An Extension Study of Subjects Who Received an Avalyn Inhaled Antifibrotic Agent (SAIL)

NCT06951217

Status	RECRUITING
Phase	Phase 2
Sponsor	Avalyn Pharma Inc.
Enrollment	340 participants

Key Eligibility Criteria

Inclusion (3)

- Previously participated in an Avalyn-sponsored inhaled antifibrotic clinical study for subjects with either idiopathic pulmonary fibrosis (IPF) (IPF subjects are excluded from the US and Canada) or progressive pulmonary fibrosis (PPF) and with the approval of the Study Physician.
- Previous participation is defined as: Having completed the final visit of the Treatment Period on the full dose of study drug (either active or placebo).
- Male subjects and female subjects of childbearing potential (FOCBP) agree to use highly effective contraception measures from the time of first dose of study drug (for the male subject) or the signing of the informed consent form (ICF) (for the female subject), during the study, and until 90 days after the last dose of study drug. Subjects agree not to donate eggs or sperm during the same period.

Exclusion (5)

- Have not previously participated in an Avalyn-sponsored inhaled antifibrotic lead-in study or if the subject was permanently discontinued from the lead-in study for any reason. Subjects who discontinued study drug but continued to attend study visits are ineligible.
- Subjects who experienced an exacerbation of asthma or of chronic obstructive pulmonary disease (COPD) requiring oral or systemic corticosteroids within 3 months of Day 1 (Screening/Baseline Visit).
- Subjects who experienced an acute exacerbation of IPF (IPF subjects are excluded from the US and Canada) or of PPF within 3 months of Day 1 (Screening/Baseline Visit).
- Participation in a concurrent clinical study or in a clinical study in which any other investigational drug product aside from the Avalyn nebulized antifibrotic medication from their lead-in study was administered within the previous 30 days, or 5 half-lives of the previously administered investigational product, whichever is shorter. Subjects may be enrolled in registries.
- History of hypersensitivity and/or allergic reaction to pirfenidone or the excipients to be used in this study.

Locations (44 total)

University of Colorado, Anschutz Medical Campus, Aurora, Colorado, United States
Renstar Medical Research, Ocala, Florida, United States
Piedmont Healthcare, Inc., Atlanta, Georgia, United States
... and 41 more locations

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