MannKind Announces Clearance from PMDA to Initiate Phase 3 Clinical Trial (ICoN-1) in Japan Evaluating Clofazimine Inhalation Suspension for the Treatment of Nontuberculous Mycobacterial (NTM) Lung Disease

09/18/24

- *Clearance to proceed also received from health authorities in South Korea and Australia, with Taiwan expected in 4Q 2024*
- *First U.S. patient randomized*

DANBURY, Conn., Sept. 18, 2024 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a company focused on the development and commercialization of innovative inhaled therapeutic products and devices for patients with endocrine and orphan lung diseases, announced today that it has received clearance from Japan's Pharmaceuticals and Medical Devices Agency (PMDA) to initiate the Phase 3 study (ICoN-1) of Clofazimine Inhalation Suspension for the treatment of NTM lung disease. The global study is now cleared by health authorities to proceed in four countries (U.S., Japan, South Korea and Australia) with a fifth (Taiwan) expected in 4Q 2024.

"We are pleased to initiate the ICoN-1 study in Japan in an effort to further develop potential therapy for those living with serious NTM lung infections," said Dr. Kozo Morimoto, lead principal investigator for ICoN-1 in Japan, Chief Doctor for the Respiratory Disease Center at Fukujuji Hospital and Japan Anti-Tuberculosis Association. "Patients living with NTM infections deserve safe, well-tolerated, convenient, and effective options to treat this serious respiratory disease that is on the rise in Japan, as well as globally."

The ICoN-1 study was initiated in the United States in June 2024 and had its first patient randomized in September. In all, approximately 230 eligible participants will be enrolled and randomized at more than 100 sites across the U.S. and globally to ensure a minimum of 180 participants are evaluable for efficacy. Details of the ICoN-1 study and sites can be found at: ClinicalTrials.gov (NCT06418711).

About the ICoN-1 Clinical Trial
The ongoing 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 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) 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.

In May 2024, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for Clofazimine Inhalation Suspension (MNKD-101) for the treatment of NTM lung disease. The FDA also previously designated Clofazimine Inhalation Suspension as both an orphan drug and a qualified infectious disease product (QIDP) for the treatment of pulmonary NTM infections. A drug that receives orphan drug exclusivity receives seven years of exclusivity, and one that also earns QIDP designation, may receive an additional five years of market exclusivity.

Clofazimine Inhalation Suspension was granted a patent (No. 11,793,808) by the United States Patent and Trademark Office covering compositions of clofazimine and methods for treating lung infections. The patent is not due to expire until June 8, 2039. A corresponding clofazimine patent was granted in Japan (7377259), and patent applications are pending in other major markets.

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) focuses on the development and commercialization of innovative inhaled therapeutic products and devices to address serious unmet medical needs for those living with endocrine and orphan lung diseases.

We are committed to using our formulation capabilities and device engineering prowess to lessen the burden of diseases such as diabetes, nontuberculous mycobacterial (NTM) lung disease, pulmonary fibrosis, and pulmonary hypertension. Our signature technologies – dry-powder formulations and inhalation devices – offer rapid and convenient delivery of medicines to the deep lung where they can exert an effect locally or enter the systemic circulation, depending on the target indication.

With a passionate team of Mannitarians collaborating nationwide, we are on a mission to give people control of their health and the freedom to live life.

Please visit mannkindcorp.com to learn more, and follow us on LinkedIn, Facebook, X or Instagram.

Forward-Looking Statements
This press release contains forward-looking statements about the regulatory clearance to proceed with a clinical study that involve risks and uncertainties. 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, the risk that continued testing of an investigational drug product may not yield successful results or results that are consistent with earlier testing, and other risks detailed in MannKind’s filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2023, and subsequent periodic reports on Form 10-Q and current reports on Form 8-K. 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.

MNKD-101 is an investigational product that is not approved for any use in any country.

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Source: MannKind