Lisata Therapeutics Announces Enhancements to Ongoing Phase 2b ASCEND Trial of LSTA1

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Target enrollment increased to 155 subjects with the addition of a cohort testing a second dose of LSTA1

Results to be used to explore possible conditional approvals globally

Futility analysis results expected in the third quarter of 2023

BASKING RIDGE, N.J., May 24, 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 protocol changes to the ongoing ASCEND trial, a Phase 2b trial evaluating LSTA1, Lisata's lead investigational drug, in combination with standard-of-care ("SOC") gemcitabine/nab-paclitaxel in patients with first-line, metastatic pancreatic ductal adenocarcinoma ("mPDAC"). The objective of the original ASCEND trial was to confirm, in a rigorous, controlled, double-blind study, the positive results of the Phase 1b/2a open label study evaluating LSTA1 in mPDAC patients receiving one dose of LSTA1 plus SOC. The amended protocol retains this objective while adding the goals of optimizing the dose of LSTA1 in this indication and establishing effect size for a possible Phase 3 study. The protocol amendment includes an additional cohort (Cohort B) to assess whether a second dose solely of LSTA1, administered 4 hours after the original dose of LSTA1 plus SOC, will further improve efficacy and patient outcomes.

The ASCEND trial is now 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 ("CTC") at the University of Sydney as the Coordinating Centre. The trial is fully funded by Lisata through an unrestricted research support agreement. 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 ("PFS") rate in the experimental arm vs. the control arm (SOC + placebo). Additionally, the protocol prescribes a futility analysis to be conducted when 30 enrolled patients on the experimental arms have been followed for at least six months. Those results, as determined by an independent data safety monitoring committee, are expected to be announced during the third quarter of 2023. Trial enrollment completion is projected for the second quarter of 2024; however, current enrollment already exceeds 50% of the target, so earlier enrollment completion may be achieved.

"We are excited to announce the enhancements to the ASCEND trial design, including the addition of a second cohort for the evaluation of a second dose of LSTA1 in patients with mPDAC. We intend to use these results to design an efficient Phase 3 program and to explore possible conditional approvals globally," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Lisata. "Pancreatic cancer has one of the highest mortality rates of all cancers and affects hundreds of thousands of patients worldwide each year. Although progress has been made in understanding and treating pancreatic cancer, there remains significant unmet medical need. We are delighted to be working with AGITG and CTC, a preeminent clinical trials group in Australia and New Zealand, to develop this promising potential treatment for patients in serious need."

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. 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 standard-of-care 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 projects the announcement of many clinical study and business milestones over the next 2 years, having indicated 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.

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. We're 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. Our 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, 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, 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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