

INFLO-1 Data Readout: Strengthening the Nintedanib DPI Opportunity in IPF

July 29, 2026



Cautionary Statement

Statements in this presentation that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. Words such as “believes”, “anticipates”, “plans”, “expects”, “intend”, “will”, “goal”, “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon MannKind’s current expectations.

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Agenda

- 1 The IPF Opportunity
 - 2 Clinical Overview
 - 3 Closing Remarks
 - 4 Q&A
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Michael Castagna,
PharmD
Chief Executive Officer



Dr. Wassim Fares
Senior Vice President,
Therapeutic Area Head,
Respiratory

Major Catalysts Driving 2026 & Beyond



Afrezza® Pediatrics

- Population expansion; INHALE-1ST
- Unique value proposition addressing patient unmet needs
- Compounds growth as adolescents age into adults

APPROVED 



Furoscix ReadyFlow™ Autoinjector

- Reduces administration from hours to seconds
- Supports broader adoption
- Would significantly reduce cost of goods

APPROVED 



Nintedanib DPI

- Urgent need for new, effective therapies in IPF
- Lung targeted delivery addresses IPF tolerability barriers
- Key clinical de-risking step

Ph1b Readout Q3 
Ph2 First Patient Q2 

The IPF Opportunity

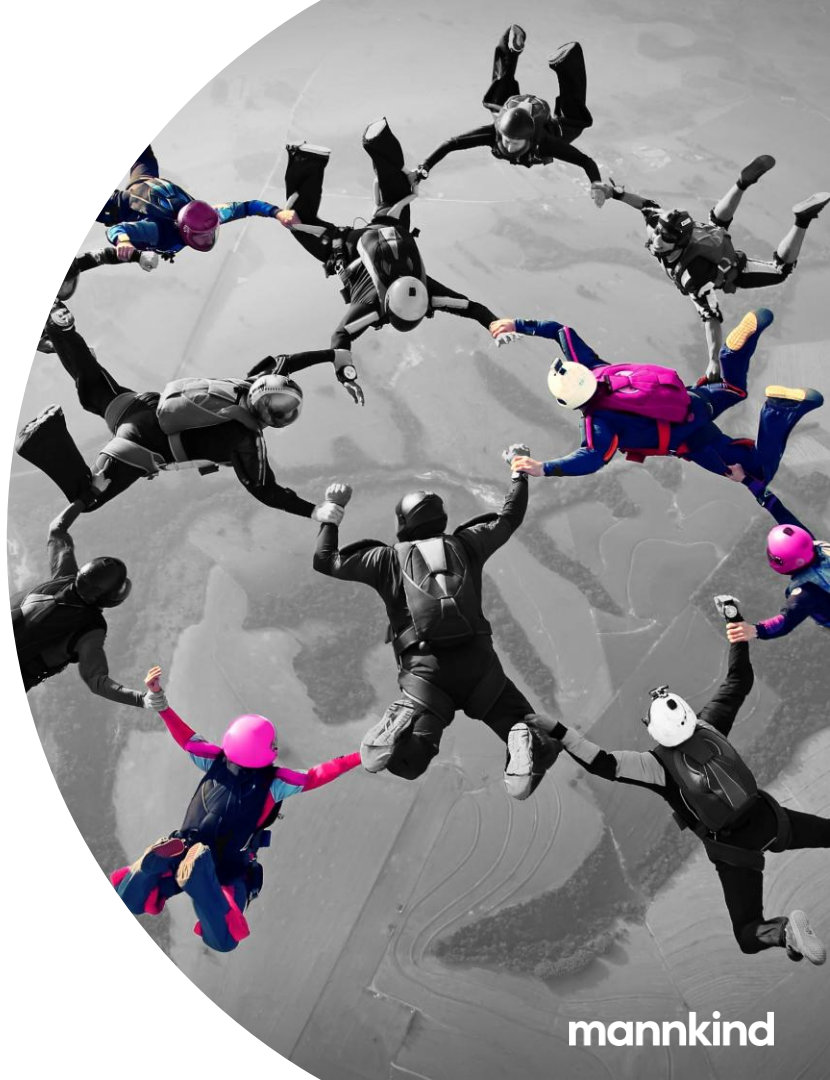
Highlights

✓ Phase 1b study demonstrated **safety** and **tolerability** in patients with IPF

- No serious adverse events
- No GI burden
- No discontinuations
- No difference in spirometry parameters between placebo (empty cartridge) and Nintedanib DPI

✓ Phase 2 global study underway

- First patient dosed; **enrollment ramping** through 2026



A Validated Category + Persistent Unmet Need Creates an Opportunity for Targeted Inhaled Approaches

U.S. MARKET LANDSCAPE

~650,000 patients with ILDs
>200 ILD subtypes can progress to fibrosis

**~100,000+
patients with IPF**
20% rise in the last decade

**~180,000
PPF patients**
larger adjacent fibrosing
ILD segment

Approved oral therapies: OFEV® · Esbriet® · JASCAID®



>\$150K

annual brand pricing / patient



>\$40B

implied U.S. total addressable
market



>\$4B

OFEV global revenue in 2025 —
blockbuster precedent

IPF: A Progressive and Fatal Disease with Problematic Therapies

- Current therapies exhibit major safety and tolerability issues
- Discontinuation rates are as high as 50%¹
- A minority of patients even start IPF therapy
- 80% of patients die within 36-60 months³

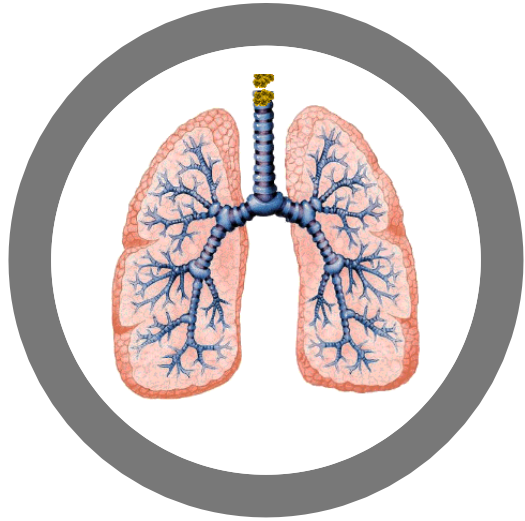
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out of

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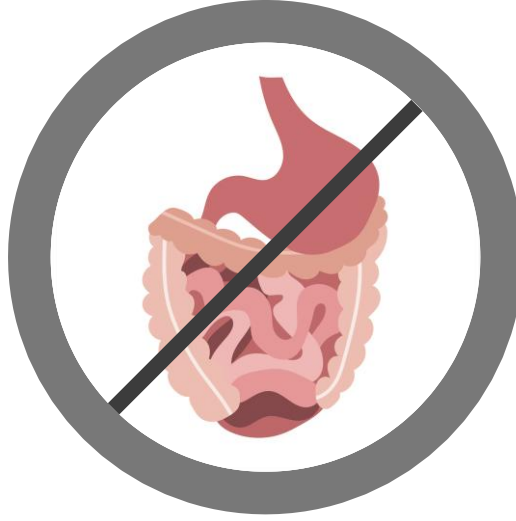
patients with IPF are **not** on an approved antifibrotic therapy¹

Local Delivery, Systemic Advantage: A Potentially Better Path Forward



Target the lungs directly

*Efficient, targeted
deep-lung delivery*



Bypass the GI tract

Lower systemic exposure



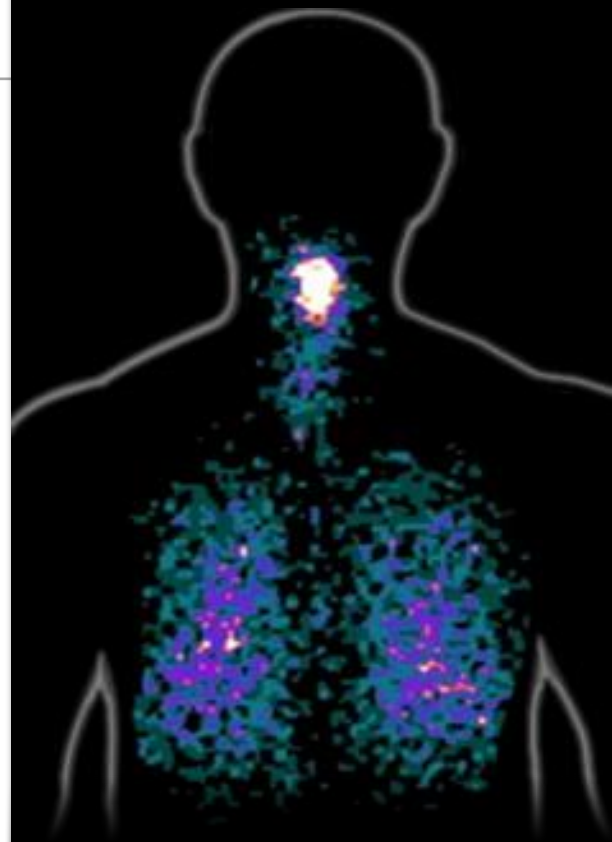
Improve efficacy and tolerability

*May support long-term
adherence*

Our Technology is Differentiated

Versatile Platform with Competitive Advantages

- Technosphere® technology provides highly efficient delivery
 - Dry powder administered via portable inhalers
 - Rapid, uniform distribution deep into the lung
- FDKP (fumaryl diketopiperazine) microparticles drive extensive distribution throughout the lung
- Proven platform utilized in two FDA-approved products (Afrezza, Tyvaso DPI®)



Technosphere Particles Driven Predominantly by FDKP



Afrezza
90% FDKP
10% active API



Tyvaso DPI
99% FDKP
1% active API

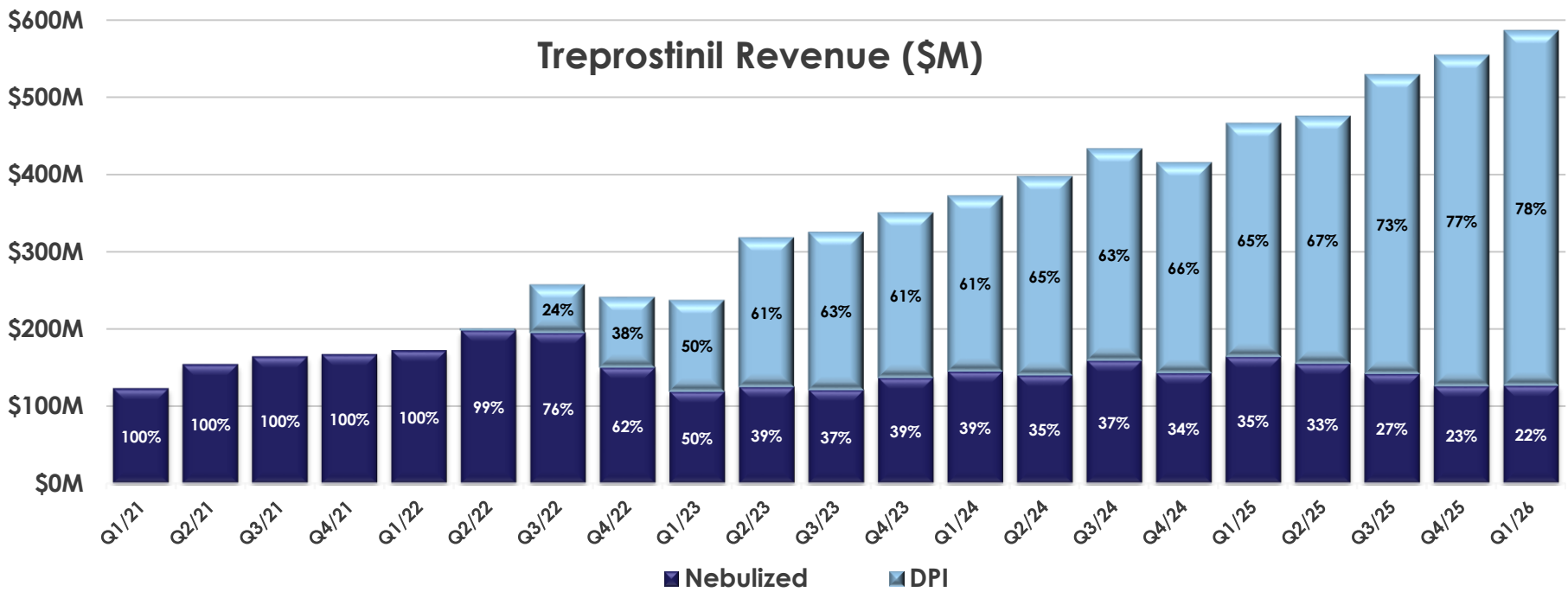


Nintedanib DPI
80% FDKP
20% active API

Pipeline
Target powder is
10mg max per
dose and is **80-99%**
FDKP and 1-20%
drug load

**Technosphere
Powder**
Used in >50,000
patients

Case Study: Patient Preference in Rare Lung Disease



The inhaled treprostinil market is **dominated by DPI usage**, which has grown to nearly **80% of the market**

Clinical Overview

Wassim Fares, MD, MSc, FCCP

Senior Vice President, Therapeutic Area Head, Respiratory

Board-certified pulmonologist with 18+ years leading respiratory clinical development—from early-stage studies through Phase 3 and post-approval

- Deep experience spanning academic medicine, clinical research, and biopharma leadership focused on serious, rare lung diseases
- Leadership roles at PureTech Health, Merck, Acceleron Pharma, Bellerophon Therapeutics and Johnson & Johnson
- Clinical trial principal investigator, published author, and inventor on patented pulmonary therapies
- Former Associate Professor of Medicine, Yale University; Adjunct Faculty, University of North Carolina



Strong Preclinical Safety and Lung-Targeted PK Established the Foundation for Clinical Development



PK signal: lung concentrations were ≥ 100 -fold higher than plasma with minimal systemic exposure



Initial Tox

Two 28-day repeat-dose studies in two species showed no systemic toxicity and non-adverse respiratory tract histologic findings



Long-term Chronic Tox

6-month repeat-dose study revealed no clinical toxicity and wide safety margin



PK & Exposure

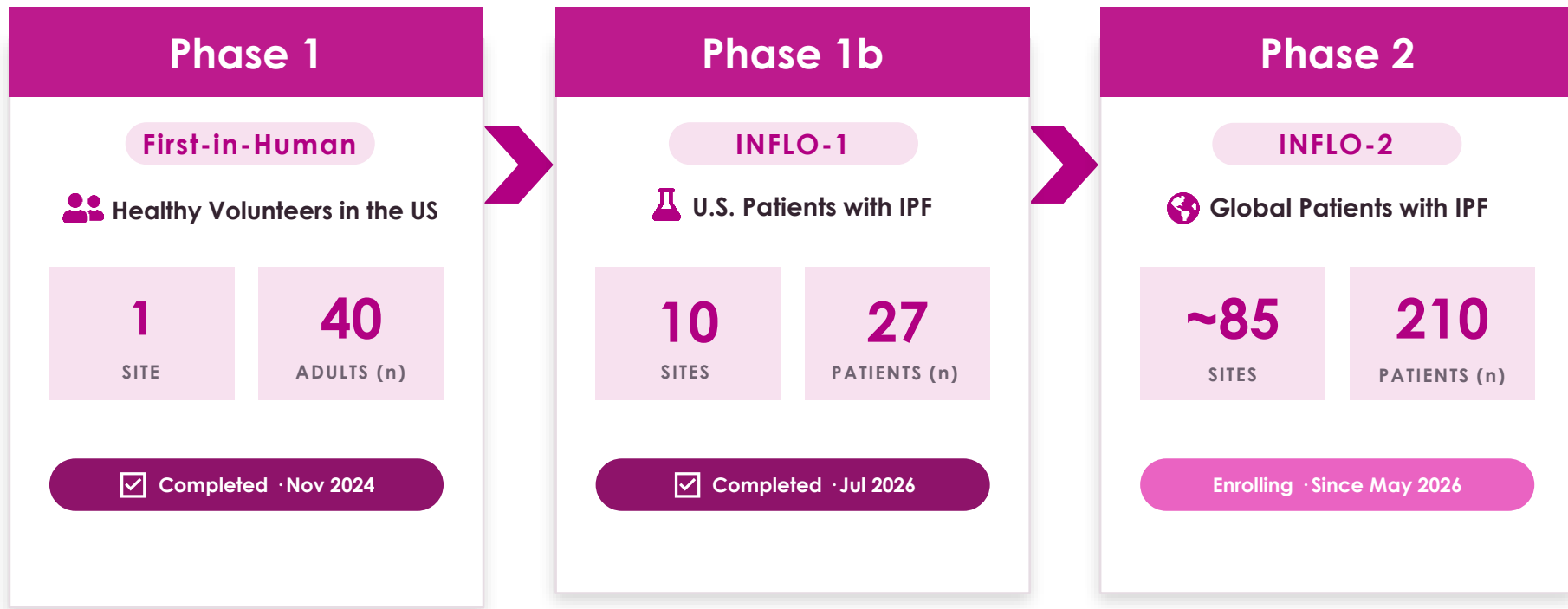
Dose-proportional concentrations; high lung concentrations with minimal systemic exposure and rapid plasma absorption, reflecting immediate delivery to deep lungs

Clinical development justification

Five non-GLP animal PK / PD and dose-ranging toxicokinetic studies informed the GLP program and supported the advancement of Nintedanib DPI, demonstrating **robust safety margins** and favorable **tolerability**.

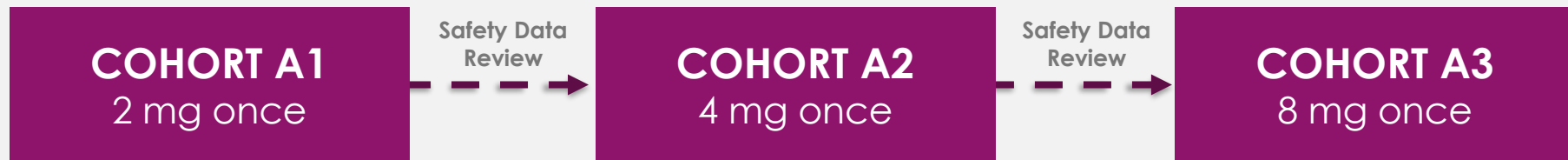
Nintedanib DPI Clinical Development

Rapidly de-risking program scaling from first-in-human to a 210-patient global study



Phase 1a: Study Designed to Evaluate Pharmacokinetics and Safety

Part A: Single-Ascending Dose (n = 24; 3:1 randomization)



Part B: Multiple-Ascending Dose (7 Days) (n = 16; 3:1 randomization)



Phase 1a: Proven Molecule, Now Proven Tolerability in First-in-Human

Safe and well-tolerated over 7 days in healthy adult volunteers — no safety signals

0

Safety Signals

0

Serious AEs

0

Discontinuations

Adverse Events

- Mild, reversible cough, typically after the first dose with no worsening (consistent with Technosphere® powder)
- No systemic AEs typical of Ofev (e.g. diarrhea, nausea, vomiting, headache)

Pharmacokinetics

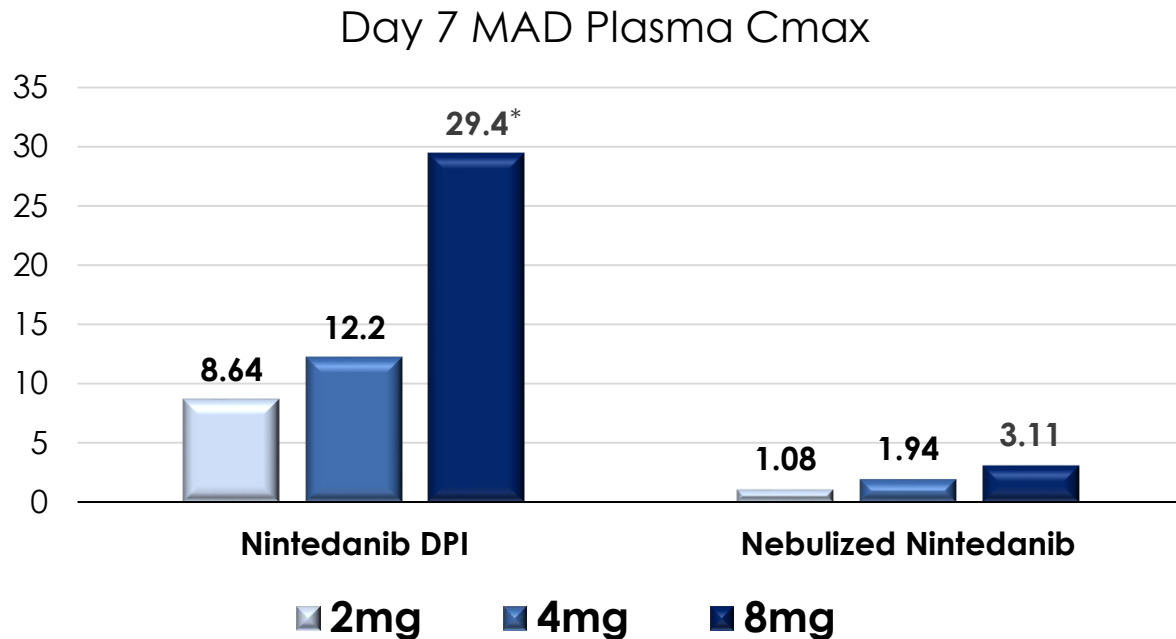
- Immediate peak in plasma with rapid distribution into tissues (see next slide)

C_{max} Drives Efficacy in Pulmonary Fibrosis



- **C_{max}, not AUC, drives nintedanib efficacy** — hitting a threshold peak concentration matters more than total lung exposure.
- **Beyond that peak, more exposure adds little** — large oral-derived tissue levels contribute minimal extra anti-fibrotic benefit.
- **Brief, high peaks are sufficient** — short bursts of high concentration were sufficient to inhibit fibrotic pathways.

Phase 1a: PK Data for Nintedanib DPI



Nintedanib DPI delivers **more drug** to the deep lung — **6x to 8x higher** plasma Cmax than nebulized nintedanib at every comparable dose

*Results for 8 mg Nintedanib DPI are from the 8 mg SAD Cohort (i.e., Day-1).

References: Fares and Castagna. Safety and Pharmacokinetic Data for Inhaled Administration of Nintedanib Dry Powder Inhalation for Treatment of Pulmonary Fibrotic Diseases. J Aerosol Med Pulm Drug Deliv. 2026 Aug;39(4):185-197; Palacios M, Pham S, Surber M, et al. Inhaled Nintedanib (AP02) for the Treatment of IPF: Safety, Tolerability, and Pharmacokinetics After Single Ascending Doses to Healthy Subjects and patients with IPF. Am J Respir Crit Care Med. 2025;211(Suppl 1):A2915.



Nintedanib DPI Phase-1b Study (U.S.)

A Randomized, Double-Blind, Placebo-Controlled, Phase 1b Clinical Study of the Safety, Tolerability, and Pharmacokinetics of Nintedanib Dry Powder Inhalation (MNKD-201) in Patients with Idiopathic Pulmonary Fibrosis.

INFLO-1 Phase 1b: First-in-Patient Study to Assess Safety, Tolerability and Pharmacokinetics

Multiple-Ascending Dose (7 Days) (n = 27; 2:1 randomization)

COHORT 1
2 mg TID

Safety Data Review
(Sponsor & External DSMB)

COHORT 2
4 mg BID

Objectives

01

Early Safety Data

First-in-patient safety readout in idiopathic pulmonary fibrosis

02

Pulmonary Tolerability

Short-term pulmonary safety & tolerability profile

03

Multiple-Ascending Dose

7-day dose escalation; safety-focused with no efficacy objectives

Phase 1b: A Clean Safety Profile in First IPF Study

0

Safety Signals

None of the diarrhea, nausea or vomiting that limits oral nintedanib (OFEV®)

0

Bronchospasms

A known risk for inhaled powders — none observed, even in fibrotic lungs

0

Discontinuations

Where current oral therapies see discontinuation rates as high as 50%

A tolerability profile built for chronic use – de-risking the program as it advances into Phase 2

Phase 1b Cough: Mild and Transient

Most patients had no cough — and when it occurred, it was mild and led to zero discontinuations. Cough was not correlated to powder mass.

~60% of patients had
NO cough

(11 of 18 on active drug)

~30% of patients had
a **mild** cough

No severe cough

0 discontinuations
from cough

0 serious AEs



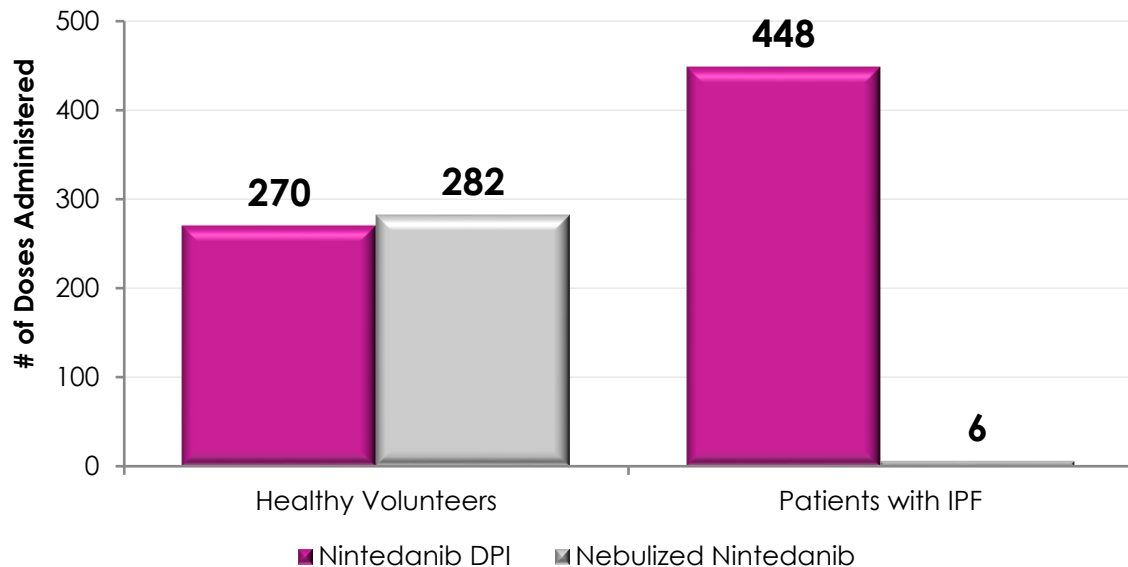
THE PHASE 1b SUMMARY

- ~90% of patients had no cough or a mild cough event (Grade 1); none were severe (Grade ≥ 3)
- Cough typically follows the first dose and does not worsen with continued use
- **No** cough-related discontinuations and **no** serious AEs
- No dose reductions after over ~450 inhalations administered over 7 days



PROVEN PLATFORM: Technosphere® powder in two FDA-approved DPI products, with clinical data showing <3% discontinuation due to cough.

Nintedanib DPI Delivers Deep Inhaled Exposure in Patients with IPF



WHY IT MATTERS

448

doses in patients with IPF with
Nintedanib DPI

~75×

the IPF dosing experience vs.
the other inhaled nintedanib
formulation



Nintedanib showed no difference in spirometry
between placebo (empty cartridge) and active drug.



FDKP carrier utilized in underlying lung disease

Thousands of ILD patients have already used our
Technosphere powder (Tyvaso DPI in PH-ILD).



Nintedanib DPI Phase-2 Study (Global)

A Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, and Efficacy of Two Different Doses of Nintedanib Dry Powder Inhalation (MNKD-201) in Patients with Idiopathic Pulmonary Fibrosis.

INFLO-2 Phase 2: Global Enrollment Underway in IPF



- Randomization 2:2:1:1
- Sample size 210
- Aged 40-85
- Patients with IPF without current background IPF treatment or **on stable pirfenidone and / or nerandomilast background therapy**
- N=70 / Active Study Arm

STUDY DESIGN

Phase 2 Controlled Study
(12 weeks)

Nintedanib DPI 4 mg BID

Nintedanib DPI 2 mg QID

Placebo DPI BID

Placebo DPI QID

Phase 2 Open-Label Extension
(24 weeks)

Nintedanib DPI 4 mg BID

Nintedanib DPI 2 mg QID

Nintedanib DPI 4 mg BID

Nintedanib DPI 2 mg QID

01 1° Objectives: Safety and tolerability

02 Efficacy Endpoint: FVC (Forced Vital Capacity)

Closing Remarks

A Layered Patent Estate Extends Protection to 2046+

Product-specific Patent Estate (MNKD-201)

COMPOSITION

Composition for treating pulmonary fibrosis

To 2041

Covers FDKP-nintedanib + surfactant dry powders and the methods of making and using them.

METHOD OF USE

Methods for treating lung diseases

To 2043

Covers kinase inhibitors and their methods of use across pulmonary fibrotic disease.

METHOD OF TREATMENT

Method for treating lung diseases

To 2046

Extends the product-specific estate's longest-dated protection potentially to 2045.

THE PLATFORM MOAT

>1,400

patents in force worldwide, plus
>300 pending applications

>125

U.S. patents on FDKP synthesis &
Technosphere® particles

Manufacturing complexity

adds a practical barrier to entry
beyond the patent estate

Nintedanib DPI: Lung-Targeted Delivery Without the Nebulizer Burden or Systemic AEs

DPI

A proven, portable platform designed to make inhaled nintedanib practical for chronic use



PROVEN PLATFORM

Technosphere® particles are validated in 2 FDA-approved DPI products used in adult patients, including elderly individuals with compromised lung function

<3%

discontinuation due to cough in approved products



PRACTICAL ADMINISTRATION

Portable, handheld dosing with rapid administration and no need for nebulizer setup, cleaning, or maintenance

Designed to support long-term adherence



PULMONARY EXPERIENCE

Demonstrated safety and tolerability in patients with underlying lung diseases

Our platform technology (Tyvaso DPI®) is approved for use in PAH and PH-ILD, including patients living with IPF who also have PH

Nintedanib DPI is Positioned to Anchor the Future of IPF Therapy

Nintedanib is the gold standard —
but oral GI burden caps its use.

1 **2 oral anti-fibrotics**
Oral nintedanib and pirfenidone

2014 – Today



2 **Novel MOAs & delivery routes**
JASCAYD · Next-gen agents (e.g., Tyvaso,
Tyvaso DPI, Ralinepag DPI, admilparant) ·
Nintedanib DPI

Emerging



Nintedanib DPI
can become the **backbone** even
as IPF shifts to combination therapy

**Nintedanib
DPI** +

3 **Combination therapy**
Nintedanib DPI + multiple agents

Future

The pattern is proven – chronic respiratory diseases have evolved from monotherapy to combination regimens

MannKind Has Three Shots on Goal in IPF

One proven platform. One large, under-served market.

1

Nintedanib DPI

Wholly-owned



Proven molecule, now with **proven tolerability** in IPF. **Phase 2 underway.**

2

Tyvaso DPI

United Therapeutics Partnership



Currently **approved** in PAH and PH-ILD. **Future expansion into IPF.**

3

Ralinepag DPI

United Therapeutics Partnership



Next-gen prostacyclin with multi-indication opportunity. **Progressing to IND.**

Q&A

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mannkind