A Study Evaluating the Safety and Efficacy of Inhaled AP01 in Participants With Progressive Pulmonary Fibrosis

NCT06329401

Status	RECRUITING
Phase	Phase 2
Sponsor	Avalyn Pharma Inc.
Enrollment	375 participants

Key Eligibility Criteria

Inclusion (17)

- Participant meets criteria for PPF, as follows:
- In subjects with interstitial lung disease (ILD) of known or unknown etiology other than idiopathic pulmonary fibrosis (IPF) who have radiological evidence of pulmonary fibrosis, PPF is defined as:
- Physiological evidence of disease progression with at least 1 of the following criteria despite treatment with approved or unapproved medications commonly used in practice (per Investigator):
- Relative decline in FVC e10% predicted within the previous 24 months based on documented historical spirometry assessments
- Relative decline in FVC e5% to \<10% predicted within the previous 24 months based on documented historical spirometry assessments with at least 1 of the 2 following criteria:

... and 12 more (see full listing online)

Exclusion (9)

- Current treatment with oral pirfenidone or treatment with oral pirfenidone within 3 months prior to Screening.
- Elevated liver enzymes and liver injury at Screening defined as:
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) Ã 3 times the upper limit of normal (ULN)
- Bilirubin \>2.0 x ULN
- Renal disease with a creatinine clearance \< 30 mL/min, calculated according to the Chronic Kidney Disease Epidemiology Collaboration formula. Retesting is allowed once.

... and 4 more (see full listing online)

Locations (152 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
Mayo Clinic- Scottsdale, Scottsdale, Arizona, United States
University of Southern California, Los Angeles, California, United States
... and 149 more locations