Rein Therapeutics Wins U.K. Approval to Launch Phase 2 Clinical Trial of LTI-03 in Idiopathic Pulmonary Fibrosis

August 19, 2025

AUSTIN, Aug. 19, 2025 (GLOBE NEWSWIRE) -- 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, today announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has authorized the Company to initiate its Phase 2 "*RENEW*" clinical trial of LTI-03, the Company's lead drug candidate for idiopathic pulmonary fibrosis (IPF).

IPF is a serious, progressive lung disease that affects hundreds of thousands of people worldwide. It scars the lungs, leaving patients short of breath and with limited treatment options. Median survival after diagnosis is just 3–5 years.

Rein's LTI-03 is a first-in-class therapy that is designed to directly target fibrosis while also protecting the lung's ability to regenerate healthy tissue. If successful, it could represent a major breakthrough in how pulmonary fibrosis is treated.

Brian Windsor, Chief Executive Officer of Rein Therapeutics, commented, "This MHRA approval marks an important milestone not only for Rein, but also for patients living with IPF. We are now working towards patient recruitment in the U.K., advancing LTI-03 into the next stage of development. Our approach is designed not only to slow disease progression, but also to preserve, and potentially restore, the lung cells that are critical to everyday breathing and quality of life. We believe LTI-03 has the potential to transform outcomes for patients while also creating substantial value for our shareholders."

Next Steps

The *RENEW* trial is expected to enroll up to 120 patients worldwide, evaluating two dose groups of LTI-03 against a placebo. The primary objective of the trial is to assess safety and tolerability over 24 weeks of treatment. Secondary endpoints will include measures of lung function and imaging-based assessments of fibrosis progression.

Rein is actively working with clinical sites in the UK to begin patient recruitment soon, with initial data expected in 2026.

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. LTI-03 has received Orphan Drug Designation in the U.S. and is in clinical development. 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.

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 expectations for the Company's LTI-03 product candidate, the planned UK Phase 2 clinical trial of LTI-03 and the initial data readouts from the planned UK clinical trial. 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 (i) the risk that the Company may not be able to successfully undertake the planned UK Phase 2 clinical trial of LTI-03, (ii) success in early phases of pre-clinical and clinicals trials do not ensure later clinical trials will be successful; (iii) the risk that the Company may not be able to obtain additional working capital with which to initiate and complete planned UK clinical trial, (iv) the risk that the Company may not be able to announce initial data readouts from the planned UK clinical trial in 2026 or, if it is able to do so, that the data may not be favorable and (v) those other risks disclosed 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.

Rein Investor Relations & Media Contact:

Investor Relations

IR@ReinTx.com