Clinician - PACT
New Clinical Trial and Research

Trial title	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of BG00011 in Patients With Idiopathic Pulmonary Fibrosis (IPF)
Trial synopsis	The primary objective of this study is to evaluate the efficacy of BG00011 compared with placebo in participants with Idiopathic Pulmonary Fibrosis (IPF). The secondary objectives of this study are: to evaluate the efficacy of BG00011 compared with placebo in participants with IPF as determined by change in percent predicted forced (expiratory) vital capacity (FVC); to assess progression-free survival in participants who receive BG00011 compared with placebo; to assess the occurrence of IPF exacerbation in participants who receive BG00011 compared with placebo; to assess the incidence of absolute decline in FVC ≥10% in participants who receive BG00011 compared with placebo; to assess the time to death or lung transplantation in participants who receive BG00011 compared with placebo, and the transplant-free survival rate at Week 26 and Week 52; to assess the time to non-elective hospitalizations in participants who receive BG00011 compared with placebo; to assess additional pulmonary function test (PFT) findings in participants who receive BG00011 compared with placebo; To assess performance on the 6 minute walk test (6MWT) in participants who receive BG00011 compared with placebo; to evaluate the safety and tolerability of BG00011; and to evaluate the serum concentration of BG00011.
Investigational medicinal product, comparator and randomisation	BG00011 vs placebo, 1:1
Disease target	IPF
Sponsor	Biogen
Duration	Up to 64 weeks
Trial Status	Study completed
Trial phase	2
Key inclusion criteria	• Female subjects must be surgically sterile, postmenopausal (minimum 1 year without menses), or agree to use 1 or more forms of highly effective contraception from the time of signing of the informed consent form (ICF) until 3 months after the last injection of study medication. Male subjects must also agree to use 1 or

	more forms of highly effective contraception for either themselves or their partners from signing of ICF until 4 months after last injection of study medication. • IPF diagnosed based on modified ATS/ERS/JRS/ALAT IPF guideline for diagnosis and management, within 3 years of Screening. • Combination of high-resolution computed tomography (HRCT) pattern and, if one has been obtained, surgical lung biopsy pattern, consistent with diagnosis of IPF. • Carbon monoxide diffusion capacity (DLco) (corrected for hemoglobin): 30% to 79% predicted of normal at Screening, with no clinically significant deterioration between the Screening Visit and randomization, as determined by the Investigator. • Forced (expiratory) vital capacity (FVC) ≥50% predicted of normal at Screening, with no clinically significant deterioration between the Screening Visit and randomization, as determined by the Investigator. • If a subject is taking nintedanib or pirfenidone, they must be on a stable dose for at least 8 weeks prior to randomization
Key exclusion criteria	• Unable to perform pulmonary functional tests (PFTs) or undergo HRCT procedure. • Peripheral capillary oxygen saturation (SpO2) <90% at rest (if on oxygen supplementation, must be ≤2 L/min at rest). • Airway obstruction (i.e., prebronchodilator FEV1/FVC <0.7) or evidence of a bronchodilator response as defined by an absolute increase of ≥12% and an increase of ≥200 milliliters (mL) in FEV1 or FVC, or both, after bronchodilator use, compared with the values before bronchodilator use at Screening. • End-stage fibrotic disease likely requiring organ transplantation within 12 months, or if the subject has initiated active evaluation for organ transplantation. • Unable to perform pulmonary functional tests (PFTs) or undergo HRCT procedure. • Peripheral capillary oxygen saturation (SpO2) <90% at rest (if on oxygen supplementation, must be ≤2 L/min at rest). • Airway obstruction (i.e., prebronchodilator FEV1/FVC <0.7) or evidence of a bronchodilator response as defined by an absolute increase of ≥12% and an increase of ≥200 milliliters (mL) in FEV1 or FVC, or both, after bronchodilator use, compared with the values before bronchodilator use at Screening.

	• End-stage fibrotic disease likely requiring organ transplantation within 12 months, or if the subject has initiated active evaluation for organ transplantation. • The extent of emphysema in the lungs exceeds fibrosis, based on central review of HRCT scans. • Body weight <60 kg at Screening. • History of or ongoing malignant disease, including solid tumors and hematologic malignancies, with the exception of basal cell carcinomas, squamous cell carcinomas, and carcinoma in situ of the cervix that have been completely excised and considered cured >2 years prior to Screening. • Significant cardiac disease (e.g., New York Heart Association Class 3 or 4; myocardial infarction within the past 6 months; unstable angina; coronary angioplasty or coronary artery bypass graft within the past 6 months; uncontrolled atrial or ventricular cardiac arrhythmias; or pulmonary hypertension requiring pharmacologic treatment). • 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. • Other disease that may interfere with testing procedures or, in the judgment of the Investigator, may interfere with study participation or may put the patient at risk when participating in this study. • Other unspecified reasons that, in the opinion of the Investigator or Biogen, make the subject unsuitable for enrollment. NOTE: Other protocol defined Inclusion/Exclusion criteria may apply.
Primary endpoint	Yearly rate of change in FVC (expressed in mL over 52 weeks) in subjects randomized to BG00011 compared with placebo.
Number of participants sought	290
Lead site(s) in Australia	The Prince Charles Hospital, Qld Lung Research Qld
Lead site(s) in New Zealand	N/A
Additional sites	St Vincent's Hospital, NSW The Alfred Hospital, VIC John Hunter Hospital, NSW

	Princess Alexandra Hospital, Qld Frankston Hospital, VIC Royal Prince Alfred Hospital, NSW Fiona Stanley Hospital, WA Royal Adelaide, SA Institute of Breathing and Sleeping (Austin Hospital), VIC Trials West, WA
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