Lisata Therapeutics Receives Paediatric Investigation Plan Waiver from the European Medicines Agency for Certepetide in Pancreatic Cancer

May 20, 2024

Waiver confirms that paediatric studies of certepetide in pancreatic cancer are not needed

Significant clinical trial burden and costs avoided due to waiver

BASKING RIDGE, N.J., May 20, 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, today announced that it has reached agreement with the European Medicines Agency (the "EMA") on a Paediatric Investigation Plan ("PIP") for Lisata's lead investigational product, certepetide (formerly LSTA1), in pancreatic cancer. The EMA has agreed to a product-specific full pediatric waiver for certepetide in pancreatic cancer.

The Paediatric Committee ("PDCO") of the EMA recommended and the EMA granted a waiver for certepetide for all subsets of the pediatric population for the treatment of pancreatic cancer on the grounds that "pancreatic cancer occurs only in adults." This waiver removes any requirement for Lisata to conduct clinical studies of certepetide in children in support of an overall marketing authorization application in Europe for pancreatic cancer. It also allows Lisata to focus its development efforts on bringing this therapy to relevant patients with pancreatic cancer as quickly as possible. By eliminating any requirement for pediatric clinical studies in pancreatic cancer, the waiver significantly reduces the clinical trial burden and overall cost of completing development and achieving market registration in Europe.

"We are pleased that the European Medicines Agency has confirmed that pediatric studies evaluating certepetide are not needed to support a market authorization application in pancreatic cancer," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "With a waiver in hand, we are now able to streamline our development program as we work toward certepetide's product registration in Europe. This full waiver is specific to pancreatic cancer and will not affect our commitment to evaluate certepetide in other pediatric solid tumors as required."

In 2007, the European Union implemented the Paediatric Regulation, a landmark change that significantly impacted the development of medicines for children. This regulation aims to increase the research and development of medicinal products; specifically, those applicable to children. A key part of the regulation was the establishment of the PDCO. The PDCO coordinates the EMA's work on pediatric medicines by determining the study(ies) companies must conduct in children as part of their overall development program for Europe. A PIP is a development plan designed to ensure that the necessary data are obtained through studies in children to support the authorization of a medicine for children. In some instances, a PIP waiver by the PDCO for certain conditions is recommended and then granted by the EMA when development of a medicine for use in children is not feasible or appropriate.

About Certepetide

Certepetide (formerly 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. Certepetide 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. Certepetide also has been shown to modify the tumor microenvironment diminishing the immunosuppressive nature of the tumor microenvironment and inhibiting the metastatic cascade. 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, certepetide 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. Lisata is exploring the potential of certepetide to enable a variety of treatment modalities to treat a range of solid tumors more effectively. 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 (U.S.) and osteosarcoma (U.S.). Additionally, certepetide has received Rare Pediatric Disease Designation for osteosarcoma (U.S.).

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, certepetide (formerly LSTA1), 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 two years and believes that its projected capital will fund operations into early 2026, encompassing anticipated data milestones from its ongoing and planned clinical trials. 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.

Contact:

Investors and Media:

Lisata Therapeutics, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: 908-842-0084
Email: jmenditto@lisata.com

Media:

ICR Westwicke
Elizabeth Coleman
Senior Associate
Phone: 203-682-4783
Email: elizabeth.coleman@westwicke.com