Centre of Research Excellence in Pulmonary Fibrosis
PACT PF Australasian Clinical Trials

AVALYN AP01Study

Trial title	A Study Evaluating the Safety and Efficacy of AP01 (inhaled pirfenidone) in Participants with Progressive Pulmonary Fibrosis (PPF).
Trial synopsis	This is a randomized, double-blind, placebo-controlled clinical study to evaluate the safety and efficacy of 2 doses of AP01 versus placebo on top of standard of care in participants with PPF over 52 weeks.
Investigational medicinal product, comparator and randomisation	AP01 (Inhaled pirfenidone) Participants will be randomized to 1 of 3 treatment arms: AP01 high dose, AP01 low dose, or placebo.
Disease target	Progressive Pulmonary Fibrosis (PPF) – (Formerly PF-ILD)
Sponsor	Avalyn Pharma
Duration	56 Weeks
Trial Status	Active
Trial phase	Phase 2b
Key inclusion criteria	• > 18 years of age • Diagnosis of PPF • Meeting all of the following criteria: I. FVC ≥45% of predicted normal II. FEV1/FVC ≥0.7 or ≥age-adjusted lower limit of normal Global Lung Function Initiative III. DLCO ≥30% of predicted, corrected for hemoglobin IV. Subject can perform acceptable spirometry • Fibrosing lung disease on HRCT • For subjects already on nintedanib must have been on it for at least 6 months • For subjects who have discontinued nintedanib: Must have been off it for at least 12 weeks • Stable medication for 12 weeks • For subjects who have discontinued rituximab: Must have received the last dose of rituximab at least 6 months prior to Screening.
Key exclusion criteria	• Current treatment with oral pirfenidone or treatment with oral pirfenidone within 3 months • Elevated liver enzymes and liver injury

	• Renal disease • Diagnosis of idiopathic pulmonary fibrosis (IPF) • Greater extent of emphysema than of fibrotic ILD on HRCT. • Significant clinical worsening of PPF between Screening Visit 1 and Visit 3
Number of participants sought	300
Lead site(s) in Australia	• Westmead Hospital (public) • Lung and Sleep (private)
Lead site(s) in New Zealand	Canterbury Respiratory Research Group
Additional sites	Australia Public sites: • The Canberra Hospital (ACT) • Royal Prince Alfred Hospital (NSW) • John Hunter Hospital (NSW) • The Alfred Hospital (VIC) • Eastern Health (VIC) • Box Hill Hospital (VIC) Australia Private sites: • Nepean Lung and Sleep (NSW) • Lung & Sleep Victoria (VIC) • Institute for Respiratory Health (WA) New Zealand sites: • Greenlane Clinical Centre • Dunedin Hospital • Bay of Plenty Clinical School Health
Contact	enquiries@pactnetwork.com.au