Lisata Therapeutics Announces Encouraging Preliminary Results from the Pancreatic Cancer Cohort of the CENDIFOX Trial

September 29, 2025

Results to be presented at the AACR Special Conference in Cancer Research: Advances in Pancreatic Cancer Research—Emerging Science Driving Transformative Solutions

BASKING RIDGE, N.J., Sept. 29, 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 encouraging preliminary data from the pancreatic ductal adenocarcinoma ("PDAC") cohort of the Phase 1/2a CENDIFOX trial (NCT05121038). The investigator-initiated trial, led by Anup Kasi, M.D., M.P.H., at The University of Kansas ("KU") Cancer Center, is evaluating Lisata's proprietary investigational iRGD cyclic peptide product candidate, certepetide, in combination with FOLFIRINOX-based therapies for the treatment of pancreatic, colon, and appendiceal cancers.

The preliminary data will be presented in poster A070, titled *"CENDIFOX: Phase I/II Trial of CEND-1 (LSTA1, certepetide) with Neoadjuvant mFOLFIRINOX in Resectable and Borderline Resectable PDAC,"* at the American Association for Cancer Research ("AACR") Special Conference in Cancer Research: Advances in Pancreatic Cancer Research—Emerging Science Driving Transformative Solutions on September 29, 2025, from 4:30 p.m. - 7:00 p.m. in Boston, Massachusetts. The poster presentation will highlight findings from patients with resectable and borderline resectable PDAC, with the full abstract available on the AACR website.

"The preliminary trial data has been very promising, and we're excited to share these findings with the broader oncology community," stated Dr. Anup Kasi. "The ability of certepetide to improve drug delivery and influence the tumor microenvironment may offer a potential new and exciting treatment approach for pancreatic cancer. We are optimistic studies like CENDIFOX will pave the way for more effective combination therapies for difficult-to-treat solid tumor cancers."

"The initial results from the CENDIFOX trial are very encouraging, showing that certepetide can enhance the effectiveness of standard-of-care chemotherapy in pancreatic cancer," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "We believe these findings are a significant step forward in a disease with few beneficial treatment options. By improving drug delivery and modulating the tumor microenvironment to re-engage the immune system, we see a path forward for this program and the potential to change the outlook for patients."

The abstract highlights that the combination of certepetide with FOLFIRINOX was safe and feasible in patients with resectable and borderline resectable PDAC, with no serious adverse events attributed to certepetide. Among the 35 patients enrolled in the PDAC cohort, 10 completed the protocol-prescribed pre-surgical courses of therapy and were eligible to undergo pancreatic cancer resection. Based on these 10 patients, the R0 resection rate (no residual cancer at the surgical margins) was 50%, and 70% experienced a pathologic partial response. The results also demonstrated promising early survival data, including a 60% two-year overall survival rate and a 12-month median disease-free survival. Additionally, analysis of tumor tissue demonstrated enhanced immune cell infiltration, along with increased expression of immune markers such as CD68, PD-1, and PD-L1. These findings support the potential of certepetide to transform pancreatic tumors from "immune-cold" to "immune-hot," which may make them more responsive to immunotherapies.

Pancreatic cancer has one of the poorest prognoses among cancers, ranking as the 6th leading cause of cancer mortality worldwide[1]. With a five-year survival rate of just 13%, underscoring the aggressive nature of the disease and the limited efficacy of existing treatments. This highlights the need for the significant investment in new approaches, including targeted therapies and treatment options.

About Certepetide

Certepetide (formerly LSTA1), an *internalizing* RGD (arginyl-glycyl-aspartic 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 the fourth quarter of 2026, encompassing anticipated data milestones from its ongoing and planned clinical trials. For a comprehensive overview of certepetide's mechanism of action, please view our informative short film. For more information on the Company, please visit www.lisata.com.

About The University of Kansas Cancer Center

The University of Kansas Cancer Center is transforming cancer research and clinical care by linking an innovative approach to drug discovery, delivery and development to a nationally accredited patient care program. Our consortium center includes cancer research and health care professionals associated with the University of Kansas Medical Center and The University of Kansas Health System; the University of Kansas, Lawrence; The Stowers Institute for Medical Research; Children's Mercy; and in partnership with members of the Masonic Cancer Alliance.

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 solid tumors; our beliefs about the potential uses and benefits of certepetide; the potential of the collaboration with Catalent to develop new treatment options; the expected expiration of our patents for certepetide; our ability to obtain patent term extension on our U.S. composition of matter patent; 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 preliminary data 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 27, 2025, 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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[1] Bray F, Laversanne M, Sung H, Ferlay J, Siegel RL, Soerjomataram I, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2024;74(3):229–63.