

## PACT – Clinician New Clinical Trial and Research

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Trial title	A participant and investigator-blinded, randomized, placebo-controlled, multicentre, platform study to investigate efficacy, safety, and tolerability of various single treatments in participants with idiopathic pulmonary fibrosis
Trial synopsis	The purpose of this proof-of-concept platform study is to determine whether selected systemic investigational products have an adequate clinical profile to support further clinical development in mild to moderate IPF. This platform design allows several investigational drugs to be tested in an adaptive way under the same conditions in one study.
Investigational medicinal product, comparator and randomisation	Arm 1: LTP001 6 mg q.d. p.o. Arm 2: Matching placebo
Disease target	Idiopathic pulmonary fibrosis (IPF)
Sponsor	Novartis
Duration	42 day screening period + 26 weeks + 30 days follow up
Trial Status	Recruiting
Trial phase	II
Key inclusion criteria	<ul style="list-style-type: none"> <li>• Male and female participants at least 40 years of age</li> <li>• IPF diagnosed based on ATS/ERS/JRS/ALAT IPF 2018 modified guideline for diagnosis and management, within 5 years of screening</li> <li>• FVC <math>\geq</math>45% predicted at screening with no clinically significant deterioration between the screening visit and randomization, as determined by the investigator.</li> <li>• DLCO, corrected for haemoglobin, <math>\geq</math>25% predicted (inclusive) at screening with no clinically significant deterioration between the screening visit and randomization, as determined by the investigator.</li> <li>• Unlikely to die from cause other than IPF within the next 2 years, in the opinion of the investigator</li> </ul>



	<ul style="list-style-type: none"> <li>• Unlikely to undergo lung transplantation during this trial in the opinion of the investigator</li> <li>• If a participant is taking nintedanib or pirfenidone, they must be on a stable regimen for at least 8 weeks prior to randomization</li> </ul>
Key exclusion criteria	<ul style="list-style-type: none"> <li>• Unable to perform PFTs, 6MWT or undergo HRCT procedure at time of screening</li> <li>• Peripheral capillary oxygen saturation (SpO<sub>2</sub>) &lt;90% at rest (if on supplemental oxygen, must be ≤2 L/min at rest)</li> <li>• Airway obstruction (i.e., prebronchodilator FEV<sub>1</sub>/FVC &lt; 0.7) or evidence of a bronchodilator response at screening as defined by an absolute increase of ≥12% and an increase of ≥200ml in FEV<sub>1</sub> or FVC, or both, after bronchodilator use, compared with the values before bronchodilator use at screening.</li> <li>• Emphysema &gt;20% on screening HRCT as assessed visually by Fibrosis &lt;10% on screening HRCT as assessed visually by central reader.</li> <li>• Clinical diagnosis of any connective tissue disease (including but not limited to scleroderma, polymyositis/ dermatomyositis, systemic lupus erythematosus, and rheumatoid arthritis) or a diagnosis of interstitial pneumonia with autoimmune features as determined by the investigator applying the recent ERS/ ATS research statement</li> <li>• Other known causes of interstitial lung disease (e.g. domestic or occupational environmental exposures, drug toxicity) or another identifiable interstitial lung disease</li> </ul>
Primary endpoint	The primary objective of this study is to assess the efficacy of the investigational products compared to placebo in participants with IPF measured by FVC expressed in percent predicted.
Number of participants sought	Australian target = 20 pts Global target = 94 pts
Lead site(s) in Australia	<ul style="list-style-type: none"> <li>• <b>Lead private</b> TrialsWest (WA)</li> <li>• <b>Lead public</b> Westmead Hospital (NSW)</li> </ul>



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**Pulmonary Fibrosis**



Lead site(s) in New Zealand	N/A
Additional sites	<ul style="list-style-type: none"><li>• Royal Prince Alfred Hospital (NSW)</li><li>• Lung Research Queensland (QLD)</li><li>• Austin Hospital (VIC)</li></ul>
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