Patient - 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	Avalyn Pharma, Inc. has begun a study of an investigational drug (also known as the "study drug") called AP01 (Pirfenidone Solution for Inhalation) as a possible treatment for IPF. The active component of the study drug (pirfenidone) is approved in Australia and New Zealand as treatment for IPF when it is given as a tablet or capsule for oral use, but in this study, it is considered experimental because it will be given as a solution for inhalation. The nebuliser device that will be used to administer the study drug is not approved and is therefore also considered experimental. The main purpose of this study is to learn how well the study drug works and how safe the study drug is. This study is a randomised open label research study. "Randomised" means that participants are randomly assigned to one of a number of different treatment groups. In this study there are two groups; each group will be given a different amount of the same treatment, AP01, as described below. "Open-label" means that you will know which group you have been assigned to, and the researchers will know as well. Having different groups in the study allows the researchers to compare the safety and effectiveness between the groups. If the study doctor determines that you meet all of the requirements to be in the study, you will be randomly assigned (like the flip of a coin) to receive the study drug in one of the following treatment groups: • 50 mg AP01 once daily • 100 mg AP01 twice daily (at least 4 hours apart) During the study, you will take the study drug every day for up to 18 months. The study drug will be taken using a PARI eFlow® nebuliser (a device that converts a liquid into a mist that you breathe in to your lungs). The study is divided into Part A and Part B. You will be in this study for approximately 6 months in Part A and 12 months for Part B, and you will need to come to the study site at least 13 times over this entire period.

	Part A includes a screening visit and a 24-week (approximately 6 months) treatment period, where you will be asked to visit the study site once every four weeks. Part B includes a 48-week (approximately 1 year) treatment period where you will be asked to visit the study site once every 12 weeks. During the treatment periods you will take the study drug at home every day, and you will use a device (spirometer) to check your lung function every week.
Investigational medicinal product, comparator and randomisation	Pirfenidone solution for inhalation
Disease target	Idiopathic Pulmonary Fibrosis
Sponsor	Avalyn Pharma
Duration	18 months
Trial Status	Recruiting
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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