MannKind Receives U.S. FDA Fast Track Designation for Clofazimine Inhalation Suspension for the Treatment of Nontuberculous Mycobacterial (NTM) Lung Disease

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DANBURY, Conn. and WESTLAKE VILLAGE, Calif., May 06, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track designation of Clofazimine Inhalation Suspension (MNKD-101) for the treatment of nontuberculous mycobacterial (NTM) lung disease. Fast track designation is intended to facilitate the development, and expedite the review, of medicines to treat serious conditions and fill an unmet medical need.

"We are pleased with the FDA's decision to grant Fast Track designation for Clofazimine Inhalation Suspension, providing us an opportunity to accelerate our efforts to potentially bring an important medicine to patients living with NTM," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "We are looking forward to the progression of the ICoN-1 study as well as an expedited review with a rolling submission."

ICoN-1 is a multi-national, randomized, double-blind, placebo-controlled trial 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. This single registrational study anticipates getting underway in June 2024 in the U.S., and internationally in the second half of 2024.

The U.S. FDA 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.

Pulmonary NTM infection is recognized as a major global health concern due to its rising prevalence worldwide, association with shortened life span and significant impact on patients' daily living. 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. 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 prone to NTM getting established in the lungs, creating an infection and progressive worsening of lung function.

NTM lung disease is more common in women over the age of 65, with a predominance in those of Caucasian and Asian descent. In 2022, there were approximately 122,000 and 159,000 patients living with NTM in the U.S. and Japan, respectively, with as much as 20% of those cases being refractory. The disease state is on the rise, with an estimated annual growth rate averaging 8%.

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 initiation of a clinical study and a planned regulatory submission 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.

MANNKIND is a registered trademark of MannKind Corporation.

For MannKind:
Christie Iacangelo, Corporate Communications
(818) 292-3500
Email: media@mannkindcorp.com

Rose Alinaya, Investor Relations
(818) 661-5000
Email: ir@mannkindcorp.com

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