Rein Therapeutics Doses First Patient in Phase 2 Trial of LTI-03 for Idiopathic Pulmonary Fibrosis

March 3, 2026

Randomized, placebo-controlled study to evaluate safety, tolerability, and potential for positive impact on lung function

AUSTIN, Texas, March 03, 2026 (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, announced that it has dosed the first patient in its Phase 2 clinical trial evaluating LTI-03 for idiopathic pulmonary fibrosis (IPF), a progressive and fatal lung disease with limited treatment options.

This milestone follows the FDA's recent clearance to resume the Phase 2 program and reflects Rein's successful efforts to address the Agency's requests and advance the trial. The Phase 2 study is a randomized, double-blind, placebo-controlled trial designed to evaluate the safety, tolerability, and impact to lung function and structure of LTI-03, an inhaled therapy intended to regulate multiple fibrosis pathways and preserve lung function.

The study will enroll approximately 120 patients across placebo, low dose, and high dose groups at clinical sites in five countries. In addition to safety and tolerability, the trial will closely monitor changes in lung function, including forced vital capacity (FVC), a key tool in the measurement of respiratory health in patients with IPF.

Rein expects to enroll patients through mid-2027, with interim data anticipated in the second half of 2026.

Brian Windsor, Ph.D., Chief Executive Officer of Rein Therapeutics, commented, “Dosing the first patient in this Phase 2 trial marks an important step forward for Rein and, more importantly, for patients living with IPF. Current therapies offer limited benefit and often come with significant side effects. Our goal with LTI-03 is to go beyond slowing disease progression and help preserve lung function by addressing the underlying biology of fibrosis. This milestone reflects our team's focus on execution and brings us closer to understanding the potential impact of LTI-03 for patients.”

The trial is currently active at five clinical sites in the United States, with more sites expected to open in the coming months. Rein plans to expand to up to 50 sites as enrollment progresses.

Idiopathic pulmonary fibrosis affects approximately 100,000 people in the United States each year and is characterized by scarring of lung tissue, leading to progressive loss of lung function and a median survival of three to five years from diagnosis.

LTI-03 is designed to mimic the activity of Caveolin-1, a cell associated protein that plays a role in regulating normal tissue function and repair. By modulating multiple fibrotic pathways and supporting the health of alveolar epithelial progenitor cells, LTI-03 aims to address the underlying drivers of fibrosis rather than targeting a single pathway.

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. 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. 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 Phase 2 clinical trials of LTI-03; (ii) the data derived from our Phase 2 clinical trials of LTI-03 may not support or validate our expectations concerning the potential benefits of LTI-03; (iii) success in early phases of pre-clinical and clinical trials do not ensure later clinical trials will be

successful; (iv) the risk that the Company may not be able to obtain additional working capital with which to complete the planned clinical trials of LTI-03; 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.

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