Rein Therapeutics and Qureight Ltd Announce Planned Integration of Deep-Learning Platform for Phase 2 Trial of LTI-03 in Patients with IPF

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AUSTIN, Texas, May 1, 2025 /PRNewswire/ -- Rein Therapeutics ("Rein") (NASDAQ: RNTX), a biopharmaceutical company advancing a novel pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications, and Qureight Ltd, a Core Imaging Laboratory developing deep-learning image analytics, today announced a collaboration for the integration of Qureight's deep-learning platform into Rein's planned Phase 2 trial of its lead asset LTI-03, a novel, multi-pathway, Caveolin-1-related peptide, for the treatment of idiopathic pulmonary fibrosis (IPF).

Rein previously announced positive topline results from Cohort 2 (5 mg BID) of the Phase 1b clinical trial of LTI-03 in IPF, in which a positive trend was observed in seven out of eight biomarkers evaluated, with five biomarkers demonstrating dose-dependent effects and four biomarkers achieving statistical significance in the combined Cohort 1 and Cohort 2 data set.

The Phase 2 clinical trial of LTI-03 will evaluate the safety and tolerability of LTI-03 in patients with IPF, as well as its activity across multiple biomarkers, and measure lung function and the potential for healthy tissue regeneration. In the trial, Qureight will provide full end-to-end imaging core lab services, including site qualification, data handling, quality control and deep-learning AI image analysis. Qureight's deep-learning platform will be used to analyze lung imaging data and identify potential correlations between any volumetric changes within the lungs of IPF patients and LTI-03's activity across the biomarkers. Qureight's AI tools will measure the volume of fibrotic, vascular and airway lung compartments to allow a more detailed examination of LTI-03's potential ability to simultaneously modulate pro-fibrotic activity and protect critical alveolar epithelial cells. Additionally, Qureight's technology is designed to improve the efficiency of the clinical trial workflow and significantly reduce the time required for image interpretation, in turn accelerating the trial.

"In our Phase 1b clinical trial of LTI-03, we emphasized the importance of biomarkers for measuring progress in patients with IPF treated with LTI-03 as well as for illustrating the dual mechanism of LTI-03 in the body," said Brian Windsor, Ph.D., President and Chief Executive Officer of Rein Therapeutics. "We are taking the evaluation of biomarkers a step further with the application of cutting-edge deep-learning imaging technology and detailed AI-based data analysis by collaborating with Qureight on this Phase 2 trial. These tools will be critical in gaining a deeper understanding of the potential therapeutic effect of LTI-03."

Dr. Muhunthan Thillai, Chief Executive Officer of Qureight, said, "We're delighted that our core platform and AI technology will be supporting Rein Therapeutics in advancing its treatment, LTI-03, for patients with IPF. Our AI tools will provide precise, quantitative insights into how LTI-03 affects lung structure and function. This partnership represents another milestone in accelerating fibrotic lung disease treatment, which is so desperately needed for patients."

Rein plans to announce further details on the design of the Phase 2 trial of LTI-03 in IPF in the near term.

About IPF

IPF is a chronic lung disease characterized by progressive tissue scarring that prevents proper lung function. It is a progressive, fatal, age-associated lung disease affecting approximately 100,000 people in the United States[1]. IPF typically presents in adults 65 or older and is usually fatal within two to five years after diagnosis[2].

About LTI-03 and Caveolin-1 (Cav1)

LTI-03 is a seven amino acid peptide, the sequence of which is derived from the caveolin scaffolding domain (CSD), an important binding region of the Cav1 protein. Cav1 normally serves a critical function in the prevention of fibrosis by maintaining a balance between pathways that both initiate and arrest lung repair and cell movement. Through the CSD, caveolin interacts with a large number of signaling molecules, all of which possess a caveolin binding domain region. Cav1 expression is decreased in IPF lung tissues and has been demonstrated to decrease during the fibrotic phase of bleomycin, or BLM, lung injury in mice. Restoring the balance of important biological signals in the lung may not only slow lung function decline but could also restore healthy lung function through the protection of healthy epithelial cells.

About Rein Therapeutics

Rein Therapeutics is a clinical-stage biopharmaceutical company advancing a novel pipeline of first-in-class therapies to address significant unmet medical needs in orphan pulmonary and fibrosis indications. Rein's lead product candidate, LTI-03, is a novel, synthetic peptide with a dual mechanism targeting alveolar epithelial cell survival as well as inhibition of profibrotic signaling. A Phase 2 clinical trial of LTI-03 for the treatment of idiopathic pulmonary fibrosis is anticipated to be initiated in the first half of this year. Rein's second product candidate, LTI-01, is a proenzyme that has completed Phase 1b and Phase 2a clinical trials for the treatment of loculated pleural effusions. LTI-01 has received Orphan Drug Designation in the U.S. and E.U. and Fast Track Designation in the U.S. For more information, please visit the company's website at reintx.com, or follow them on LinkedIn and X.

About Qureight

Founded in 2018 and headquartered in Cambridge, UK, Qureight is a Core Imaging Laboratory, a rapidly-scaling techbio company deploying its technology on a global scale. The cloud-based, vendor-agnostic Core Imaging Platform is GDPR, HIPPA and NHS Digital compliant. The platform has ISO13485 and ISO27001 accreditation to interrogate clinical trial data. The team is led by co-founder & CEO Dr Muhunthan Thillai, a pulmonologist who trained in lung fibrosis.

References

[1]Pergolizzi, Jr., J., LeQuang, J., Varrassi, M., Breve, F., Magnusson, P., Varrassi, G., (2023). What Do We Need to Know About Rising Rates of Idiopathic Pulmonary Fibrosis? A Narrative Review and Update. Springer Nature, Published online 2023 Jan 24. Doi: 10.1007/s12325-022-02395-9.

[2]Nathan et al. "Long-term Course and Prognosis of Idiopathic Pulmonary Fibrosis in the New Millennium". Chest Journal Volume 140, ISSUE 1, P221-229, July 2011.

Forward-Looking Statements

This press release may contain forward-looking statements of Rein Therapeutics, Inc. ("Rein", the "Company", "we", "our" or "us") within the meaning of the Private Securities Litigation Reform Act of 1995, including statements with respect to: the timing of the planned Phase 2 clinical trial of LTI-03; the integration of Qureight Ltd.'s ("Qureight") deep-learning platform into the planned Phase 2 clinical trial; and future expectations, plans and prospects for the Company. We use words such as "anticipate," "believe," "estimate," "expect," "hope," "intend," "may," "plan," "predict," "project," "target," "potential," "would," "can," "could," "should," "continue," and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks and uncertainties related to: changes in applicable laws or regulations; the possibility that the Company may be adversely affected by other economic, business, and/or competitive factors, including risks inherent in pharmaceutical research and development, such as: adverse results in the Company's drug discovery; preclinical and clinical development activities; the risk that the results of preclinical studies and early clinical trials may not be replicated in later clinical trials, including in the planned Phase 2 clinical trial of LTI-03, or that partial results of a trial will be indicative of the full results of the trial; the Company's ability to enroll patients in its clinical trials; and the risk that any of its clinical trials may not commence, continue or be completed on time, or at all; the Company's ability to successfully integrate Qureight's deep-learning platform into its planned Phase 2 clinical trial of LTI-03; decisions made by the U.S. Food and Drug Administration and other regulatory authorities; investigational review boards at clinical trial sites and publication review bodies with respect to the our development candidates; our ability to obtain, maintain and enforce intellectual property rights for our platform and development candidates; competition; the sufficiency of the Company's cash resources to fund its planned activities for the periods anticipated and the Company's ability to manage unplanned cash requirements; and general economic and market conditions; as well as the risks and uncertainties discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2024, which is on file with the United States Securities and Exchange Commission (the "SEC") and in subsequent filings that the Company files with the SEC. These forward-looking statements should not be relied upon as representing the Company's view as of any date after the date of this press release, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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