Study of the Efficacy and Safety of Inhaled Treprostinil in Subjects With Progressive Pulmonary Fibrosis (TETON-PPF)

NCT05943535

Status	RECRUITING
Phase	Phase 3
Sponsor	United Therapeutics
Enrollment	698 participants

Key Eligibility Criteria

Inclusion (21)

- Subject gives voluntary informed consent to participate in the study.
- Subject is e18 years of age, inclusive, at the time of signing informed consent.
- Subject has radiological evidence of pulmonary fibrosis of \>10% extent on an HRCT scan in the previous 12 months (confirmed by central review).
- Subject has a diagnosis of PPF (other than IPF) that fulfills at least 1 of the following criteria for progression within 24 months of screening despite standard treatment of ILD, as assessed by the Investigator:
- Clinically significant decline in % predicted FVC based on e10% relative decline

... and 16 more (see full listing online)

Exclusion (13)

- Subject is pregnant or lactating.
- Subject has primary obstructive airway physiology (forced expiratory volume in 1 second/FVC \<0.70 at Screening) or greater extent of emphysema than fibrosis on HRCT (confirmed by central review).
- Subject has a diagnosis of IPF.
- Subject has shown intolerance or significant lack of efficacy to a prostacyclin or prostacyclin analogue that resulted in discontinuation or inability to effectively titrate that therapy.
- Subject has received any PAH-approved therapy, including prostacyclin therapy (epoprostenol, treprostinil, iloprost, or beraprost; except for acute vasoreactivity testing), IP receptor agonists (selexipag), endothelin receptor antagonists, phosphodiesterase type 5 inhibitors (PDE5-Is), soluble guanylate cyclase stimulators, or activin signaling inhibitors (sotatercept) within 60 days prior to Baseline. As needed use of a PDE5-I for erectile dysfunction is permitted, provided no doses are taken within 48 hours prior to any study-related efficacy assessments.

... and 8 more (see full listing online)

Locations (150 total)

UAB Lung Health Center, Birmingham, Alabama, United States
Banner University Medical Center Phoenix Lung Institute, Phoenix, Arizona, United States
Norton Thoracic Institute, Phoenix, Arizona, United States
... and 147 more locations