



SAIL Study

Trial title	A Multinational, Long-Term, Open-Label Extension Study of Subjects Who Have Participated in Avalyn Pharma Studies of Inhaled Antifibrotic Agents (AP-LTE-008 [SAIL]).
Trial synopsis	Study AP-LTE-008 is a multinational, multicentre, open-label, long-term extension study to evaluate the long-term safety, tolerability, and efficacy of Avalyn nebulized antifibrotic medications, including AP01 (pirfenidone inhalation solution), in addition to standard of care in subjects who previously participated in an Avalyn lead-in study and if eligible to do so, choose to continue dosing of study drug for their condition (progressive pulmonary fibrosis [PPF] or idiopathic pulmonary fibrosis [IPF]). Subjects are eligible if they have completed the protocol-required final visit of the Treatment Period while on the full dose of study drug (either active or placebo) in the lead-in study. The study visits will be a continuation from the lead-in study, with the first study visit of AP-LTE-008 on the same day as the last study visit of the lead-in study. The study will consist of a Screening/Baseline Visit (Day 1), an open-label Treatment Period, and a Follow-up/End of Study (EOS) phone call.
Investigational medicinal product, comparator and randomization	AP01 100 mg (two 4 mL blow-fill-seal [BFS] ampoules of 12.5 mg/mL pirfenidone) will be administered two times a day (BID) via the eFlow nebulizer (inhaled).
Disease target	Progressive pulmonary fibrosis [PPF] or idiopathic pulmonary fibrosis [IPF]
Sponsor	Avalyn Pharma
Duration	Subjects will begin dosing on Day 1 (Screening/Baseline Visit) of the study and may continue with treatment until the Avalyn nebulized antifibrotic medication from their lead-in study is approved for marketing authorization and is commercially available in the country/region of the subject's residence, the Investigator deems treatment should discontinue, the subject meets withdrawal criteria, or until the study is terminated.
Trial Status	Recruiting



Trial phase	Phase 2b
Key inclusion criteria	<ul style="list-style-type: none">• Provide written informed consent per the Institutional Review Board/Ethics Committee (IRB/EC).• Previously participated in an Avalyn-sponsored inhaled antifibrotic clinical study for subjects with either IPF or PPF and with the approval of the Investigator. 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).
Key exclusion criteria	<ul style="list-style-type: none">• 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 or of PPF within 3 months of Day 1 (Screening/Baseline Visit).• Any conditions or abnormalities (including electrocardiogram [ECG] or laboratory abnormalities) which, in the opinion of the Investigator may compromise the safety of the subject or interfere with the subject participating in or completing the study.
Number of participants sought	Up to approximately 340 subjects may be enrolled, including up to 40 subjects from Study AP01-005 and up to 300 subjects from Study AP01- 007. The total number of subjects is dependent on the number of subjects who choose to roll over from each lead-in study and are eligible for AP- LTE-008
Lead site(s) in Australia	<ul style="list-style-type: none">• Westmead Hospital (NSW)• Nepean Lung and Sleep (NSW)



PACT

PF Australasian Clinical Trials

Lead site(s) in New Zealand	<ul style="list-style-type: none">• Greenlane Clinical Centre (NZ)
Additional sites	<ul style="list-style-type: none">• Canberra Hospital• Royal Prince Alfred Hospital (NSW)• Macquarie University Clinical Trials Unit (NSW)• John Hunter Hospital (NSW)• The Prince Charles Hospital (QLD)• Lung Research Queensland (QLD)• Alfred Hospital (VIC)• Lung and Sleep Victoria (VIC)• The Queen Elizabeth Hospital (SA)• Respiratory Clinical Trials (SA)• Institute for Respiratory Health (WA) • Christchurch Hospital NZ)• Dunedin Hospital (NZ)• Bay of Plenty Clinical Trials Unit (NZ)• Waikato Hospital (NZ)
Contact	enquiries@pactnetwork.com.au