Lisata Therapeutics Announces Outcome of Interim Futility Analysis for its Phase 2b ASCEND Trial of LSTA1 in Metastatic Pancreatic Ductal Adenocarcinoma

September 6, 2023

Independent Data Safety Monitoring Committee recommends study continuation (criteria for futility not met)

BASKING RIDGE, N.J., Sept. 06, 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, today announced a positive outcome of the prespecified interim futility analysis for the ASCEND trial, a Phase 2b study evaluating LSTA1, Lisata's lead investigational product, in combination with standard-of-care ("SOC") gemcitabine/nab-paclitaxel in patients with first-line, metastatic pancreatic ductal adenocarcinoma ("mPDAC"). Based on the results of the interim futility analysis, which was reviewed by the study's Independent Data Safety Monitoring Committee ("IDSMC"), the ASCEND trial will continue as planned without modification.

"We are pleased that the IDSMC has recommended that we continue the ASCEND trial without change and we see this as an indication of LSTA1's potential to improve outcomes for patients and its acceptable safety profile," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "ASCEND continues to enroll at a rapid pace and we affirm our projection of last patient in during the first half of 2024."

The ASCEND trial is a 155-patient, double-blind, randomized, placebo-controlled Phase 2b clinical trial being conducted at up to 40 sites in Australia and New Zealand, led by the Australasian Gastro-Intestinal Trials Group ("AGITG") in collaboration with the University of Sydney and with the National Health and Medical Research Council ("NHMRC") Clinical Trial Centre at the University of Sydney as the Coordinating Centre. The trial is fully funded by Lisata through an unrestricted research support agreement. The trial is approved by the Sydney Local Health District (SLHD) Ethics Review Committee (Royal Prince Alfred Hospital Zone) (2021/ETH00985). ASCEND, based upon Cohort A (the group receiving a single dose of LSTA1 plus SOC), has 80% power with 95% confidence to detect a 16% increase in the 6-month progression free survival rate in the experimental arm vs. the control arm (SOC + placebo). Trial enrollment completion is projected for the first half of 2024; however, current enrollment already exceeds 80% of the target, so earlier enrollment completion may be achieved.

About LSTA1

LSTA1 is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered (i.e., covalently bound) 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. Lisata and its collaborators have amassed significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies and RNA-based therapeutics. Additionally, LSTA1 has demonstrated favorable safety, tolerability and activity in clinical trials to enhance delivery of SOC chemotherapy for pancreatic cancer. Lisata is exploring the potential of LSTA1 to enable a variety of treatment modalities to treat a range of solid tumors more effectively.

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 product candidate, LSTA1, 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. Based on Lisata's CendR Platform ® Technology, Lisata has already established noteworthy commercial and R&D partnerships. The Company expects to announce numerous clinical study and business milestones over the next two years and has projected that its current business and development plan is funded with available capital through these milestones and into early 2026. For more information on the Company, please visit www.lisata.com.

About the AGITG

The Australasian Gastro-Intestinal Trials Group (AGITG) is a multi-disciplinary collaborative group that undertakes patient-centric research to advance medical care and practice in the treatment of gastro-intestinal cancer. Since 1991, the AGITG has led 74 GI cancer clinical trials, enrolling 8,800 patients across 129 hospitals in Australia and New Zealand, and 125 sites globally.
Learn more

About the University of Sydney

As Australia's first university – founded in 1850 – the University of Sydney has a proud history of global leadership in education and research and inspiring people from all backgrounds to contribute to positive real-world change. The University of Sydney is a world-renowned teaching and research institution – our research combines the expertise and talents of scholars from many disciplines.
Learn more

About the NHMRC Clinical Trials Centre, University of Sydney

Based at the University of Sydney, the NHMRC Clinical Trials Centre designs and manages clinical trials. This includes responsibility for study coordination, monitoring, data acquisition and management and statistical analysis. The NHMRC Clinical Trials Centre has health economics,

biostatistics, systematic reviews and biomarker teams work with trial data and inform healthcare providers about best practice.
Learn more

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 and capital, 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 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 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 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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