# MannKind Reports Positive Phase 1b INFLO-1 Results, Demonstrating Safety and Tolerability of Nintedanib DPI and Clinical Validation of Its DPI Technology in IPF

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- *Generally well-tolerated with no serious adverse events, bronchospasm or diarrhea; no study drug discontinuations*
- *90% of patients had no [60%] or mild [30%] cough*
- *~450 total inhalations administered in patients with IPF*
- *Global Phase 2 INFLO-2 trial actively enrolling patients*
- *Conference call and webcast scheduled for July 29 at 4:30 p.m. ET*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., July 29, 2026 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a biopharmaceutical company focused on developing innovative, patient-centric therapies for chronic diseases, today announced positive topline results from INFLO-1, its Phase 1b randomized, double-blind, placebo-controlled study evaluating nintedanib dry powder inhalation (DPI) in patients with idiopathic pulmonary fibrosis (IPF).

The study met its primary objective, demonstrating that nintedanib DPI was generally safe and well tolerated in patients with IPF. The Phase 1b study enrolled 27 patients across 10 U.S. sites and evaluated two multiple-ascending dose regimens of nintedanib DPI administered over seven days.

**INFLO-1 Topline Results**
Key findings from the study included:

- No serious adverse events
- No drug-related gastrointestinal side effects (i.e., diarrhea, nausea, vomiting)
- No bronchospasm events
- No treatment discontinuations or dose reductions
- No differences in spirometry parameters between nintedanib DPI and placebo (empty cartridges)
- Most patients experienced no cough; reported cough events were predominantly mild, transient and resolved

Additional data will be presented at a future conference.

"The INFLO-1 results represent an important milestone for our nintedanib DPI program and further validates the potential of our Technosphere® platform in pulmonary fibrosis," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "Across our Phase 1a and Phase 1b studies, participants have received more than 700 inhalations of nintedanib DPI, including nearly 450 inhalations administered to people living with IPF. Importantly, cough was not a meaningful barrier to treatment. When observed, cough events were generally mild, transient and resolved, with no cough-related discontinuations or dose reductions. These findings provide growing confidence as we continue to advance Phase 2 development."

**Phase 1a Program Established Foundation for Clinical Development**
The INFLO-1 findings build upon previously reported results from MannKind's completed Phase 1a first-in-human study in healthy volunteers. In that study, nintedanib DPI demonstrated favorable safety and tolerability with no serious adverse events, no discontinuations, and no safety signals identified. Pharmacokinetic analyses demonstrated rapid absorption and dose-proportional increases in plasma concentrations consistent with deep-lung delivery following inhalation.

Across the completed Phase 1a and Phase 1b studies, a total of 48 individuals have received nintedanib DPI, 18 of whom were patients with IPF, providing the largest reported clinical dataset with an inhaled nintedanib therapy in patients with IPF to date.

**Global Phase 2 INFLO-2 Study Underway**
MannKind's global Phase 2 INFLO-2 study is actively enrolling patients with IPF. The randomized, double-blind, placebo-controlled trial is expected to enroll approximately 210 participants across approximately 85 sites worldwide and is designed to further evaluate the safety, tolerability and efficacy of nintedanib DPI.

Participants are being randomized to receive either nintedanib DPI (2mg four times daily or 4mg twice daily) or placebo for 12 weeks, followed by a 24-week open-label extension in which all participants will receive active treatment. The primary objective of the study is to assess safety and tolerability 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 was a Phase 1b, randomized, double-blind, placebo-controlled study of nintedanib DPI in patients with IPF. The U.S. trial consisted 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).

**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 in adult patients.

**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]

**Investor Call**
Management of the Company will host a conference call to discuss results at 4:30 p.m. ET on July 29, 2026. Presenting from the Company will be its Chief Executive Officer, Michael Castagna, PharmD, and Wassim Fares, M.D., MSc, FCCP, Senior Vice President, Therapeutic Area Head – Respiratory.

To view and listen to the webcast, visit MannKind's website at https://investors.mannkindcorp.com/events-and-presentations. A replay will also be available on MannKind's website for approximately 90 days.

**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 continuing development of MNKD-201 and the potential of our platform in pulmonary fibrosis. 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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