MannKind Announces IND Clearance From U.S. FDA to Start Phase 3 Study of Clofazimine Inhalation Suspension for Nontuberculous Mycobacterial (NTM) Lung Disease

April 29, 2024 10:05 AM EDT

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., April 29, 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 cleared the company's Investigational New Drug (IND) application for MNKD-101 (Clofazimine Inhalation Suspension), enabling the initiation of a Phase 3 study for the treatment of nontuberculous mycobacterial (NTM) lung disease.

"Oral clofazimine has been utilized as a treatment option for patients living with NTM lung disease and we believe that by reducing the dose and administering it directly to the lung we can demonstrate improved dosing, tolerability and safety," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "Advancing this program to a Phase 3 trial, we are encouraged that MNKD-101 could potentially address a serious unmet need that is on the rise globally – particularly in the U.S. and the Asia Pacific region."

This single registrational study, identified as ICoN-1, anticipates getting underway by end of 2Q 2024 in the U.S., and internationally in the second half of 2024. 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.

"Current regimens for patients living with NTM lung disease require the use of multiple medications that are often associated with significant adverse reactions and safety concerns, prolonged periods of administration, and suboptimal outcomes both short-term and long-term," said Dr. Burkhard Blank, Executive Vice President, Research & Development and Chief Medical Officer of MannKind Corporation. "Patients living with NTM deserve safe, well-tolerated, convenient, and effective options to treat this serious respiratory disease."

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 the potential attributes of an investigational product to address an unmet medical need 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

Source: MannKind