Mannkind Successfully Completes Phase 1 Study of Inhaled Clofazimine

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- *Study supports the dosing regimen that will be pursued in further clinical programs*
- *No serious adverse events or QT prolongation identified*
- *Planning underway to discuss results and the ongoing clinical program with the FDA*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Sept. 06, 2022 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a company focused on the development and commercialization of inhaled therapeutic products for patients with endocrine and orphan lung diseases, announced today that it has successfully completed a Phase 1 study of clofazimine inhalation suspension (MNKD 101) and is planning discussions with the U.S. Food and Drug Administration (FDA) regarding results and the ongoing clinical program.

Clofazimine is being developed as an inhalation treatment option for nontuberculous mycobacterial (NTM) lung disease. NTM lung disease is a serious infection that is caused by bacteria common in the environment that can lead to a reduction in lung function, cough, fatigue, and quality of life. It is estimated that approximately 86,000 people in the U.S. are living with NTM lung disease, and it is on the rise growing 8% each year with women, the elderly, and those with underlying lung conditions at greatest risk. MNKD-101 has been designated by the FDA as both an orphan lung and a qualified infectious disease product (QIDP) for the treatment of pulmonary NTM infections.

“There is a high unmet need to develop medicines that are well tolerated and effective in alleviating symptoms for those living with NTM lung disease,” said Michael Castagna, PharmD, Chief Executive Office of MannKind Corporation. “As we continue to expand our orphan lung diseases focus at MannKind, we are encouraged by what we are seeing with inhaled clofazimine and the future potential to help patients.”

Study MKC-CI -001 was a Phase I randomized, double-blind, placebo-controlled, single- (SAD) and multiple-ascending dose (MAD) study to evaluate the safety, tolerability, and pharmacokinetics (PK) of MNKD-101 in healthy volunteers. The key safety findings of the study included:

- Clofazimine inhalation solution found to be generally well tolerated at daily doses of up to 90 mg over a seven-day period
- No lab abnormalities, QT prolongation, or serious adverse events identified

“The safety and tolerability results for inhaled clofazimine are encouraging and we look forward to advancing the nebulized formulation of clofazimine to the next phase of development,” said Thomas Hofmann, Chief Scientific Officer of MannKind Corporation. “Clofazimine presented as being very lipophilic and demonstrated the expected therapeutic plasma concentrations we were targeting. In future studies, we plan to evaluate the potential for MNKD-101 to produce drug levels that exceed the minimum inhibitory concentration in the lung beyond the treatment period.”

In the SAD portion of the study, 24 adults were enrolled in one of three cohorts (n = 8 per cohort) that received a single inhaled dose of 30 mg, 60 mg or 90 mg clofazimine, respectively. Participants resided at the clinical research unit until day 5 post-dose, during which time they were evaluated for safety and samples were collected for PK assessment. Participants returned on days 8 and 15 for additional safety assessments and sample collection. During the MAD portion of the study, 16 adults were enrolled in one of two cohorts (n = 8 per cohort) that received a daily inhaled dose of 30 mg or 90 mg clofazimine for a seven-day period. Participants resided at the clinical research unit until day 8 post-dose, during which time they were evaluated for safety and samples were collected for PK assessment. Participants returned on days 15 and 36 for additional safety assessments and sample collection.

Additional data collected during the MKC-CI-001 study is currently undergoing final analysis. Detailed data findings will be presented in upcoming publications and scientific conferences.

About MannKind
MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of innovative 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, pulmonary arterial hypertension (PAH) and nontuberculous mycobacterial (NTM) lung disease. 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.

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, Twitter or Instagram.

Forward-looking Statements
This press release contains forward-looking statements about the implications of clinical data 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, 2021 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.

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