



Lisata Therapeutics and WARPnine Announce iLSTA Trial Enrollment Completion and Provide Preliminary Data Update

July 17, 2025

Compelling new preliminary data consistent with previously reported preclinical findings demonstrating certepetide's potential ability to enhance the effectiveness of immunotherapy

BASKING RIDGE, N.J. and SUBIACO, Australia, July 17, 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, gastrointestinal and rare cancers, today announced the successful completion of patient enrollment in the Phase 1b/2a iLSTA trial ([ACTRN12623000223639](https://actrn.gov.au/actrn12623000223639)) in Australia. The study is evaluating certepetide (formerly LSTA1), Lisata's proprietary 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") and was conducted wholly at St John of God Subiaco Hospital, a tertiary private hospital with one of the busiest clinical trial units in the Southern Hemisphere.

"The completion of patient enrollment in the iLSTA trial marks a pivotal moment for Lisata and WARPnine, underscoring our shared dedication to advancing breakthrough therapies for gastrointestinal solid tumors," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "It is especially important to note that this is the first study in which we are evaluating locally advanced non-resectable PDAC, an earlier stage in the disease process than metastatic PDAC. Immunotherapy has largely been ineffective in this patient population, and thus, we were encouraged by the preliminary data presented this year at ASCO-GI, followed by updated preliminary data presented earlier this month at ESMO-GI. We are hopeful that final data from the study will be equally encouraging."

The Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic iLSTA trial is being conducted at St John of God Subiaco Hospital in Western Australia, a leading center for clinical research and innovation with a proven track record in early drug development research. The study is evaluating certepetide in combination with SoC chemotherapy (nab-paclitaxel and gemcitabine) plus SoC immunotherapy (durvalumab), compared to SoC alone, in patients with locally advanced, unresectable PDAC. This collaboration exemplifies the power of uniting global expertise with local excellence to meet the urgent needs of people with pancreatic cancer. It brings together drug supply and clinical strategy from Lisata, drug supply from AstraZeneca, and operational execution and funding support from WARPnine. 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 updated preliminary data from the iLSTA trial, presented at the 2025 ESMO Gastrointestinal Cancers (ESMO-GI) Congress on July 3, 2025, demonstrated an overall response rate of 60% and an overall disease control rate of 100%. After 4 treatment cycles, 13/20 participants showed a RECIST partial response (11 patients in Cohort 3), and 1 participant (Cohort 2) exhibited a RECIST complete response. The remaining 6 participants demonstrated stable disease (<22.0% decrease in tumor size). No participant showed an increase in tumor size. Additionally, 16/20 participants experienced a decrease in CA19-9 levels, with 7 participants showing a >90% reduction (5 patients in Cohort 3) and 9 participants showing a >50% reduction in CA19-9 levels (6 patients in Cohort 3). For a detailed summary of the poster presentation, please see the abstract available on the ESMO-GI website: https://cslide.cimeetingtech.com/coasis_21393/attendee/confcal_1/presentation/list?q=lsta-1.

"We are delighted to have completed enrollment in the iLSTA trial. This achievement not only reflects the dedication of our team and collaborators at St John of God Subiaco Hospital, but also brings us closer to potentially offering a new, much-needed treatment option for patients battling locally advanced PDAC," stated Meg Croucher, Chief Executive Officer of WARPnine. "Given the highly promising preliminary data presented at ESMO-GI, which highlighted a 60% overall response rate and 100% overall disease control rate, we are even more optimistic about the potential impact of this therapy. We look forward to analyzing the final data from the study and continuing our work to bring more effective treatments to those who need them most."

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 WARPINE Incorporated

WARPINE is Western Australia's research into pancreatic, gastro-intestinal, and rare cancers. Established by a group of leading cancer specialists, WARPINE 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 WARPINE, please visit www.warpine.org.au.

About St John of God Subiaco Hospital

St John of God Subiaco Hospital was founded in 1898 by the Sisters of St John of God during the Western Australian Gold Rush of the 1890's. The hospital is one of the leading private hospitals in Australia providing oncology, surgery, obstetrics and gynecology services. The clinical trials unit is one of the busiest in the country currently with 58 open trials and numerous publications from the extensive research carried out at the hospital. The hospital has 578 beds and 20 operating theatres.

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; 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.

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

WARPINE Contact:

WARPINE Incorporated:

Meg Croucher

Chief Executive Officer

Phone: 0406 818 810

Email: meg@warpine.org.au

www.warpine.org.au

This press release was published by a CLEAR® Verified individual.