



MannKind to Proceed With Phase 1 Nintedanib Dpi (Mnkd-201) Study for Pulmonary Fibrotic Diseases

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- *First-in-human study to evaluate safety, tolerability and pharmacokinetics (PK) in healthy volunteers*
- *Enrollment of first study participant anticipated in June 2024*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., April 30, 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 it will proceed with a first-in-human Phase 1 study of nintedanib DPI (MNKD-201) for pulmonary fibrotic diseases, including idiopathic pulmonary fibrosis (IPF).

"We are pleased to progress nintedanib DPI which comes on the heels of furthering our Phase 3 study of Clofazimine Inhalation Suspension for nontuberculous mycobacterial (NTM) lung diseases," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "This puts two studies in motion by mid-year that will explore potential treatment options for patients living with serious lung diseases."

The Phase 1 randomized, double-blind, placebo-controlled, single- (SAD) and multiple-ascending dose (MAD) study will evaluate the safety, tolerability, and pharmacokinetics (PK) of nintedanib inhalation powder (MNKD-201) in healthy volunteers.

"Pulmonary fibrotic diseases – in particular IPF – are chronic, progressive diseases that result in loss of lung function and, for far too many, shortened lifespans," said Dr. Wassim Fares, MSc, FCCP, Senior Vice President, Therapeutic Area Head, Orphan Lung Diseases of MannKind Corporation. "The team is eager and excited to initiate this study of MNKD-201 with results anticipated later this year, which will inform the next study of nintedanib DPI in patients with pulmonary fibrotic diseases."

The Pulmonary Fibrosis Foundation indicates that there are over 250,000 Americans living with pulmonary fibrosis (PF) today, and 50,000 new cases are diagnosed each year. While it is unknown the number of people affected by IPF – the most common form of pulmonary fibrosis – the latest estimates indicate that 1 in 200 adults over the age of 70 are impacted in the United States. IPF is predominantly identified in men, but it 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 commencement of clinical studies of MNKD-201 and Clofazimine Inhalation Solution as well as the timing of the data read-out from a Phase 1 clinical study of MNKD-201. 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.

MANNKIND is a registered trademark of MannKind Corporation.

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