Centre of Research Excellence in Pulmonary Fibrosis

Lung Foundation Australia
Pulmonary Fibrosis Clinical Trials

PACT – Clinician
New Clinical Trial and Research

Trial title	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over at least 52 weeks in patients with Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs)
Trial synopsis	The purpose of this trial is to evaluate the efficacy, safety, and tolerability of BI 1015550 9 mg bid and 18 mg bid compared to placebo in patients with progressive fibrosing ILDs in addition to patient's standard of care over the course of at least 52 weeks. New treatments with better tolerability are needed for patients with ILDs to further reduce the decline in lung function and improve quality of life. Based on its anti-inflammatory and antifibrotic properties and the preliminary clinical evidence described, BI 1015550 may provide an additional treatment option to patients with pulmonary fibrosis irrespective of concomitant treatment with standard of care.
Investigational medicinal product, comparator and randomisation	1:1:1 (9mg : 18mg : placebo)
Disease target	Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs)
Sponsor	Boehringer Ingelheim
Duration	Part A - 52-weeks Part B – until last participant globally reaches 52-weeks
Trial Status	Recruiting
Trial phase	Phase 3
Key inclusion criteria	• Patients ≥18 years old • Progressive fibrosing ILD other than IPF based on predefined criteria • FVC ≥45% of predicted normal • DLCO ≥25% and <90% predicted normal • On stable treatment with Nintedanib for at least 12 weeks or not on treatment with nintedanib for at least 8 weeks
Key exclusion criteria	• Relevant airways obstruction (prebronchodilator FEV1/FVC <0.7) • Acute ILD exacerbation within 3 months and/or during the screening period • Treated with immunomodulatory medications (other than oral corticosteroids) or prednisone >15 mg/day or equivalent for respiratory or pulmonary reasons • Active, unstable or uncontrolled vasculitis within 8 weeks • Any suicidal behaviour in the past 2 years

	• Any suicidal ideation of type 4 or 5 on the C-SSRS in the past 3 months
Primary endpoint	The primary endpoint is the absolute change from baseline in FVC [mL] at Week 52.
Number of participants sought	1,041 Globally
Lead site(s) in Australia	Lung Research Queensland
Lead site(s) in New Zealand	Aotearoa Clinical Trials
Additional sites	Australia: • Alfred Hospital • Austin Hospital • Lung Research Victoria • Mater Hospital – Brisbane • Princess Alexandra Hospital • The Prince Charles Hospital • TrialsWest • Fiona Stanley Hospital • Royal Adelaide Hospital • Canberra Hospital • Royal Prince Alfred Hospital • Westmead Hospital • Macquarie University New Zealand: • Greenlane Clinical Centre • Waikato Hospital • Tauranga Hospital
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