Rein Therapeutics Announces First Patient Dosed in RENEW Phase 2 Trial of LTI-03 in Patients with IPF

May 27, 2025

Trial is evaluating the safety, tolerability, and efficacy of LTI-03 in idiopathic pulmonary fibrosis (IPF) with topline interim data expected in the first half of 2026

AUSTIN, Texas, May 27, 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, announced today that the first patient has been dosed in the RENEW Phase 2 trial of its lead asset, LTI-03, a novel, multi-pathway, Caveolin-1-related peptide for the treatment of IPF.

"We are pleased to have dosed the first patient in our RENEW Phase 2 trial of LTI-03 following initiation of the trial. We are profoundly focused on our mission to rein in fibrosis and look forward to continuing our momentum in the clinic," said Brian Windsor, Ph.D., President and Chief Executive Officer of Rein Therapeutics. "We are encouraged by the strong body of evidence supporting LTI-03 as a potentially innovative treatment for patients with IPF whose needs are unmet by the current standard of care (SoC). I am grateful to our team at Rein, the patients, investigators, and staff participating in our trial for the efficient progress that we are making."

The RENEW trial is a Phase 2 multi-center, randomized, double-blind, placebo-controlled study evaluating the safety, tolerability, and efficacy of LTI-03 in patients with IPF. Rein is collaborating with IQVIA (NYSE: IQV), a leading global provider of clinical research services, commercial insights and healthcare intelligence to the life sciences and healthcare industries, on enrollment for the trial. RENEW is designed to enroll approximately 120 patients diagnosed with IPF within 5 years of screening, who may be receiving SoC antifibrotic therapy, across up to 50 sites globally. The primary endpoint for the trial is the incidence of treatment-emergent adverse events (TEAEs) from Day 1 through Week 24. The key secondary endpoint is the efficacy of LTI-03 measured through forced vital capacity (FVC), percent predicted FVC (ppFVC), and high-resolution computer tomography (HRCT), in collaboration with Qureight Ltd. Topline interim data from RENEW is expected in the first half of 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 currently being evaluated in a Phase 2 trial, titled the RENEW trial, in patients with idiopathic pulmonary fibrosis. 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.

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 RENEW

Phase 2 clinical trial of LTI-03, including with respect to the timing of the trial and the assumption that the Company will raise the funds necessary to conduct the trial; the therapeutic potential of LTI-03; 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: the ability of the Company to obtain the cash resources to fund the RENEW Phase 2 trial through its completion and the Company's operations for the anticipated periods and the Company's ability to manage unplanned cash requirements; 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 RENEW Phase 2 trial, 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 Ltd.'s deep-learning platform into the RENEW Phase 2 trial; 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 our development candidates; 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.

Rein Investor Relations & Media Contact:
Argot Partners
rein@argotpartners.com
212-600-1902

View original content to download multimedia:https://www.prnewswire.com/news-releases/rein-therapeutics-announces-first-patient-dosed-in-renew-phase-2-trial-of-lti-03-in-patients-with-ipf-302464618.html

SOURCE Rein Therapeutics, Inc.