Centre of Research Excellence in Pulmonary Fibrosis
PACT PF Australasian Clinical Trials

BI 1819479 Study

Trial title	A randomised, double-blind, placebo-controlled, dose-finding study evaluating efficacy, safety, and tolerability of different oral doses of BI 1819479 over at least 24 weeks in patients with idiopathic pulmonary fibrosis (IPF)
Trial synopsis	This study is to find out whether a medicine called BI 1819479 helps people with Idiopathic Pulmonary Fibrosis (IPF). This study compares three different doses of BI 1819479 with placebo. BI 1819479 is being developed to test whether it can improve lung function in people with IPF. New treatments are needed that further reduce the decline in lung function, positively affect symptoms and improve quality of life in patients with IPF. Participants will receive either one of three different doses of BI 1819479 or placebo. It will be decided by chance (like flipping a coin) which one each participant will receive. Participants will take BI 1819479 and/or placebo as 2 tablets once a day. Participants in this trial will undergo treatment for at least 6 months. After this treatment period, participants will continue to receive the trial medication until 12 months of treatment is reached or the last participant who joined the study has completed the 6 months, whichever comes first. That means that individual participation in this study can be between 6 months and 12 months.
Investigational medicinal product, comparator and randomisation	BI 1819479 Placebo controlled. Randomisation is 1:1:1:2 (placebo qd: low dose: medium dose: high dose)
Disease target	Idiopathic Pulmonary Fibrosis
Sponsor	Boehringer Ingelheim
Duration	At least 24-week and up to 52-week participation
Trial Status	Recruiting
Trial phase	Phase II
Key inclusion criteria	• Patients ≥40 years old at the time of signed informed consent. • Signed and dated written informed consent in accordance with ICH-GCP and local legislation prior to admission to the trial.

	• Diagnosis of Idiopathic Pulmonary Fibrosis (IPF) • On stable treatment with nintedanib or pirfenidone for at least 12 weeks or not on treatment with either nintedanib or pirfenidone for at least 12 weeks • Forced Vital Capacity (FVC) ≥45% of predicted normal. • Diffusion capacity of the lung for carbon monoxide (DLCO) ≥25% of predicted normal corrected for hemoglobin (Hb). • Women of childbearing potential (WOCBP) must use highly effective methods of birth control with low user dependency and additional barrier contraception for male partners (use of condom) until end of follow-up period. • Male trial participants with WOCBP partners must use contraception (condom) to avoid exposure via seminal fluid. Female partners of male trial participants must use highly effective methods of contraception during treatment until end of follow-up period.
Key exclusion criteria	• Acute exacerbation of IPF within at least 12 weeks prior to screening and/or during the screening period • Treated with immunosuppressive medications (other than oral corticosteroids) or prednisone >15 mg/day or equivalent for respiratory or pulmonary reasons. • Patients who must or wish to continue the intake of restricted medications or any drug considered likely to interfere with the safe conduct of the trial. • The patient is currently enrolled in another investigational device or drug trial, or their Visit 1 occurs less than 30 days or 5 half-lives (whichever is longer) after completing a previous investigational device or drug trial or receiving other investigational treatments. • Patients with a significant disease or condition other than the IPF under study, which in the opinion of the investigator, may put the patient at risk because of participation, interfere with trial procedures, or cause concern regarding the patient's ability to participate in the trial or any medical condition which could lead to a life expectancy <12 months. • Relevant airways obstruction (pre-bronchodilator forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC) <0.7). • In the opinion of the Investigator, other clinically significant pulmonary abnormalities. • Lower respiratory tract infection requiring treatment within 4 weeks prior to Visit 1 and/or during the screening period.
Number of participants sought	• Australia – 14 • New Zealand – 4
Lead site(s) in Australia	Public – Canberra Hospital (ACT) – Not yet recruiting Private – Launceston Respiratory and Sleep Centre (TAS)

Lead site(s) in New Zealand	Waikato Hospital
Additional sites	**Australia:** • Lung Research Victoria (VIC) • The Alfred Hospital (VIC) • Royal Prince Alfred Hospital (NSW) • Macquarie University (NSW) • Institute of Respiratory Health (WA) **New Zealand:** • Greenlane Clinical Trials Aotearoa Clinical Trials Trust
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