# MannKind Enters Data-Rich Development Period with Completion of Randomization in Phase 1b INFLO-1 Study and Enrollment of First Patient in Phase 2 INFLO-2 Trial for Nintedanib DPI in Patients with IPF

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- *Phase 1b INFLO-1 study data readout anticipated in Q3 2026*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., June 03, 2026 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a biopharmaceutical company focused on developing innovative, patient-centric therapies for chronic diseases, today announced key clinical execution milestones in the development of nintedanib DPI for idiopathic pulmonary fibrosis (IPF), including the completion of patient randomization in the U.S. Phase 1b INFLO-1 clinical trial and enrollment of the first patient in the global Phase 2 INFLO-2 study. These milestones mark the advancement of the nintedanib DPI program and support its progression into mid-stage clinical evaluation.

**Positioning for Continued Clinical Development in IPF**
MannKind expects to report data from the INFLO-1 study in the third quarter of 2026, which is expected to provide an initial clinical assessment of safety, tolerability, and pharmacokinetics in patients with IPF. INFLO-2 is expected to enroll approximately 210 participants across approximately 85 sites worldwide. The first patient was enrolled in Windsor, Canada.

“We are encouraged by the emerging data from our Phase 1b study, which continues to support our hypothesis around the safety and tolerability of inhaled nintedanib DPI,” added Wassim Fares, M.D., MSc, FCCP, Senior Vice President, Therapeutic Area Head – Respiratory. “These findings reinforce the potential of nintedanib DPI as a simple and convenient administration to efficiently deliver therapy directly to the lungs, with potential to maintain antifibrotic effect and improve tolerability and long-term adherence. It may also facilitate the opportunity for use in combination with current and future IPF therapies.”

**Differentiated Approach to a Significant Unmet Need**
IPF is a chronic, progressive lung disease characterized by irreversible fibrosis and declining lung function. Despite available therapies, the disease remains associated with substantial morbidity and mortality.

Nintedanib, currently approved as an oral therapy for IPF, has demonstrated the ability to slow disease progression but can be associated with systemic side effects that may limit tolerability, treatment persistence, and the ability to use combination therapies. Nintedanib DPI (MNKD-201) leverages MannKind’s Technosphere ® dry powder inhalation technology to deliver nintedanib directly to the deep lung, with the goal of achieving therapeutic concentrations at the site of disease while reducing systemic exposure. MannKind has developed two FDA-approved dry powder inhalation therapies utilizing its proven Technosphere formulation technology, with clinical data demonstrating less than 3% discontinuation due to cough.

“Advancing into this next stage of development represents an important inflection point for our nintedanib DPI program,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. “With Phase 1b data expected in Q3 2026 and a global Phase 2 study now underway, we believe we are well-positioned to generate early clinical validation of our inhaled approach and to further define its potential in IPF.”

**About INFLO-2**
A randomized, double-blind, placebo-controlled clinical trial of the efficacy and safety of nintedanib DPI in patients with IPF followed by an open-label extension. The global study will randomize participants in a 1:1:1 ratio to receive either nintedanib DPI (2 mg four times daily or 4 mg twice daily) or placebo for 12 weeks, followed by a 24-week open-label extension in which all participants may receive active treatment.

The primary objective of the study is to assess safety and tolerability and to determine an optimal dose of nintedanib DPI. Secondary objectives include evaluating a potential efficacy signal, including the annualized rate of decline in forced vital capacity (FVC), a key measure of lung function in IPF. Additional endpoints will assess disease progression, pulmonary exacerbations, exercise capacity, patient-reported outcomes, and pharmacokinetics.

**About INFLO-1**
INFLO-1 is a Phase 1b, randomized, double-blind, placebo-controlled study of nintedanib DPI in patients with IPF. The U.S. trial consists of multiple ascending doses (MAD) with the primary objective to evaluate safety, tolerability and pharmacokinetics of nintedanib DPI compared to placebo in patients with IPF. More information on INFLO-1 is available at: ClinicalTrials.gov (NCT07344558).

**About IPF**
Idiopathic pulmonary fibrosis is a chronic, progressive lung disease characterized by irreversible scarring of lung tissue that leads to worsening lung function over time. Despite available therapies, IPF remains associated with significant morbidity and mortality. According to the American Lung Association and GlobalData, there are an estimated 100,000 IPF patients in the U.S. with a 20%

rise in the last decade. IPF affects an estimated 1-1.5 million people worldwide, based on global prevalence analyses reporting approximately 13-20 patients per 100,000 population.[1]

**About MannKind**
MannKind Corporation (Nasdaq: MNKD) is a biopharmaceutical company dedicated to transforming chronic disease care through innovative, patient-centric solutions. Focused on cardiometabolic and orphan lung diseases, we develop and commercialize treatments that address serious unmet medical needs, including diabetes, pulmonary hypertension, and fluid overload in heart failure and chronic kidney disease.

With deep expertise in drug-device combinations, MannKind aims to deliver therapies designed to fit seamlessly into daily life.

Learn more at mannkindcorp.com.

**Forward-Looking Statements**
Statements in this press release that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. Forward-looking statements include statements regarding the future development of MNKD-201, including potential safety and efficacy outcomes, patient enrollment expectations as well as the timing of results from ongoing clinical studies. 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 a drug 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, 2025 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.



[1] National Library of Medicine (U.S.). *Idiopathic pulmonary fibrosis*. MedlinePlus Genetics. Available at: https://medlineplus.gov/genetics/condition/idiopathic-pulmonary-fibrosis/.

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