Rein Therapeutics Receives European Regulatory Approval to Initiate Phase 2 Trial of LTI-03 in Idiopathic Pulmonary Fibrosis

October 9, 2025

- EMA approval covers study sites in Germany and Poland as part of the Company's global Phase 2 RENEW trial
- Trial will evaluate LTI-03, a first-in-class therapy designed to both reduce lung scarring and promote repair

AUSTIN, Texas, Oct. 09, 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 it has received authorization from the European Medicines Agency (EMA) to initiate the Company's Phase 2 "RENEW" clinical trial of its lead candidate, LTI-03, for the treatment of idiopathic pulmonary fibrosis (IPF).

The approvals cover clinical trial sites in Germany and Poland, which will serve as key European centers for the global study. Rein has already received regulatory clearance from the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA).

Brian Windsor, Chief Executive Officer of Rein Therapeutics, commented, "These new authorizations mark another important milestone in our global RENEW trial. With approvals now in the U.K., Germany, and Poland, we are well positioned to begin enrolling patients in multiple regions and advance LTI-03 toward our goal of redefining how pulmonary fibrosis is treated. We are grateful to our clinical partners across Europe for their collaboration and commitment to improving outcomes for patients with IPF."

About the RENEW Trial

The RENEW trial is a randomized, double-blind, placebo-controlled Phase 2 study evaluating the safety, tolerability, and efficacy of LTI-03 in patients with IPF. The study will enroll up to 120 patients globally, with a treatment duration of 24 weeks across two dosing groups.

Key secondary endpoints include changes in lung function (FVC) and imaging-based assessments of fibrosis progression.

LTI-03 is a Caveolin-1–derived peptide designed to both inhibit fibrosis and support regeneration of healthy lung tissue by protecting alveolar progenitor cells that are critical for repair.

About Idiopathic Pulmonary Fibrosis (IPF)

IPF is a chronic, progressive lung disease characterized by irreversible scarring that makes it increasingly difficult for patients to breathe. Median survival is 3–5 years after diagnosis, even with currently approved therapies, which primarily aim to slow disease progression rather than restore lung function.

According to the National Institutes of Health (NIH), IPF has an estimated prevalence of 13 to 20 per 100,000 people worldwide. In just the United States alone, about 100,000 people have IPF, and approximately 30,000 to 40,000 new cases are diagnosed each year.

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 Germany and Poland, (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 Germany and Poland 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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