BI 1839100 Study

Trial title	A Phase IIa/IIb, randomised, double blind, placebo-controlled, parallel- group dose-finding study to examine the efficacy and safety of BI 1839100 administered orally over a 12-week treatment period in patients with idiopathic pulmonary fibrosis or progressive pulmonary fibrosis with clinically meaningful cough.
Trial synopsis	The purpose of this study is to find out how well BI 1839100 helps reduce coughing in people with IPF or PPF. Participants who have IPF are put into 4 groups by chance. Participants in 3 groups get different doses of BI 1839100. Participants in 1 group get placebo. Placebo looks like BI 1839100 but does not contain any medicine. Participants take the treatment for 3 months. After 1 month of treatment, participants who take the highest dose will have coughing measured to find out if the medicine works. If it does not work, the study may be stopped. Participants who have IPF are in the study for slightly longer than 4 months. During this time, they visit the study site 7 times. This study will also measure the effects of BI 1839100 on coughing and lung function in a smaller group of people with PPF.
Investigational medicinal product, comparator and randomization	**Investigational medicinal product information:** BI 1839100 is an oral drug. **Comparator and randomisation:** Placebo controlled. IPF: Randomisation is 2:1:1:2 (placebo: low dose: medium dose: high dose) PPF: Randomisation is 1:1 (placebo: high dose)
Disease target	Idiopathic Pulmonary Fibrosis or Progressive Pulmonary Fibrosis
Sponsor	Boehringer Ingelheim
Duration	**IPF cohort:** 12 weeks **PPF cohort:** 4 weeks
Trial Status	Recruiting

Trial phase	Phase IIa/IIb
Key inclusion criteria	For Idiopathic Pulmonary Fibrosis (IPF) cohort: • Minimum age: 40 years. • Diagnosis of IPF. • Chronic cough (>8 weeks prior to Visit 1) attributed to IPF and refractory to treatment for known causes (Principal Investigator (PI) assessment). • Cough Severity visual analogue scale (VAS) ≥30 mm at Visit 1 and Visit 2B. • Forced vital capacity (FVC) ≥45% of predicted normal at Visit 1. • Diffusing capacity of the lungs for carbon monoxide (DLCO) >25% of predicted normal at Visit 1. • Patients may be either: o On stable therapy with nintedanib or pirfenidone for ≥12 weeks prior to Visit 1 and are planning to stay on this background treatment for the whole trial duration. Combination of nintedanib plus pirfenidone will not be allowed. o Not on therapy with nintedanib or pirfenidone for ≥12 weeks prior to Visit 1 (either antifibrotic (AF)-treatment naïve or previously discontinued) and do not plan to start or re-start AF treatment during the trial. It is not permitted to delay nintedanib or pirfenidone therapy for the purpose of participating in this trial. For Progressive Pulmonary Fibrosis (PPF) cohort: • Minimum age: 18 years. • Diagnosis of PPF. • Chronic cough (>8 weeks prior to Visit 1) attributed to PPF, refractory to treatment for known causes (PI assessment). • Cough Severity VAS ≥30 mm at Visit 1 and Visit 2B. • FVC ≥45% of predicted normal at Visit 1. • DLCO ≥25% of predicted normal at Visit 1. • If receiving immunomodulatory therapy for interstitial lung disease (ILD), allowed

	medications include tacrolimus, mycophenolate mofetil, or azathioprine (stable dose for 12 weeks prior to Visit 1) • Patients may be either: o On a stable therapy with nintedanib for ≥12 weeks prior to Visit 1 and are planning to stay on this background treatment for the whole trial duration o Not on a therapy with nintedanib for ≥12 weeks prior to Visit 1 (either AF-treatment naïve or previously. discontinued) and do not plan to start or re-start AF treatment during the trial. It is not permitted to delay nintedanib or pirfenidone therapy for the purpose of participating in this trial. Further inclusion criteria apply.
Key exclusion criteria	Exclusion criteria for IPF and PPF cohorts: • Acute exacerbation of IPF/PPF within 12 weeks prior to Visit 1. • Forced expiratory volume in 1 second (Forced expiratory volume in 1 second (FEV1))/FVC <0.7 at Visit 1. • Known reversible airflow obstruction/response to bronchodilators. • In the opinion of the Investigator, other clinically significant pulmonary abnormalities, including primary bronchitic and bronchiectatic disorder. • Upper or lower respiratory tract infection within 4 weeks prior to Visit 1. • Ongoing chronic pulmonary infection (e.g. mycobacterial or fungal disease). • Current smokers (tobacco use within the 6 months prior to Visit 1). • Initiation or change in supplemental oxygen requirement during 4 weeks prior to Visit 1. Further exclusion criteria apply.
Number of participants sought	Australia – 10 New Zealand – 3
Lead site(s) in Australia	Public Site – Canberra Hospital (ACT) Private Site – Institute for Respiratory Health (WA)
Lead site(s) in New Zealand	Waikato Hospital

Additional sites	**Australia** • Lung Research Victoria (VIC) • Austin Health (VIC) • The Alfred Hospital (VIC) • Royal Prince Alfred Hospital (NSW) • Macquarie University (NSW) • Launceston Respiratory & Sleep Centre (TAS) **New Zealand** • Greenlane Clinical Trials • Christchurch Hospital
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