Lisata Therapeutics and Kuva Labs Announce Global License Agreement for Solid Tumor Imaging

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License provides Lisata's innovative certepetide targeting agent for use with Kuva's NanoMark™ MR imaging platform to advance non-invasive, high-precision cancer diagnostics

BASKING RIDGE, N.J. and HOUSTON, Dec. 03, 2024 (GLOBE NEWSWIRE) -- Lisata Therapeutics, Inc. (Nasdaq: LSTA) ("Lisata"), a clinical-stage pharmaceutical company developing innovative therapies for the treatment of advanced solid tumors and other serious diseases, and Kuva Labs, a wholly owned subsidiary of Mi2 Holdings, LLC ("Kuva"), are pleased to announce a global collaboration and license agreement.

Under the terms of this agreement Kuva gains access to Lisata's iRGD cyclic peptide product candidate, certepetide, as a targeting and enhanced delivery agent to be used with Kuva's NanoMark™ platform technology. This combination creates a new class of advanced magnetic resonance (MR) imaging agents that enable the safe, non-invasive and unambiguous detection of solid tumor cancers.

Under the agreement, Kuva will assume full responsibility for all research, development, and commercialization costs for NanoMark, while Lisata will be responsible for supplying certepetide. The agreement provides significant value creation for both parties and includes an upfront license fee as well as potential substantial milestone payments and royalties on future product sales to Lisata.

"We are excited to join forces with Kuva Labs to further the development of an innovative cancer diagnostic technology while continuing to unlock the full potential of certepetide," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "This license agreement exemplifies certepetide's broad versatility, extending its application beyond our current focus on solid tumor treatments and into the realm of cancer diagnosis. Leveraging certepetide, NanoMark should enable solid tumors to be detected with more diagnostic accuracy, leading to earlier treatment and improved patient outcomes."

"Medical imaging plays a vital role in fighting cancer, but the limitations of current methods hinders rapid and definitive diagnosis," stated Andrew Hopkins, PhD, Chief Scientific Officer of Kuva Labs. "We are excited about our partnership with Lisata. The ability to selectively activate tumor cells enables NanoMark technology to directly MR image just the tumor and will transform the manner in which we see cancer. NanoMark will provide the first targeted, non-radioactive imaging option with unparalleled contrast resolution, significantly advancing the early detection and diagnosis of solid tumors."

More information on the terms of this license agreement can be found in Lisata's corresponding Form 8-K filing as listed under the Investors & News section of the company's website at www.lisata.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 product candidate, certepetide, is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to selectively target and penetrate solid tumors more effectively. Lisata has already established noteworthy commercial and R&D partnerships based on its CendR Platform® technology. The Company expects to announce numerous milestones over the next 1.5 years and believes that its projected capital will fund operations into early 2026, encompassing anticipated data milestones from its ongoing and planned clinical trials.

About Certepetide

Certepetide, an internalizing RGD, or Arginylglycylaspartic acid, (iRGD) cyclic peptide product, is an investigational drug designed to selectively activate the C-end rule active transport mechanism in a tissue-specific manner, resulting in systemically co-administered agents more efficiently penetrating and accumulating in the tissue. To date, certepetide has demonstrated favorable safety, tolerability, and clinical activity in completed and ongoing oncology clinical trials designed to demonstrate its ability to enhance the effectiveness of standard-of-care chemotherapy for pancreatic cancer, as well as the combination of chemotherapy and immunotherapy in a variety of solid tumors. Beyond its promising applications in oncology, certepetide's unique mechanism of action has the potential to be explored in various non-oncology settings. Its ability to selectively target specific tissues could offer new therapeutic possibilities for a range of diseases. Certepetide has been awarded Fast Track designation (U.S.) and Orphan Drug Designation for pancreatic cancer (U.S. and E.U.), as well as Orphan Drug Designation for glioma, osteosarcoma, and cholangiocarcinoma (U.S.). Additionally, certepetide has received Rare Pediatric Disease Designation for osteosarcoma (U.S.).

About Kuva Labs

Kuva Labs is a preclinical bioscience company developing the proprietary NanoMark direct MR imaging platform. Kuva was founded in 2019, after its founders experienced tragic losses in cancer cases which could have been presented with better tools. In partnership with leading oncology research organizations Kuva is seeking to transform the way cancer is seen and ultimately treated. This technology enables the selective and unambiguous imaging of solid tumors with the highest contrast and spatial resolution without the use of ionizing radiation. This information speeds both accurate diagnosis and treatment - delivering better and quicker clinical intervention and better overall outcomes. For more information, please visit www.kuvalabs.com.

About NanoMark

NanoMark is the creation of a new imaging agent with the ability to be selectively targeted and delivered to defined tissue, designed to be directly imaged by MRI, without interference from water or fat and unique imaging sequences, compatible with existing MR assets to deliver those images. Although Kuva's initial focus is on solid cancers, the NanoMark platform presents the optionality to target many different tissues and deliver a new, and ubiquitous imaging modality.

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 cholangiocarcinoma 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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