity in completed and ongoing clinical trials designed to test its ability to enhance the effectiveness of standard-of-care chemotherapy for pancreatic cancer. Lisata is exploring the potential of certepetide to enable a variety of treatment modalities to treat a range of solid tumors more effectively. Certepetide has been awarded Fast Track designation (U.S.) and Orphan Drug Designation for pancreatic cancer (U.S. and E.U.) as well as Orphan Drug Designation for glioma (U.S.) and osteosarcoma (U.S.). Additionally, certepetide has received Rare Pediatric Disease Designation for osteosarcoma (U.S.).

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, certepetide (formerly LSTA1), is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to selectively target and penetrate solid tumors more effectively. Lisata has already established noteworthy commercial and R&D partnerships based on its CendR Platform® technology. The Company expects to announce numerous milestones over the next two years and believes that its projected capital will fund operations into early 2026, encompassing anticipated data milestones from its ongoing and planned clinical trials. 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 the Company's clinical development programs 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 certepetide as a treatment for patients with metastatic pancreatic ductal 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 February 29, 2024, 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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