Lisata Therapeutics and WARPNINE Announce Encouraging Preliminary Results from the Phase 1b/2a iLSTA Trial Evaluating Certepetide in Locally Advanced Non-Resectable Pancreatic Ductal Adenocarcinoma

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Data corroborate previously reported preclinical data demonstrating certepetide's ability to enhance the effectiveness of immunotherapy

Preliminary results to be presented at the 2025 ASCO Gastrointestinal Cancers Symposium

BASKING RIDGE, N.J. and SUBIACO, Australia, Jan. 23, 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, and WARPNINE Incorporated ("WARPNINE"), Western Australia's first not-for-profit clinical research organization for pancreatic, gastro-intestinal and rare cancers, today announced encouraging preliminary results from the Phase 1b/2a iLSTA trial (ACTRN12623000223639) evaluating certepetide (formerly LSTA1), Lisata's proprietary investigational iRGD cyclic peptide product candidate, in combination with standard-of-care (SoC) chemotherapy and immunotherapy as a first-line treatment in locally advanced non-resectable pancreatic ductal adenocarcinoma (PDAC). The preliminary data will be presented in a poster session, entitled, *"Immunotherapy combined with a novel iRGD peptide plus nab-paclitaxel and gemcitabine for locally advanced pancreatic ductal adenocarcinoma: A prospective study,"* at the 2025 American Society of Clinical Oncology Gastrointestinal (ASCO GI) Cancers Symposium on Friday, January 24, 2025 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: https://meetings.asco.org/abstracts-presentations/241611

The Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic iLSTA trial, being conducted at St John of God Subiaco Hospital in Western Australia, a leading center for clinical research and innovation, is evaluating certepetide in combination with SoC chemotherapy (nab-paclitaxel and gemcitabine) plus SoC immunotherapy (durvalumab) versus SoC alone in patients with locally advanced non-resectable PDAC. This collaboration highlights the strength of combining global expertise with local excellence to address the urgent needs of patients with pancreatic cancer. Participants in the iLSTA trial were divided into three treatment cohorts (1:1:4 ratio): Cohort 1 (n=5) received SoC chemotherapy in combination with placebo durvalumab and placebo certepetide. Cohort 2 (n=5) received SoC chemotherapy plus certepetide and placebo durvalumab. Cohort 3 (n=20) received SoC chemotherapy plus durvalumab and certepetide. The preliminary results, representing an interim analysis of the first 17 of 30 targeted patients of the iLSTA trial are as follows:

Five of 16 patients evaluable by RECIST criteria experienced a partial response after 2 cycles of treatment (4 patients were in cohort 3), with the remaining 11 patients presenting with stable disease. After 4 cycles of treatment, 9 of 16 patients demonstrated partial response (8 patients were in cohort 3). Of the remaining 7 patients, 6 demonstrated stable disease, and 1 patient (cohort 2) exhibited a complete response. Fourteen of 17 patients who completed 4 treatment cycles showed a decrease in CA19-9 levels. Six patients demonstrated >90% reduction in CA19-9 (5 of whom in cohort 3), with the remaining 8 patients showing a >50% reduction in CA19-9 levels (6 of whom in cohort 3). Five patients had their repeat biopsies analyzed for tumor infiltrating lymphocytes (4 of whom from cohort 3), with all patients showing significant immune cell infiltration (15% to 50% stroma infiltration). These results demonstrate the potential value of adding certepetide to the SoC regimen consisting of gemcitabine, nab-paclitaxel, and durvalumab in this patient population.

"These initial results from the iLSTA trial suggest that certepetide, when combined with SoC chemotherapy and immunotherapy, can positively impact treatment outcomes for patients with locally advanced non-resectable PDAC," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "This patient population has historically demonstrated limited response to immunotherapy alone. These encouraging findings not only validate certepetide's unique mechanism of action but also support our hypothesis that it can enhance the effectiveness of various cancer treatments, regardless of the modality of the co-administered therapies. The results also reinforce certepetide's potential to impact patients across the spectrum of pancreatic cancer."

"The preliminary results from the iLSTA trial underscore the importance of collaborative efforts in addressing the unmet needs of patients with pancreatic cancer," stated Meg Croucher, Chief Executive Officer of WARPNINE. "At WARPNINE, we are dedicated to supporting innovative trials like iLSTA that push the boundaries of treatment possibilities and offer hope to those battling these aggressive malignancies. We look forward to continuing our work with Lisata Therapeutics to advance outcomes for patients."

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.

About WARPNINE Incorporated

WARPNINE is Western Australia's research into pancreatic, gastro-intestinal, and rare cancers. Established by a group of leading cancer specialists, WARPNINE seeks to address the inequity in cancer outcomes for what are essentially underfunded and under-researched malignancies. We are committed to providing real and meaningful benefit to patients, while building on Western Australia's best-in-the-world outcomes for these cancers. For more information on WARPNINE, please visit www.warpnine.org.au.

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; our beliefs about the potential uses and benefits of certepetide; 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.

Lisata Therapeutics Contact:

Investors:
Lisata Therapeutics
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: 908-842-0084
Email: jmenditto@lisata.com

Media:
ICR Healthcare
Elizabeth Coleman
Account Supervisor
Phone: 203-682-4783
Email: elizabeth.coleman@icrhealthcare.com

WARPNINE Contact:

WARPNINE Incorporated:
Meg Croucher
Chief Executive Officer
m: 0406 818 810
e: meg@warpnine.org.au
www.warpnine.org.au

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