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MannKind Expands Patent Portfolio With New Clofazimine Formulation Patent

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- Patent covers compositions of clofazimine, and methods for treating lung infections
- Development of MNKD-101 (inhaled clofazimine) continues for the potential treatment of nontuberculous mycobacterial (NTM) lung disease

DANBURY, Conn., Oct. 30, 2023 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq: MNKD), a company focused on the development and commercialization of inhaled therapeutic products and devices for patients with endocrine and orphan lung diseases, today announced a new patent (No. 11,793,808) issued by the United States Patent and Trademark Office covering clofazimine inhalation suspension (MNKD-101), which is under development for the potential treatment of nontuberculous mycobacterial (NTM) lung disease. The patent will expire on June 8, 2039.

"We believe this patent represents important protection for our lead pipeline asset, MNKD-101, that could potentially improve therapy for a disease that is increasingly on the rise globally," said Michael Castagna, PharmD, Chief Executive Officer for MannKind Corporation. "Patients living with NTM typically rely on a series of drug treatments that often may be associated with severe side effects. Early data for MNKD-101 is promising as it suggests rapid and targeted delivery of clofazimine deep into the lung has the potential to be better tolerated."

Pulmonary NTM infection is recognized as a major global health concern due to its rising prevalence worldwide. It 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 86,000-180,000 people in the U.S. alone 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 drug and a qualified infectious disease product (QIDP) for the treatment of pulmonary NTM infections.

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 and the potential safety of an investigational product 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 fillings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2022 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.

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