

SNDX-6352-0506 IPF Study

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	Recruiting
Trial phase	IIb
Key inclusion criteria	<ul style="list-style-type: none"> • Chest HRCT to confirm IPF criteria within 12 months of Screening Visit 1. • FVC $\geq 45\%$ of predicted number during the Screening period. • FEV1/FVC ≥ 0.7 during the Screening Period. • DLCO $\geq 30\%$ and $\leq 90\%$ during the Screening Period.
Key exclusion criteria	<ul style="list-style-type: none"> • Emphysema present on $\geq 50\%$ of the HRCT • Interstitial lung disease associated with known primary disease. • Clinically significant ECG abnormalities • Inability to meet protocol-specified baseline stability criteria.

	<ul style="list-style-type: none"> • Acute IPF exacerbation within 3 months prior to screening. • Receiving nintedanib in combination with pirfenidone.
Number of participants sought	135
Lead site(s) in Australia	<ul style="list-style-type: none"> • Wallace Street Specialist Centre (QLD)
Additional sites	<p>VIC</p> <ul style="list-style-type: none"> • Monash Health • St Vincent's Melbourne <p>QLD</p> <ul style="list-style-type: none"> • Mater Misericordiae • Wallace Street Specialist Centre • Mackay Hospital & Health Service • Sunshine Coast University Hospital • Griffith University Clinical Trial Unit <p>NSW</p> <ul style="list-style-type: none"> • Royal Prince Alfred Hospital <p>WA</p> <ul style="list-style-type: none"> • Institute for Respiratory Health
Lead site(s) in New Zealand	N/A
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