# MannKind Provides Update on Phase 3 ICoN-1 Trial of Nebulized Clofazimine for NTM Lung Disease

11/10/25

- *MannKind has made the decision to discontinue the ICoN-1 Phase 3 clinical trial evaluating nebulized clofazimine inhalation suspension for nontuberculous mycobacterial (NTM) lung disease, following a futility determination based on medical monitoring data*
- *This outcome does not impact the development of MNKD-102, MannKind's dry powder inhalation (DPI) formulation of clofazimine, which remains under consideration for future clinical advancement*
- *MannKind extends its sincere gratitude to the study participants, investigators, advisors, and clinical site teams for their invaluable contributions to the ICoN-1 study*
- *MannKind will host a conference call today at 9:00 AM EST to discuss this update in more detail*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Nov. 10, 2025 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today announced the discontinuation of its Phase 3 ICoN-1 clinical trial evaluating MNKD-101, a nebulized clofazimine inhalation suspension, for the treatment of refractory nontuberculous mycobacterial (NTM) lung disease.

As part of routine study monitoring and in accordance with the trial protocol, an analysis was conducted on sputum culture conversion data from the first 46 participants who completed the double-blind treatment phase. No conversions were observed, prompting concerns regarding the likelihood of achieving the study's key primary endpoint. Following an *ad hoc* meeting held on November 8, 2025, the independent Data Safety Monitoring Board (DSMB) reviewed the data and agreed with the decision to discontinue the trial due to futility. Importantly, the DSMB did not identify any safety concerns at any point during the study.

"We are disappointed that the nebulized formulation did not demonstrate efficacy in this patient population," said Dr. Ajay Ahuja, Chief Medical Officer of MannKind Corporation. "However, we remain hopeful regarding the potential of MNKD-102, our dry powder inhalation (DPI) formulation of clofazimine, which has been progressing toward Phase 1 development. We are committed to understanding the factors that contributed to this outcome in the nebulized formulation and applying those insights to guide our future development efforts."

MannKind extends its deep appreciation to the study participants, investigators, clinical site teams, and all stakeholders who contributed to the ICoN-1 study and continue to support the advancement of therapies for NTM lung disease.

**Conference Call**
MannKind will host a conference call and presentation webcast to discuss these findings today at 9:00 a.m. Eastern Standard Time. The webcast will be accessible via a link on MannKind's website. A replay will also be available in the same location within 24 hours after the call and accessible for approximately 90 days.

**About the ICoN-1 Clinical Trial**
The ICoN-1 trial is a multi-national, randomized, double-blind, placebo-controlled, Phase 3 registrational study to evaluate the efficacy and safety of clofazimine inhalation suspension for nebulized inhalation when added to guideline-based therapy in adults with refractory NTM lung disease caused by mycobacterium avium complex (MAC), followed by an open-label extension. The co-primary endpoints in the U.S. are sputum culture conversion (negative for NTM for 3 consecutive months) from baseline to end of Month 6 and change in quality of life (QoL) during the same timeframe. Outside the U.S., the primary endpoint is sputum culture conversion.

**About NTM – A Global Health Concern**
Pulmonary NTM infection is a rare disease with a global health impact due to its rising prevalence worldwide and association with shortened life span, high morbidity, and significant impact on patients' quality of life. NTM is a group of bacteria naturally found in our environment, including water and soil, that can lead to cough, fatigue, a reduction in lung function, and poor quality of life among other debilitating symptoms. While most people are exposed to NTM daily, the organisms generally do no harm. Individuals with underlying conditions such as COPD, asthma, and bronchiectasis are at increased risk of NTM getting established in the lungs creating an infection and progressive worsening of lung function.

There are nearly 200 species of NTM; the most common is MAC, which accounts for about 80% of all NTM lung disease cases in the United States. While not everyone is at risk of contracting NTM from MAC, for those who are, it can cause serious lung damage. NTM lung disease is more common in women over the age of 65. Estimated 2022 NTM disease prevalence is more than 100,000 in the U.S. and over 150,000 in Japan. Approximately 15-20% of NTM patients are refractory. The prevalence rate of NTM is increasing globally – within the U.S. alone claims-based studies suggest an annual rise of 7.5%. To learn more about NTM, please visit LearnAboutNTM.com.

**About MannKind**
MannKind Corporation (Nasdaq: MNKD) is a biopharmaceutical company dedicated to transforming chronic disease care through innovative, patient-centric solutions. Focused on cardiometabolic and orphan lung diseases, we develop and commercialize

treatments that address serious unmet medical needs, including diabetes, pulmonary hypertension, and fluid overload in heart failure and chronic kidney disease.

With deep expertise in drug-device combinations, MannKind aims to deliver therapies designed to fit seamlessly into daily life.

Learn more at mannkindcorp.com.

**Forward-Looking Statements**
Statements in this press release that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. These statements include, without limitation, statements regarding MannKind's plan to investigate the causes for the failure of MNKD-101 to produce sputum culture conversion and to apply its findings to the development of MNKD-102. Words such as “believes,” “anticipates,” “plans,” “expects,” “intends,” “will,” “goal,” “potential,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon MannKind’s current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with developing product candidates; risks and uncertainties related to unforeseen delays that may impact the timing of clinical trials and reporting data; and other risks detailed in MannKind’s filings with the Securities and Exchange Commission (“SEC”), including under the “Risk Factors” heading of its most recently filed Quarterly Report on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.



MannKind Contacts:
Media Relations
Christie Iacangelo, (818) 292-3500
Email: media@mnkd.com

Source: MannKind