Rein Therapeutics Announces Initiation of RENEW Phase 2 Trial of LTI-03 in Patients with IPF

May 12, 2025

The RENEW Phase 2 trial will enroll up to 120 IPF patients with topline data expected in the first half of 2026

In the previously reported Phase 1b study, LTI-03 showed a positive trend in seven out of eight biomarkers evaluated in Cohort 2, with five showing dose dependence and four showing statistically significant improvement in the combined Cohort 1 and 2 data set

AUSTIN, Texas, May 12, 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, today announced that the RENEW 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), has been initiated with screening and recruitment of patients underway.

"The initiation of the RENEW trial in patients with IPF marks a significant step forward for Rein as we prepare to ultimately identify and share the potential benefits of LTI-03 on patient lung function," said Brian Windsor, Ph.D., President and Chief Executive Officer of Rein Therapeutics. "Following productive FDA interactions and positive topline results from the Phase 1b trial, we have designed our RENEW trial to test the promise of our dual mechanism approach to targeting alveolar epithelial cell survival and the inhibition of profibrotic signaling in this patient population. We are pleased to have begun screening patients for RENEW."

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. In addition, the trial is designed to assess the activity of inhaled dry powder LTI-03 across multiple biomarkers and to measure lung function and the potential for healthy tissue regeneration. The trial is designed to enroll approximately 120 patients diagnosed with IPF within 5 years of screening, who may be receiving standard of care (SoC) antifibrotic therapy, across up to 50 sites globally, including sites in the United States (U.S.), United Kingdom (U.K.), Germany, Austria and Poland.

Patients will be randomized into two blinded placebo-controlled cohorts that will run concurrently. Patients in the low dose cohort will receive 2.5 mg of either LTI-03 or placebo administered twice daily (BID) for a total dose of 5 mg/day, while participants in the high dose cohort will receive 5 mg BID for a total dose of 10 mg/day. The primary endpoint 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. Patients will undergo a 28-day screening period prior to being randomized and entering the 24-week treatment period, with a four-week follow-up.

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.

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. LTI-03 has received Orphan Drug Designation in the U.S. A Phase 2 clinical trial of LTI-03 for the treatment of idiopathic pulmonary fibrosis was initiated in May 2025. 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.

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 planned 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]; 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 trial and the Company's operations for the necessary periods of time 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 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 RENEW 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 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.

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