Lisata Therapeutics and Qilu Pharmaceutical Announce First Patient Treated in Qilu's Phase 2 Trial in China of LSTA1 in Patients with Metastatic Pancreatic Ductal Adenocarcinoma

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Results of Phase 1b/2 in China reinforce global clinical development rationale and plans for LSTA1

BASKING RIDGE, N.J. and JINAN, China, April 23, 2024 (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 Qilu Pharmaceutical Co., Ltd. ("Qilu"), one of the leading vertically integrated pharmaceutical companies in China that develops, manufactures, and distributes both finished products and active pharmaceutical ingredients, announced that the first patient has been treated in Qilu's Phase 2 trial in China evaluating LSTA1 (also known as "CEND-1"), Lisata's lead product candidate, in combination with standard-of-care ("SoC") chemotherapy as a first-line treatment for metastatic pancreatic ductal adenocarcinoma ("mPDAC").

Qilu, the licensee of LSTA1 in Greater China, including Taiwan, Hong Kong and Macau, is enrolling subjects in its Phase 2 120-patient, randomized, double-blind, multi-center, placebo-controlled trial evaluating 3.2 mg/kg of LSTA1 administered as a single IV push in combination with SoC chemotherapy, nab-paclitaxel and gemcitabine, versus SoC alone in patients with mPDAC. The study is planned to take approximately 18 months to complete enrollment accrual and another 13 months for patient follow-up and data analysis and reporting. For more information on this trial, please visit ClinicalTrials.gov (Identifier: NCT06261359).

"In China, both the incidence and prevalence of mPDAC cases are on the rise. Promising data from our completed Phase 1 trial suggest that LSTA1 has the potential to be a safe and effective treatment for mPDAC," stated Xiaoyan Kang, M.D., Chief Medical Officer of Qilu. "We are committed to working with Lisata to bring the potential clinical benefits of LSTA1 to mPDAC patients in China."

"Despite recent advances in cancer treatment, mPDAC is an aggressive disease that results in poor patient outcomes, highlighting the urgent need for innovative therapies," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Lisata. "The first patient enrolled in Qilu's Phase 2 trial in China represents a significant step forward in our mission to improve and extend the lives of patients with pancreatic cancer globally with LSTA1. We are committed to working with Qilu in this partnership to maximize the potential of LSTA1 to address the unmet medical need in mPDAC."

Preliminary data from the Qilu Phase 1b/2 trial (CEND1-201) evaluating LSTA1 (formerly known as CEND-1) in combination with nab-paclitaxel and gemcitabine demonstrated a median overall survival (mOS) of 11.1 months (CI 7.89-14.92). These data corroborate the Phase 1 trial (CEND1-001) conducted in Australia which demonstrated a mOS of 12.8 months (CI 9.9-22.8).

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 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, 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. Pursuant to the Collaboration and License Agreement, Qilu has exclusive rights to LSTA1 in Greater China, including Taiwan, Hong Kong and Macau. Accordingly, Qilu is responsible for all development and commercialization activities and costs in the licensed territories and Lisata is eligible to receive up to $221 million in remaining milestone payments across multiple indications based on certain development and commercial achievements as well as tiered double-digit royalties on product sales in the region.

About Qilu Pharmaceutical

Qilu Pharmaceutical is a leading vertically integrated pharmaceutical company focused on discovering, developing, manufacturing and commercializing both generic and innovative medicines. With a diverse pipeline of novel therapeutics, 12 manufacturing sites and more than 36,000 employees worldwide, Qilu is dedicated to transforming scientific innovation by internal R&D across 6 R&D centers based in the US (Seattle WA, Boston MA, San Francisco CA) and China (Shanghai, Jinan and Haikou), and external partnership globally into healthcare solutions to address unmet medical needs. To date, Qilu has launched 300+ products with 60+ products "First to launch" in China and 3 products "D181 launch" in US with approximately US$5.42 billion sales revenue in 2023. For more information, please visit http://en.qilu-pharma.com.

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.

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, the potential efficacy of LSTA-1 as a treatment for patients with metastatic pancreatic ductal adenocarcinoma and other solid tumors, 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.

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