Haystack Oncology and Lisata Therapeutics Initiate Research Collaboration to Use the Haystack MRD™ Technology to Evaluate Efficacy of Pancreatic Cancer Therapy

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BALTIMORE, Md. and BASKING RIDGE, N.J., July 18, 2024 (GLOBE NEWSWIRE) -- Haystack Oncology, a Quest Diagnostics (NYSE: DGX) company, and Lisata Therapeutics, Inc. (Nasdaq: LSTA), a clinical-stage pharmaceutical company developing innovative therapies for the treatment of advanced solid tumors and other serious diseases, today announced a research collaboration. Lisata will deploy the highly sensitive Haystack MRD™ technology for the detection of circulating tumor DNA (ctDNA) in a clinical study evaluating certepetide plus chemotherapy as an investigational treatment for metastatic pancreatic cancer.

In the FORTIFIDE study, Lisata is investigating the safety, tolerability, and efficacy of its lead product candidate, certepetide, when given as a 4-hour continuous infusion in combination with standard-of-care treatment in subjects with metastatic pancreatic ductal adenocarcinoma (mPDAC) who have progressed on FOLFIRINOX, a treatment for pancreatic cancer. As part of this research, Lisata has engaged Haystack to use its MRD technology to measure serum ctDNA levels at multiple timepoints in patients throughout the study as an exploratory endpoint for analyzing the early therapeutic effect of certepetide. Certepetide 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.

"Our collaboration with Lisata underscores the value of our Haystack MRD technology in helping to drive forward the development of novel treatments for solid tumor cancers," said Dan Edelstein, Vice President and General Manager of Haystack Oncology. "Haystack's technology was engineered to detect ctDNA with exceptional sensitivity, and we aim to continue to gain insights into ctDNA kinetics via serial measurements as an important and early indication of therapeutic response."

The American Cancer Society estimates more than 66,000 individuals nationwide will be diagnosed with pancreatic cancer in 2024. mPDAC accounts for more than 90% of pancreatic cancer cases and is a highly aggressive form of the disease. Typically, mPDAC advances to this stage because of a lack of early diagnosis or limited patient response to treatments.[1]

"A significant challenge in the development of anti-cancer therapies for pancreatic tumors is the early measurement of response to treatment. Most clinical trials evaluating pancreatic cancer require waiting for long-term survival outcomes to discern treatment effect," said Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Lisata. "Conventional response assessment via imaging may lack sensitivity in certain situations, and highly sensitive ctDNA assays offer the potential to quickly identify clinically meaningful biologic activity in difficult to treat cancers. The Haystack MRD test has the level of sensitivity required for us to better identify the selective tumor penetrating effect of certepetide, our lead candidate, for the treatment of solid tumors."

About Haystack Oncology
Haystack Oncology represents the culmination of over 20 years of collaboration to advance technical and clinical development in liquid biopsy technologies by cancer genomics pioneers at Johns Hopkins School of Medicine. The company, a wholly owned subsidiary of Quest Diagnostics, developed Haystack MRD™, a next generation tumor-informed approach for the measurement of minimal residual disease. Haystack MRD uses an error-corrected ctDNA technology to detect down to one ctDNA molecule in a million normal DNA molecules. Haystack Oncology works with biopharmaceutical companies to accelerate and better inform clinical development programs and advance important therapeutics to global markets, from early phase clinical development to companion diagnostics.

Haystack MRD was developed and validated in a CLIA-certified laboratory and is available for testing in laboratories located in Baltimore, Maryland; Hamburg, Germany; and Helsinki, Finland. Learn more at haystackmrd.com.

About Quest Diagnostics
Quest Diagnostics works across the healthcare ecosystem to create a healthier world, one life at a time. We provide diagnostic insights from the results of our laboratory testing to empower people, physicians and organizations to take action to improve health outcomes. Derived from one of the world's largest databases of deidentified clinical lab results, Quest's diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve healthcare management. Quest Diagnostics annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our nearly 50,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives and create a healthier world. www.QuestDiagnostics.com.

About Lisata Therapeutics, Inc
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, certepetide, 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

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 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.

SOURCE Quest Diagnostics

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[1] Metastatic Pancreatic Ductal Adenocarcinoma Symptoms | Pancreatic Cancer Signs (lisata.com)