Lisata Therapeutics and GATC Health Expand Relationship to Advance AI-Driven Drug Discovery and Development

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Expanded alliance combines Lisata's drug development expertise with GATC's AI-powered Multiomics Advanced Technology ® platform to accelerate and improve success rates of next-generation drug development

Lisata to lead development efforts to advance GATC's AI-discovered therapeutic for opioid use disorder into human clinical trials early in 2026

BASKING RIDGE, N.J. and IRVINE, Calif., June 17, 2025 (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 GATC Health Corp. ("GATC"), a leading tech-bio company leveraging artificial intelligence (AI) to transform drug discovery and development, today announced a strategic alliance designed to accelerate and improve the success rate of the traditional drug development process.

This collaboration builds on the foundation of earlier work performed by GATC for Lisata, in which GATC provided AI-derived analysis in support of Lisata's certepetide drug candidate. Under the expanded relationship, Lisata will enhance its therapeutic pipeline by leveraging GATC's proprietary Multiomics Advanced Technology® (MAT) platform to identify new AI-predicted combination therapies (including with certepetide) across all therapeutic areas. This approach not only opens the door to new treatment possibilities but also ensures that any resulting intellectual property will be derisked by the MAT analysis, providing predictions of safety, efficacy and side effects with a high degree of certainty.

Under the agreement, Lisata's team will contribute its proven capabilities in drug development along with its regulatory prowess to the relationship, as the companies advance the first development program for a promising new therapeutic agent targeting opioid use disorder (OUD). Discovered by GATC's MAT platform, this OUD candidate is a non-opioid small molecule new chemical entity for which preclinical studies have demonstrated a significant reduction in fentanyl intake in validated murine models. In the advanced preclinical stage, GATC's OUD asset is targeted to enter Phase 1 human trials early next year, confirming Lisata's ability to accelerate and optimize the overall development and regulatory process while also validating the ability of GATC's AI technology to generate novel drug candidates with a strong probability of development success.

"We are thrilled to join with GATC to create a much improved AI-driven paradigm of drug discovery and development. Studies predict AI technologies could create as much as $350 to $400 billion in value to the pharmaceutical industry by the end of 2025 while also shortening the drug discovery process from 5-6 years down to as little as one year[1]. This strategic alliance could be a blueprint for combining the power of advanced AI discovery with deep development expertise to unlock new therapeutic possibilities and bring potentially life-saving treatments to patients faster, more efficiently and at significantly lower cost," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "We see the arrangement between Lisata and GATC as being both strategically and financially symbiotic for our companies. I'm eager to see the successful advancement of many MAT-discovered compounds through development to patients in need starting with GATC's OUD molecule."

Validated Technology Platform

Using its MAT platform, GATC's advanced analytic reports provide critical insights regarding a drug candidate's likelihood of success or failure in the development process. Each report includes a simple ranking system to understand key metrics quickly, while the body of the report elucidates how and why a drug candidate is likely to perform positively or negatively. Validated by the University of California, Irvine, the MAT platform has predicted sensitivity at 86% and specificity at 91%. We believe, in the near future, that systems like the MAT platform will be well positioned to satisfy the FDA's recent data requirements for New Approach Methodologies, which prioritize human-relevant data over animal-based studies.

Strategic Pipeline Acceleration

"Our MAT platform continues to demonstrate its ability to rapidly identify promising drug candidates, a capability confirmed by our OUD candidate," stated Jayson Uffens, CTO at GATC Health. "Advancing this asset with Lisata marks a significant step forward in our collaboration. Their team brings a wealth of experience, which includes nearly two centuries of cumulative experience in drug development and several dozen product approvals. Their expertise, established infrastructure, history of capital efficiency, and proven ability to efficiently design and execute clinical and regulatory strategies will be instrumental in accelerating the development of our OUD drug candidate through the development process as we eventually seek a licensing or commercial partner."

Under the collaboration, GATC will assume all R&D costs for GATC development assets and Lisata will receive milestone fees and industry-standard royalties based on the net sales of any successfully commercialized products as defined on a per project basis. GATC will receive a licensing fee for any assets identified by the MAT system and acquired by Lisata.

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 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 the third quarter of 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 GATC Health Corp.

GATC Health Corp. is a technology company that is transforming drug discovery and development through its AI-driven platform and approach. The company's validated and proprietary Multiomics Advanced Technology™ ("MAT") simulates human biochemistry's billions of interactions to rapidly create novel therapeutics, identify and confirm targets, accelerate development, and derisk drug pipelines by predicting efficacy, safety, and off-target effects. Founded in 2020, GATC Health is headquartered in Irvine, CA, and has facilities in Utah, West Virginia and Washington DC.

For more information, visit https://gatchealth.com/.

About GATC Health's Multiomics Advanced Technology™ (MAT) AI Platform

GATC's Multiomics Advanced Technology® ("MAT") platform was built on advanced artificial intelligence (AI) technologies providing the capacity to accurately simulate systems biology to expedite drug development and optimize treatments. The MAT platform models disease states, identifies and validates targets, creates novel chemical entities ("NCEs") in silico, and predicts safety, efficacy and off-target outcomes with >85% precision. MAT can analyze 400 trillion data points (2,500 whole exomes) in less than eight minutes without the use of supercomputing technologies.

About GATC's OUD drug candidate

GATC Health's opioid use disorder (OUD) drug candidate is a novel, non-opioid therapy developed using advanced AI and multiomics technology. Its unique mechanism targets receptors to restore dopamine balance, anti-rumination, and increases in creativity, cognitive flexibility, and mood elevation. Preclinical studies showed significant reduction in fentanyl self-administration in animal models. With a fraction of people suffering from addiction seeking treatment, GATC's differentiated approach could make it a strong commercial contender in the large and growing addiction treatment market.

[1] https://www.scilife.io/blog/ai-pharma-innovation-challenges

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 of the strategic alliance between the Company and GATC Health to develop an OUD drug candidate and other treatment options; the potential benefit of AI-driven technologies to the drug development process; the potential efficacy of certepetide as a treatment for patients with solid tumors; our beliefs about the potential uses and benefits of certepetide; 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 27, 2025, 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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