Centre of Research Excellence in Pulmonary Fibrosis

Lung Foundation Australia Pulmonary Fibrosis Clinical Trials

PACT – Clinician
New Clinical Trial and Research

Trial title	BEACON-IPF
Trial synopsis	This is a randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of 2 doses of bexotegrast (PLN-74809) [160 and 320 mg] taken for 52 weeks by participants with IPF taking and not taking background therapy (ie nintedanib or pirfenidone). The study will consist of an up to 28-day Screening Period, a 52-week Treatment Period, and a 14 day Safety Follow-up Period. Of note, participants who are not taking background therapy at study entry will be allowed to initiate it at any time during the study.
Investigational medicinal product, comparator and randomisation	Bexotegrast is an oral, small molecule, dual-selective inhibitor of integrins avβ6 and avβ1 designed to block TGF-β mediated fibroblast- to-myofibroblast transition and collagen synthesis. [Bexotegrast (PLN-74809) 160 mg tablets/ oral; Bexotegrast (PLN- 74809) 320 mg tablets/ oral; Matching placebo tablets/ oral; 1:1:1]
Disease target	Idiopathic Pulmonary Fibrosis (IPF)
Sponsor	Pliant Therapeutics Inc
Duration	58 weeks
Trial Status	Recruiting
Trial phase	2b
Key inclusion criteria	• 40 years of age or older at screening • Diagnosis of IPF based upon ATS/ERS/JRS/LATA current guidelines within 7 years from screening • FVCpp ≥ 45% • Diffusing capacity for carbon monoxide percent predicted (haemoglobin-adjusted) ≥ 30% and < 90% • Patients on and off background therapy (e.g. nintedanib or pirefenidone) are eligible for enrolment
Key exclusion criteria	• Clinical evidence of active infection, including, but not limited to bronchitis, pneumonia, or sinusitis that can affect FVC measurement during screening or at randomization

	• Known acute IPF exacerbation, or suspicion by the Investigator of such, 6 months prior to screening • Forced expiratory volume in the first second/FVC ratio < 0.7 at screening • Receiving drug therapy for pulmonary hypertension • Receiving any unapproved or investigational agent intended for treatment of fibrosis in IPF
Primary endpoint	Change from baseline in absolute FVC (mL) at Week 52
Number of participants sought	267
Lead site(s) in Australia	Institute for Respiratory Health - Midland (WA)
Lead site(s) in New Zealand	N/A
Additional sites	• TrialsWest (WA) • Respiratory Clinical Trials (SA) • The Alfred Hospital (VIC)
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