Lisata Therapeutics and Valo Therapeutics Announce Preclinical Research Collaboration

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Study will investigate the benefits of combining Lisata's novel product candidate, certepetide, with ValoTx's platform technology, PeptiCRAd, and a checkpoint inhibitor in preclinical tumor models

BASKING RIDGE, N.J. and HELSINKI, Nov. 06, 2024 (GLOBE NEWSWIRE) -- Lisata Therapeutics, Inc. (Nasdaq: LSTA), a clinical-stage pharmaceutical company developing innovative therapies for the treatment of advanced solid tumors and other serious diseases, and Valo Therapeutics Oy ("ValoTx"), a private company developing novel, adaptable immunotherapies for the treatment of cancer, are pleased to announce a preclinical research collaboration to investigate the benefits of combining Lisata's novel product candidate, certepetide, with ValoTx's innovative platform technology, PeptiCRAd, and a checkpoint inhibitor in a melanoma mouse model. Under the agreement, ValoTx will be conducting the research, while Lisata will supply certepetide product.

"Building on previous preclinical work demonstrating certepetide's synergistic effects with immunotherapies, we aim to uncover additional benefits by combining certepetide with ValoTx's PeptiCRAd immunotherapy," stated Kristen K. Buck, M.D., Executive Vice President of Research and Development and Chief Medical Officer of Lisata. "Given the complementary mechanisms of action of these therapies, including certepetide's ability to modify the tumor microenvironment making it less immunosuppressive, we believe this approach could ultimately lead to improved patient outcomes by addressing the challenges facing current melanoma treatments, including resistance, recurrence, and metastasis."

"We are thrilled to partner with Lisata Therapeutics on this promising research collaboration," stated Sari Pesonen, Ph.D., Chief Executive Officer and Chief Scientific Officer of ValoTx. "The combination of our proprietary PeptiCRAd and Lisata's innovative certepetide tumor targeting and penetration technology has the potential to unlock new frontiers in cancer immunotherapy. Together, we hope to accelerate the development of more effective treatments for patients in desperate need, ultimately translating our preclinical findings into life-changing therapies for cancer patients."

Melanoma is a serious and potentially life-threatening form of skin cancer. According to the World Health Organization, melanoma is amongst the leading causes of cancer-related deaths globally, responsible for approximately 58,000 deaths annually. Current standard-of-care includes checkpoint inhibitor therapies with an overall response rate of 35-60%. Despite advancements in treatment, there remains a significant unmet need for effective therapies, particularly for patients with advanced or metastatic disease.

About Certepetide

Certepetide is an investigational drug designed to selectively activate the C-end rule active transport mechanism in a tumor specific manner, resulting in systemically co-administered anti-cancer agents more efficiently penetrating and accumulating in the tumor. Additionally, certepetide has been shown to modify the tumor microenvironment, diminishing its immunosuppressive nature and inhibiting the metastatic cascade. Lisata and its collaborators have amassed significant non-clinical data demonstrating enhanced delivery of various existing and emerging anti-cancer therapies, including chemotherapies, 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 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. 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 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 internalizing RGD, or Arginylglycylaspartic acid, (iRGD) cyclic peptide 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. Learn more about certepetide's mechanism of action in our short film . For more information on the Company, please visit www.lisata.com.

About PeptiCRAd

The PeptiCRAd platform is a unique immunotherapy technology that uses replication-competent adenoviruses engineered for a multifaceted approach. This virus-based platform can be customized to activate the tumor microenvironment ("TME") optimally. Its lead candidate, PeptiCRAd-1, encodes two immunostimulatory proteins—CD40L and OX40L—that are directly delivered to the TME. What sets PeptiCRAd apart from other viral immunotherapies is its ability to carry multiple tumor antigens on the virus surface, eliciting broad T-cell and antibody responses against multiple tumor antigens simultaneously. These antigens are easy to mix and match, enabling targeted treatment against the varied tumor antigen profiles in solid tumors. PeptiCRAd can be administered subcutaneously or directly into tumors, depending on disease stage. As a monotherapy, PeptiCRAd has demonstrated an abscopal effect and the induction of protective memory responses upon rechallenge with the previously treated tumor. Currently, PeptiCRAd-1, targeting NY-ESO-1 and MAGE A3-expressing tumors, is in Phase 1 clinical testing with pembrolizumab for triple-negative breast cancer, non-small cell lung cancer, melanoma, and sarcoma.

About Valo Therapeutics

Valo Therapeutics Oy (ValoTx) is an immunotherapy company developing tumor antigen-coated replication-competent viruses as therapeutic vaccines against cancer. The ValoTx lead platform, PeptiCRAd (Peptide-coated Conditionally Replicating Adenovirus), was developed out of the laboratory of Professor Vincenzo Cerullo at the University of Helsinki. It turns oncolytic adenoviruses into powerful activators of systemic anti-tumor cytotoxic T-cell immunity without the need to generate and manufacture multiple genetically modified viruses. PeptiCRAd-1 is the company's lead product made up of its proprietary virus VALO-D102 coated with MAGE-A3 and NY-ESO-1 peptides. The company is also developing PeptiCHIP, an innovative microchip-based solution that enables rapid, accurate, and standardized tumor neoantigen identification from very small tumor biopsies. Watch our film explaining the PeptiCRAd technology. For more information see our website and follow us on LinkedIn.

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 melanoma 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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