Lisata Therapeutics Reports Encouraging Preliminary Cohort A Data from the AGITG-led Phase 2 ASCEND Trial Evaluating Certepetide with Standard-of-Care Chemotherapy in Metastatic Pancreatic Ductal Adenocarcinoma

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Cohort A data to be presented in a poster session at the 2025 American Society of Clinical Oncology Gastrointestinal Cancers Symposium

Data reported positive trend in overall survival, including 4 complete responses observed in the certepetide treatment group compared to none in placebo group

Data from Cohort B expected in the coming months, with full data from both cohorts to be reported thereafter

BASKING RIDGE, N.J., Jan. 22, 2025 (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 preliminary Cohort A data from the ongoing Phase 2 ASCEND trial (NCT05042128) being conducted at 25 sites across Australia and New Zealand led by the Australasian Gastro-Intestinal Trials Group (AGITG) and coordinated by the National Health and Medical Research Council (NHMRC) Clinical Trial Centre at the University of Sydney. The data will be presented in a poster session, entitled, *"AGITG ASCEND: Randomized, double-blind Phase II study of certepetide or placebo added to gemcitabine plus nab-paclitaxel in patients with untreated metastatic pancreatic ductal adenocarcinoma: Initial results,"* at the 2025 American Society of Clinical Oncology Gastrointestinal (ASCO GI) Cancers Symposium on Friday, January 24th at 11:30 a.m. - 1:00 p.m. (PST) in San Franscisco, California. For a detailed summary of the poster presentation, please see the abstract available on the ASCO GI website: meetings.asco.org/abstracts-presentations/241497.

The Phase 2 double-blind, randomized (2:1 ratio), placebo-controlled trial is evaluating certepetide, Lisata's proprietary investigational iRGD cyclic peptide product candidate, in combination with standard-of-care (SoC) chemotherapy (gemcitabine and nab-paclitaxel) for the treatment of metastatic pancreatic ductal adenocarcinoma (mPDAC). Following the acquisition of Cend Therapeutics, Lisata collaborated with AGITG to amend the inherited trial's protocol to ensure it respected international regulatory standards and was optimized to generate clinically meaningful data that would effectively guide the next stages of development. The amended protocol is designed to assess the efficacy of two different dosing regimens of certepetide in two separate treatment cohorts: Cohort A, with 95 patients receiving a single intravenous (IV) dose of certepetide 3.2 mg/kg or placebo in combination with SoC, and Cohort B, with 63 patients receiving two IV doses of certepetide 3.2 mg/kg or placebo administered 4 hours apart in combination with SoC.

Cohort A of the ASCEND trial completed enrollment in the third quarter of 2023. The preliminary data from Cohort A demonstrate a median overall survival (mOS) of 12.68 months for the certepetide treated group, compared to 9.72 months for the placebo treated group. Despite a numerical trend in 6-month PFS favoring the certepetide treatment group, no significant improvement in median PFS was observed (mPFS of 5.5 months in both groups). However, the observed mOS and objective response rate (ORR) benefit are positive with 4/65 (6.2%) complete responses in the certepetide treated group, compared to 0/28 (0%) the placebo treated group.

"The data from Cohort A are as we expected and corroborate our decision to add Cohort B to the ASCEND protocol," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "The increase in overall survival and the observation of 4 complete responses in the certepetide-treated group compared to none in the placebo group for Cohort A, coupled with our expectation of even better outcomes in Cohort B, where we believe early indications show a strong separation in mPFS benefiting patients treated with certepetide, support our plans to advance certepetide development to Phase 3 in early 2026."

About Certepetide

Certepetide (formerly LSTA1), an *internalizing* RGD (arginylglycylaspartic acid or iRGD), cyclic peptide product candidate, 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. 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 also has been shown to modify the tumor microenvironment resulting in tumors which are more susceptible to immunotherapies. We and our collaborators have amassed significant non-clinical data demonstrating enhanced delivery of a range of 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 cyclic peptide 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. Learn more about certepetide's

mechanism of action in our short film. 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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