Clinician - PACT
New Clinical Trial and Research

Trial title	A Randomized Open-Label, Phase 1b Study of the Safety of Pirfenidone Solution for Inhalation (AP01) in Patients with Idiopathic Pulmonary Fibrosis (ATLAS Study)
Trial synopsis	This is a randomized, open-label study of Pirfenidone Solution for Inhalation (AP01) 50 mg once daily or 100 mg twice daily. This study has 2 parts. Part A (24 weeks): Patients will be randomised in a 1:1 ratio to one of two treatment arms: 50 mg once daily or 100 mg twice daily. Part B (48 weeks): Patients who, in the opinion of the investigator, are compliant with study treatment dosing and study procedures will be permitted to enter Part B. All patients will continue to receive the treatment regimen (50 mg once daily or 100 mg twice daily) to which they were randomized in Part A. If one dosing regimen is determined to be superior either from an efficacy or safety standpoint, Part B may be converted to a single dose regimen. All patients who participate in Part B will be dosed with the selected regimen. Any patients already participating in Part B will be converted to the chosen single dose regimen at that time.
Investigational medicinal product, comparator and randomisation	Open label randomized trial 1:1 randomization of either 50 mg AP01 (pirfenidone solution for inhalation) once daily, or 100 mg AP01 twice daily, delivered by PARI eFlow nebulizer
Disease target	Idiopathic Pulmonary Fibrosis
Sponsor	Avalyn Pharma
Duration	76 weeks
Trial Status	Recruiting
Trial phase	Phase 1b
Key inclusion criteria	• Male and female patients ages 40 – 90 years old (inclusive) • 40 ≤ FVC ≤ 90% predicted; The first 20 patients randomized must have FVC ≥ 50% predicted. After the first 20 patients have been randomized, patients with FVC 40% < 50% predicted will be allowed to be randomized in the study but randomization for these patients will be capped at 20. • FEV1/FVC ratio ≥ 70% • Not eligible for oral pirfenidone and nintedanib due to national formulary restrictions OR

	intolerant to or unwilling to start oral pirfenidone and nintedanib, if previously offered (nintedanib use is allowed in Part B of the study) • Confident diagnosis of IPF based on clinical, radiologic and pathologic data without evidence or suspicion of an alternative diagnosis that may contribute to their interstitial lung disease • 30 ≤ % DLCO ≤ 90%
Key exclusion criteria	• Significant clinical worsening of IPF between Screening and Day 1, in the opinion of the investigator • Not a suitable candidate for enrolment or unlikely to comply with the requirements of this study, in the opinion of the investigator • History of acute IPF exacerbation requiring hospitalization in the last 3 months • History of clinically significant environmental exposure known to cause pulmonary fibrosis, including but not limited to drugs (such as amiodarone), asbestos, beryllium, radiation, and domestic birds • Known explanation for interstitial lung disease, including but not limited to radiation, drug toxicity, sarcoidosis, hypersensitivity pneumonitis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus, viral hepatitis, and cancer • Clinical diagnosis of any connective tissue disease, including but not limited to scleroderma, polymyositis/dermatomyositis, systemic lupus erythematosus, and rheumatoid arthritis • Current diagnosis of asthma or chronic obstructive pulmonary disease • Clinical evidence of active infection, including but not limited to bronchitis, pneumonia, sinusitis, urinary tract infection, or cellulitis • Females with a positive pregnancy test at Screening or are currently breastfeeding • Any history of malignancy likely to result in significant disability or likely to require significant medical or surgical intervention within the next 6 months. This does not include minor surgical procedures for localized cancer (e.g., basal cell carcinoma) • Any condition other than IPF that, in the opinion of the investigator, is likely to result in the death of the patient within the next 6 months • History of severe hepatic impairment or end-stage liver disease or ALT or AST greater than 5

	times the upper limit of normal at Screening • History of end-stage renal disease requiring dialysis
Primary endpoint	**Primary Analysis** Safety and tolerability will be assessed by treatment emergent AE rates, post-first dose spirometry, deaths, clinically significant laboratory findings and vital signs. **Secondary Analyses** Change from baseline in FVC % predicted, DLCO, PRO domain scores, cough frequency, extent of fibrosis and lung volumes over 24 and 72 weeks will be analyzed by treatment arm.
Number of participants sought	100
Lead site(s) in Australia	Hunter Medical Research Institute, Newcastle NSW
Lead site(s) in New Zealand	Waikato Hospital, Hamilton
Additional sites	Mater Misericordiae Ltd South Brisbane, Qld The Prince Charles Hospital, Brisbane Qld Sir Charles Gairdner Hospital, Nedlands WA Fiona Stanley Hospital, Murdoch WA The Alfred Hospital, Melbourne VIC Royal Prince Alfred Hospital, Sydney NSW St Vincent's Hospital, Sydney NSW Dunedin Hospital, Dunedin NZ Auckland City Hospital, Auckland NZ Department of Medicine University of Otago, Christchurch NZ Westmead Hospital, Westmead NSW Concord Hospital, Concord West NSW The Queen Elizabeth Hospital, Woodville SA Nepean Hospital, Kingswood NSW Respiratory Clinical Trials, Kent Town SA
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