Lisata Therapeutics' Certepetide Shows Promise in Improving Standard Treatment for Intrahepatic Cholangiocarcinoma in a Preclinical Model

July 10, 2024

Certepetide shown to promote immune cell infiltration into tumors and inhibit metastasis

BASKING RIDGE, N.J., July 10, 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 announces promising preclinical results for its investigational candidate, certepetide (formerly LSTA1). The data, presented in a poster by Dr. Dan G. Duda of Massachusetts General Hospital at the 2024 Cholangiocarcinoma Foundation Annual Conference, showed that certepetide combined with standard-of-care chemotherapy and immunotherapy improved survival in mice with intrahepatic cholangiocarcinoma. These findings suggest potential benefits for human patients with this aggressive cancer and support advancing clinical development efforts for certepetide in intrahepatic cholangiocarcinoma.

"Previous preclinical and early clinical results for certepetide show promise, and Lisata is optimistic about its potential to benefit patients with advanced solid tumors, including cholangiocarcinoma," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer at Lisata. "We are currently conducting a Phase 2a clinical trial, known as the BOLSTER trial, to evaluate certepetide in combination with standard-of-care chemotherapy as first-line treatment for cholangiocarcinoma. Additionally, based on the recommendations of the investigators involved in BOLSTER and the serious unmet medical need for treatments in a second line, we will soon be adding another arm to BOLSTER to test certepetide in combination with standard-of-care chemoimmunotherapy in intrahepatic cholangiocarcinoma patients. We look forward to sharing updates on this trial throughout the year, with results anticipated for both arms during 2025."

Dr. Duda's research, titled *"Enhancing the Efficacy of Standard Therapy in Intrahepatic Cholangiocarcinoma Using LSTA1 (certepetide), a Novel Tumor Targeting and Penetration Agent,"* evaluated the efficacy of certepetide alongside standard anti-PD-1 immunotherapy and gemcitabine/cisplatin chemotherapy in an aggressive intrahepatic cholangiocarcinoma mouse model. The study demonstrated that certepetide, in combination with standard chemotherapy plus immunotherapy, significantly prolonged survival, reduced disease morbidity (ascites and pleural effusions), and lung metastasis, and decreased the risk of death by 76%. Treatment was well tolerated in mice, with no overt additional toxicities. Initial data suggest that certepetide promoted immune cell infiltration into the tumor tissues by opening the collapsed tumor vessels and enhancing immune cell infiltration.

"These preclinical data on certepetide are very encouraging," stated Prof. Dan G. Duda. "Intrahepatic cholangiocarcinoma is a devastating disease with a poor prognosis, and there remains a critical need for new and improved treatment options. These findings, while based on an animal model, support the continued development of certepetide as a potential breakthrough treatment in patients living with intrahepatic cholangiocarcinoma."

About Intrahepatic Cholangiocarcinoma

Intrahepatic cholangiocarcinoma, also known as intrahepatic bile duct cancer, is a rare, aggressive cancer that starts in the bile ducts within the liver. It is the second most common liver malignancy, making up about 10% of all cholangiocarcinoma. Intrahepatic cholangiocarcinoma has an overall poor prognosis, and symptoms are usually nonspecific, contributing to an advanced tumor stage at diagnosis.

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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