# An Open-Label Extension Study of Subjects Who Received an Avalyn Inhaled Antifibrotic Agent (SAIL)

ACTRN12625000246482

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

## Plain Language Summary

Idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF) are serious lung conditions where the lungs gradually become scarred and stiff, making breathing increasingly difficult over time. While some treatments can slow progression, there is no cure. Avalyn Pharma is developing an inhaled antifibrotic medication called AP01, which is designed to deliver the drug directly to the lungs to reduce scarring.

This open-label extension study allows participants who have already completed an earlier Avalyn-sponsored clinical trial of AP01 to continue receiving the treatment until the drug is approved, the study ends, or they choose to withdraw. This type of study is important for collecting longer-term safety and tolerability data and ensuring that participants who responded to treatment are not left without access between trials.

You are eligible if you previously completed the full treatment period of an Avalyn-sponsored inhaled antifibrotic study and were not permanently discontinued. Women of childbearing potential must agree to use contraception throughout and for 90 days after the last dose. People who had an acute exacerbation of their lung condition in the last 3 months are not eligible.

## Key Eligibility Criteria

### Inclusion (12)

- • Previously participated in an Avalyn-sponsored inhaled antifibrotic clinical
- study for subjects with either idiopathic pulmonary fibrosis (IPF) 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

... and 7 more (see full listing online)

### Exclusion (17)

- •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

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

## Locations (22 total)

Czech Republic
Poland
Netherlands

... and 19 more locations

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12625000246482