MannKind Successfully Completes Phase 1 Trial of Nintedanib DPI for Pulmonary Fibrotic Diseases

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- *Met primary objective demonstrating nintedanib DPI was safe and well tolerated*
- *Participants did not experience adverse events typically reported with oral nintedanib*
- *Expect to meet with the FDA in 1H 2025 to advance MNKD-201 into the next phase of development*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Nov. 04, 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, today announced the successful completion of its first-in-human Phase 1 study of nintedanib DPI (MNKD-201) for pulmonary fibrotic diseases, including idiopathic pulmonary fibrosis (IPF).

“These compelling results support advancing the development of nintedanib DPI for patients living with IPF, a chronic and progressive fibrotic lung disease with limited treatment options,” said Michael Castagna, PharmD, Chief Executive Officer for MannKind Corporation. “We look forward to discussing the Phase 1 trial results and our proposed late-stage development program at an end of phase 1 meeting with the FDA, planned for the first half of 2025.”

The key highlights of the study included:

- Nintedanib DPI was shown to be safe and well tolerated in healthy volunteers with the tested doses and study duration
- Participants did not experience typical adverse events seen with oral nintedanib; specifically, no GI or neurologic adverse events (AEs) were reported
- Two types of AEs noted - cough and drop in FEV-1
    - These AEs were mild, transient, and fully recovered
    - These AEs were not dose-dependent and there was no pattern of recurrence or worsening with repeated dosing
    - No bronchospasm, wheezing, other symptoms, or change in vital signs were reported
- No serious adverse events or study drug discontinuation

The completed Phase 1 was a single-site, randomized, placebo-controlled, single- (n=24) and multiple-ascending dose (n=16) study in healthy adult (older than 40 years old) participants. The primary objective of the study was to evaluate the safety and tolerability of nintedanib DPI. The secondary study objective was to evaluate the pharmacokinetics (PK) of MNKD-201.

“We are encouraged by the findings from this Phase 1 study of nintedanib DPI,” said Dr. Wassim Fares, MSc, FCCP, Senior Vice President, Therapeutic Area Head, Orphan Lung Diseases for MannKind Corporation. “Building on the known efficacy of oral nintedanib for IPF, delivery of a dry powder formulation directly to the lungs could potentially treat the disease while reducing the common adverse effects associated with oral delivery of nintedanib. Pending late-stage development trials, nintedanib DPI could offer an alternative and/or addition to current IPF therapies.”

Additionally, the preclinical chronic toxicology study did not show any adverse findings and supports further development of nintedanib DPI.

About Pulmonary Fibrosis and IPF
The Pulmonary Fibrosis Foundation indicates that there are over 250,000 Americans living with pulmonary fibrosis (PF) and interstitial lung disease (ILD) today, and 50,000 new cases are diagnosed each year. While the number of people affected by IPF is unknown, it is one of the most common forms of pulmonary fibrosis. IPF is predominantly identified in men but is also increasing in women.

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
Statements in this press release that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. These statements include, without limitation, statements regarding the continued clinical development of MNKD-201, planned interactions with the FDA as well as the potential for a new therapy to treat disease with fewer adverse events. 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-201 is an investigational product that is not approved for any use in any country.

For MannKind:
Media Relations
Christie Iacangelo
(818) 292-3500
Email: media@mnkd.com

Investor Relations
Ana Kapor
(818) 661-5000
Email: ir@mnkd.com

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