Centre of Research Excellence in Pulmonary Fibrosis

Lung Foundation Australia Pulmonary Fibrosis Clinical Trials

PACT – Clinician
New Clinical Trial and Research

Trial title	A 26-Week, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Evaluate the Efficacy, Safety, and Tolerability of Axatilimab in Subjects with Idiopathic Pulmonary Fibrosis (IPF)
Trial synopsis	This is a Phase 2b, randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy, safety, and tolerability of axatilimab administered through Week 26 to subjects with IPF. Subjects meeting eligibility criteria for the study will be randomized in a 2:1 ratio to axatilimab 0.3 mg/kg every 2 weeks (Q2W) or placebo Q2W. Efficacy will be evaluated through pulmonary function tests (PFTs) including DLCO and patient-reported outcomes.
Investigational medicinal product, comparator and randomisation	IMP: axatilimab Comparator: placebo Randomization: 2:1 axatilimab or placebo
Disease target	Idiopathic Pulmonary Fibrosis
Sponsor	Syndax Pharmaceuticals, Inc
Duration	Subjects will participate in the study for up to 44 weeks
Trial Status	Not yet recruiting
Trial phase	IIb
Key inclusion criteria	• Chest HRCT to confirm IPF criteria within 12 months of Screening Visit 1 • FVC ≥45% of predicted number during the Screening period • FEV1/FVC ≥0.7 during the Screening Period. • DL_{CO} ≥30% and ≤90% during the Screening Period
Key exclusion criteria	• Emphysema present on ≥50% of the HRCT • Interstitial lung disease associated with known primary disease • Clinically significant ECG abnormalities • Inability to meet protocol-specified baseline stability criteria

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	• Acute IPF exacerbation within 3 months prior to screening • Receiving nintedanib in combination with pirfenidone
Primary endpoint	The annualized rate of decline in morning pre-dose trough forced vital capacity (FVC) (mL) over 26 weeks
Number of participants sought	135
Lead site(s) in Australia	Lung Research Queensland
Lead site(s) in New Zealand	
Additional sites	
Contact	pactcoordinator@cre-pf.org.au