Lisata Therapeutics and WARPNINE Announce First Patient Treated in the iLSTA Trial of LSTA1, a Novel Tumor-Targeting and Penetrating Peptide, in Patients with Locally Advanced Non-Resectable Pancreatic Ductal Adenocarcinoma

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The iLSTA Trial is the first study combining LSTA1 with standard-of-care chemotherapy and immunotherapy

WARPNINE to provide funding and local trial management

BASKING RIDGE, N.J. and SUBIACO, Australia, April 18, 2023 (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 the treatment of the first patient in the iLSTA Trial of Lisata's LSTA1 in combination with standard-of-care chemotherapy and immunotherapy as a first-line treatment in locally advanced non-resectable pancreatic ductal adenocarcinoma ("PDAC").

The iLSTA Trial is a 30-patient, randomized, single-blind, single-center, safety and pharmacodynamic phase 1b/2a study evaluating LSTA1 in combination with the checkpoint inhibitor, durvalumab, plus standard-of-care chemotherapy, nab-paclitaxel and gemcitabine, versus standard-of-care alone in patients with locally advanced non-resectable PDAC. As the study sponsor, WARPNINE will provide all funding and manage all recruitment activities for the study while Lisata will provide the study drug, LSTA1, as well as regulatory support. WARPNINE and Lisata will share use of the data with the goal of advancing development of LSTA1 toward registration to the benefit of patients in need.

"The iLSTA Trial is potentially the first major opportunity that we have to enable immunotherapy to fully engage against pancreatic cancer as, to date, pancreatic cancer has been resistant to the effects of immunotherapy due to both the hostile tumour microenvironment and the protective layer of tissue surrounding the tumour (called the stroma). The use of LSTA1 in combination with standard-of-care chemotherapy and immunotherapy is intended to both augment chemotherapy delivery into the tumour and facilitate the effects of tumour infiltrating lymphocytes and immunotherapy compounds to optimize therapy against cancer of the pancreas," stated Dr. Andrew Dean, MBChB, MRCP (UK), FRACP, Medical Oncologist, Principal Investigator.

"WARPNINE exists to fund research into pancreatic, gastro-intestinal and rare cancers. We are committed to transform these cancers into curable diseases and addressing the inequity in outcomes for patients and families impacted by these devastating malignancies. The extraordinary support of the WARPNINE community has enabled us to sponsor this innovative and potentially game-changing trial. Community is power and together we are charging at "warp speed" to find the cancer treatments of the future, today," said Meg Croucher, Chief Executive Officer of WARPNINE, iLSTA Trial sponsor.

"Dosing the first patient in our iLSTA Trial of LSTA1 in patients with pancreatic cancer in Australia is an important step in our mission to create new hope for patients by providing meaningful treatments to those with few remaining alternatives. We believe that LSTA1 represents a new treatment option for these patients who haven't been fully served by standard-of-care alone," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Lisata. "We are thrilled by the progress being made to help advance LSTA1 through the clinical trial process and are grateful to WARPNINE for their financial and operational support."

About LSTA1

LSTA1 is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to penetrate solid tumors more effectively. LSTA1 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. LSTA1 also has the potential to modify the tumor microenvironment, with the objective of making tumors 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, LSTA1 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.

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.

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 lead investigational product candidate, LSTA1, is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to penetrate solid tumors more effectively. LSTA1 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, while normal tissues are not affected. LSTA1 also has the potential to modify the tumor microenvironment, with the objective of making tumors more susceptible to immunotherapies. LSTA1 has demonstrated favorable safety, tolerability,

and activity in clinical trials to enhance delivery of standard-of-care chemotherapy for pancreatic cancer. Lisata and its collaborators have also amassed significant non-clinical data demonstrating enhanced delivery of a range of emerging anti-cancer therapies, including immunotherapies and RNA-based therapeutics. Lisata is exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively. 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 strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management 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, statements relating to the long-term success of Lisata's recently completed merger (the "Merger") with Cend Therapeutics, Inc. ("Cend"), including the ongoing integration of Cend's operations; 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: the ongoing COVID-19 pandemic on Lisata's business, 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; unexpected costs, charges or expenses resulting from the Merger; potential adverse reactions or changes to business relationships resulting from the completion of the Merger; potential underperformance of Lisata's business following the Merger as compared to management's initial expectations; 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 March 30, 2023 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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