# Rein Therapeutics Receives Orphan Drug Designation from European Medicines Agency for Lead Drug Candidate in Idiopathic Pulmonary Fibrosis

January 20, 2026

## -- Designation highlights significant unmet medical need

AUSTIN, Texas, Jan. 20, 2026 (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, announced that it has received orphan drug designation from the European Medicines Agency (EMA) for LTI-03, its lead drug candidate aimed at preserving lung function in patients with idiopathic pulmonary fibrosis (IPF).

The designation follows a positive opinion from the EMA's Committee for Orphan Medicinal Products (COMP) and subsequent adoption by the European Commission, recognizing both the seriousness of IPF and the need for new treatment options for patients living with this devastating disease.

IPF is a rare, progressive lung disease characterized by irreversible scarring of lung tissue, that leads to declining lung function and, ultimately, respiratory failure. Despite existing treatments, patients continue to face poor outcomes and limited therapeutic options.

Orphan drug designation in the European Union provides important regulatory incentives, including reduced development fees, potential market exclusivity following approval, and enhanced development efficiency, which may help streamline clinical development and regulatory interactions.

The EMA's final decision was supported by preclinical data demonstrating improved survival and lung function, reinforcing the scientific rationale behind Rein's approach to targeting fibrosis. The EMA also agreed with Rein's justification that LTI-03 could be of significant benefit to those affected by the condition as compared to authorized products, which may constitute a clinically relevant advantage.

Brian Windsor, Ph.D., Chief Executive Officer of Rein Therapeutics, commented, "This designation represents an important regulatory milestone for Rein and a meaningful step forward for patients living with IPF. Receiving orphan drug designation in Europe provides external validation of our strategy that can do more than slow disease progression. We believe LTI-03 has the potential to address this unmet need."

LTI-03 has been entered into the Community Register of Orphan Medicinal Products under designation number EU/3/25/3188.

**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 clinical 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 complete the 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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