



Lisata Therapeutics Announces First Patient Treated in the Second-line Cholangiocarcinoma Cohort of the BOLSTER Trial

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Study arm initiated based upon enthusiasm and at the request of investigators who participated in first-line cholangiocarcinoma cohort

BASKING RIDGE, N.J., Sept. 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 the second-line cholangiocarcinoma ("CCA") cohort of the BOLSTER trial. This follows the recently announced successful completion of enrollment in the first-line CCA cohort.

"We are pleased to announce the dosing of the first patient in the second-line cholangiocarcinoma cohort of the BOLSTER trial," said Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "Initiation of this cohort is based on the recommendation of investigators from our BOLSTER study's first-line cholangiocarcinoma cohort to evaluate certepetide in patients who progressed after being treated with first-line standard-of-care therapy alone. We are excited to expand the evaluation of certepetide in this broadened cholangiocarcinoma population with the goal of improving outcomes for these patients in dire need."

The BOLSTER trial is a Phase 2a, double-blind, placebo-controlled, randomized, multi-center study evaluating certepetide in combination with standard-of-care in subjects with first- or second-line CCA. For more information on the BOLSTER trial, including participating sites, 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 and serious cancer that is difficult to diagnose and often misclassified. According to the American Cancer Society, approximately 8,000 people in the United States are diagnosed with cholangiocarcinoma each year, however, the actual number is likely higher due to diagnostic challenges. The five-year survival rate for cholangiocarcinoma is under 5%, highlighting the urgent need for new and effective treatments.

About Certepetide

Certepetide is an investigational drug designed to selectively activate the C-end rule active transport mechanism in a tumor specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor. Additionally, certepetide has been shown to modify the tumor microenvironment, diminishing its immunosuppressive nature and inhibiting the metastatic cascade. Lisata and its collaborators have amassed significant non-clinical data demonstrating enhanced delivery of various existing and emerging anti-cancer therapies, including chemotherapies, 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 demonstrate its ability to enhance the effectiveness of standard-of-care chemotherapy for pancreatic cancer as well as the combination of chemotherapy and immunotherapy in a variety of solid tumors. 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, osteosarcoma, and cholangiocarcinoma (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 product candidate, [certepetide](#), 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 1.5 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 cholangiocarcinoma 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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