# Rein Therapeutics Receives FDA Clearance to Resume U.S. Phase 2 Trial of LTI-03 in Idiopathic Pulmonary Fibrosis

November 3, 2025

- FDA lifts clinical hold following review of Company's Complete Response submission.
- Company expects to restart U.S. enrollment in late 2025 or early 2026 across 20 clinical sites.
- Early data suggests that LTI-03 may not only slow fibrosis but also promote lung healing.

AUSTIN, Texas, Nov. 03, 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 U.S. Food and Drug Administration (FDA) has lifted the full clinical hold on the Company's Phase 2 "RENEW" trial evaluating LTI-03 in patients with idiopathic pulmonary fibrosis (IPF).

The FDA's decision follows a review of Rein's submission, which addressed all of the agency's concerns. In its correspondence, the FDA confirmed that Study LTI-03-2001 may proceed and that any prior Full Clinical Hold concerns have been fully resolved.

Brian Windsor, Ph.D., Chief Executive Officer of Rein Therapeutics, commented, "This is a major milestone for us. The FDA's decision clears the path for us to resume enrollment and continue advancing LTI-03 through our global Phase 2 program. We're grateful for the FDA's collaboration and proud of our team for their hard work and dedication to getting to this point. We believe LTI-03 has the potential to meaningfully shift how IPF is treated by not only slowing fibrosis but also supporting lung repair."

Rein expects to resume patient recruitment in late 2025 or early 2026 across approximately 20 U.S. clinical sites located in Alabama, California, Colorado, Connecticut, Florida, Indiana, Kansas, Massachusetts, Michigan, Missouri, North Carolina, New York, Ohio, South Carolina, and Texas.

The U.S. enrollment complements Rein's broader global RENEW study, which includes approximately 30 additional sites in the United Kingdom, Germany, Poland, and Australia. The trial is designed to evaluate the safety, tolerability, and efficacy of LTI-03 in up to 120 patients with IPF.

Key secondary endpoints include changes in lung function (FVC) and imaging-based measures of fibrosis progression. Initial topline data is expected in Q3 2026.

**About LTI-03**
LTI-03 is a first-in-class, inhaled peptide therapy derived from Caveolin-1 biology, a key regulator of fibrotic signaling. The drug is designed to inhibit lung scarring while preserving alveolar progenitor cells that are critical for tissue repair and regeneration.

Early data suggests that LTI-03 may represent a dual-acting approach: slowing fibrosis and promoting lung healing.

**About Idiopathic Pulmonary Fibrosis (IPF)**

IPF is a chronic, progressive lung disease characterized by irreversible scarring that impairs the ability to breathe. Despite current FDA-approved therapies aimed at slowing progression, median survival remains only 3–5 years from diagnosis. By some estimates, the global market for fibrosis treatments is projected to exceed $11 billion by 2031, underscoring the urgent need for new and more effective options.

**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 in the United States, United Kingdom, Germany, Poland, and Australia; (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 clinical trials of LTI-03 in the United States, United Kingdom, Germany Poland, and Australia; and (iv) 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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