Rein Therapeutics Receives U.S. FDA Fast Track Designation for LTI-03 in Idiopathic Pulmonary Fibrosis

August 20, 2026

- *Designation reflects serious unmet need in idiopathic pulmonary fibrosis (IPF), where approved therapies slow but do not halt disease progression*
- *Actively enrolling patients in the RENEW Phase 2 trial evaluating LTI-03 in IPF; on track to report interim data in the second half of 2026*

AUSTIN, Texas, Aug. 20, 2026 (GLOBE NEWSWIRE) -- Rein Therapeutics ("Rein") (NASDAQ: RNTX), a biopharmaceutical company advancing a novel pipeline of first-in-class medicines in orphan pulmonary and fibrosis indications, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to LTI-03 for the treatment of idiopathic pulmonary fibrosis.

Fast Track designation is an FDA process intended to facilitate the development and expedite the review of new drugs or biologics that treat serious conditions and address an unmet medical need. The purpose is to bring important new drugs to patients earlier. A drug that receives Fast Track designation may be eligible for more frequent interactions and written communication with the FDA throughout development, and the ability to submit a marketing application on a rolling basis. Programs that receive Fast Track designation may also be eligible for consideration for Accelerated Approval and Priority Review if applicable regulatory criteria are met.

Brian Windsor, President and Chief Executive Officer of Rein Therapeutics, commented, “Receiving Fast Track designation for LTI-03 from the FDA marks a significant milestone for Rein, and underscores the urgent need for new treatment options that can not only halt disease progression, but also potentially support tissue repair and regeneration. With our Phase 2 RENEW trial well underway across five countries, we have a unique opportunity to work closely with the FDA to potentially accelerate the development and review of LTI-03. We remain on track to achieve our near-term clinical milestones and anticipate reporting interim data from this trial in the second half of this year.”

IPF is a chronic, progressive, and fatal lung disease in which scar tissue accumulates in the lungs, progressively impairing the ability to breathe. Approved therapies can slow the disease in some patients but do not halt or reverse it, and median survival following diagnosis is approximately three to five years.

LTI-03 has previously been granted Orphan Drug designation from the FDA for the treatment of IPF.

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 the RENEW Phase 2 Trial
Rein’s RENEW trial (ClinicalTrials.gov: NCT06968845) is a randomized, placebo-controlled Phase 2 clinical study designed to evaluate the safety, tolerability, and efficacy of LTI-03 in patients with idiopathic pulmonary fibrosis.

The study is expected to enroll approximately 120 patients across the United States, United Kingdom, Australia, Poland, and Germany. Patients will be randomized to receive one of two dose levels of LTI-03 or placebo. The primary endpoint is safety, measured by the incidence of treatment-emergent adverse events through Week 24, with change from baseline in forced vital capacity (FVC) as the primary efficacy endpoint.

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 both Orphan Drug and Fast Track designations in the U.S.

Cautionary Note Regarding 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 Phase 2 trial evaluating LTI-03 and the Company’s working capital requirements. 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 continue its Phase 2 clinical trials of LTI-03; (ii) the risk that the Company may not report data derived from its Phase 2 trial in the second half of 2026 or, if it does, the risk that the data 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’s present cash and cash equivalents may not be sufficient to fund the Company’s operations into the first quarter of 2028 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, 2025 filed with the SEC on March 26, 2026, and in subsequent filings that the Company makes with the SEC. These forward-looking statements should not be relied upon as representing the Company’s views as of any date after the date of this press release, and the Company expressly disclaims 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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