A Study to Evaluate Safety, Tolerability and Pharmacokinetics of MNKD-201 in Patients With Idiopathic Pulmonary Fibrosis

NCT07344558

Status	RECRUITING
Phase	Phase 1
Sponsor	Mannkind Corporation
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (10)

- Is e40 to d75 years of age at the time of signing the informed consent form.
- Diagnosis of IPF
- Either treatment-naive or is currently on background pirfenidone on a stable dose for at least 3 months prior to Screening.
- Has FVC \>45% and \<100% of predicted of normal, as determined by the central spirometry reader, during Screening.
- DLCO corrected for hemoglobin \[Visit 1\] e40% of predicted of normal, within 12 months of Screening. If no historical DLCO is available prior to Screening, this is to be done during Screening and read locally.

... and 5 more (see full listing online)

Exclusion (19)

- Known explanation for interstitial lung disease, including but not limited to radiation, sarcoidosis, hypersensitivity pneumonitis, and bronchiolitis obliterans organizing pneumonia.
- Diagnosis of any connective tissue disease, including but not limited to scleroderma/systemic sclerosis, polymyositis/dermatomyositis, systemic lupus erythematosus, and rheumatoid arthritis, regardless of whether or not it is presumed to be related to their pulmonary fibrosis diagnosis.
- Major extrapulmonary physiological restriction (e.g., chest wall abnormality, large pleural effusion), as determined by the investigator.
- Significant Cardiovascular diseases
- Has had a recent or an ongoing systemic infection

... and 14 more (see full listing online)

Locations (5 total)

VALDI, Fresno, California, United States
Palmtree Clinical Research, Palm Springs, California, United States
Southeastern Research Center, Winston-Salem, North Carolina, United States
... and 2 more locations