Lisata Therapeutics Announces Completion of Enrollment in the CENDIFOX Trial

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Phase 1b/2a open-label trial in the U.S. of certepetide in combination with neoadjuvant FOLFIRINOX-based therapies in pancreatic, colon and appendiceal cancers

BASKING RIDGE, N.J., Dec. 10, 2024 (GLOBE NEWSWIRE) -- Lisata Therapeutics, Inc. (Nasdaq: LSTA) ("Lisata"), a clinical-stage pharmaceutical company developing innovative therapies for the treatment of advanced solid tumors and other serious diseases, today announced the successful completion of patient enrollment in all three cohorts of the Phase 1b/2a CENDIFOX trial. This investigator-initiated trial, led by Dr. Anup Kasi at The University of Kansas ("KU") Cancer Center, is evaluating the safety and efficacy of Lisata's iRGD cyclic peptide product candidate, certepetide, in combination with FOLFIRINOX-based therapies for pancreatic, colon, and appendiceal cancers.

"The successful enrollment of all three cohorts in the CENDIFOX trial is another significant milestone, bringing us closer to validating certepetide's potential as a transformative treatment for advanced solid tumors," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "By addressing the unmet medical needs of patients with solid tumors, we aim to improve patient outcomes and augment the standard-of-care paradigm. We are excited about the progress of the CENDIFOX trial and eagerly anticipate reporting the results from this important study in 2025."

The open-label CENDIFOX trial is designed to assess the safety and therapeutic effects of combining certepetide with neoadjuvant FOLFIRINOX regimens, with or without panitumumab, across pancreatic, colon, and appendiceal cancers. The study, conducted solely at the KU Cancer Center, enrolled a total of 66 patients (35 resectable and borderline resectable pancreatic cancer patients, 18 high-grade colon and appendiceal cancer patients with peritoneal metastasis, and 13 colon cancer patients with oligo-metastatic disease). The trial will provide Lisata with valuable pre- and post-treatment tumor tissue data for immune profiling, along with long-term patient outcomes information. The trial is funded by the KU Cancer Center and Lisata is supplying certepetide.

"We are delighted to complete enrollment in all three cohorts in the CENDIFOX study and are encouraged by certepetide's potential to improve outcomes for patients with advanced solid tumors," stated Dr. Anup Kasi, the study's Principal Investigator at the KU Cancer Center. "We are eager to analyze the data from each cohort to determine the efficacy of this novel therapy."

For more information on the CENDIFOX trial, please visit www.clinicaltrials.gov/study/NCT05121038.

About Certepetide

Certepetide, an internalizing RGD, or arginylglycylaspartic acid, (iRGD) cyclic peptide product, is an investigational drug designed to selectively activate the C-end rule active transport mechanism in a tissue-specific manner, resulting in systemically co-administered agents more efficiently penetrating and accumulating in the tissue. To date, certepetide has demonstrated favorable safety, tolerability, and clinical activity in completed and ongoing oncology 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. Beyond its promising applications in oncology, certepetide's unique mechanism of action has the potential to be explored in various non-oncology settings. Its ability to selectively target specific tissues could offer new therapeutic possibilities for a range of diseases. 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 internalizing RGD, or arginylglycylaspartic acid, (iRGD) 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.

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 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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