

Clinician - PACT

New Clinical Trial and Research



Trial title	A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 2 Study of the Efficacy and the Safety and Tolerability of BMS-986278 in Participants with Pulmonary Fibrosis
Trial synopsis	This clinical trial will last approximately 34 weeks including a 4-week screening period, 26-week study treatment period, and a 4-week follow-up period; with participant offered an optional 26-week study treatment extension. Eligibility will be established using the key Inclusion/Exclusion Criteria. During the screening period, the medical history, disease activity, and safety assessments of potential participants will be evaluated. There are 3 main periods to the study: screening, study treatment, and follow-up.
Investigational medicinal product, comparator and randomisation	Randomized in a 1:1:1 ratio to BMS-986278 30 mg BID, BMS-986278 60 mg BID, or placebo.
Disease target	Idiopathic pulmonary fibrosis (IPF) and Progressive fibrotic interstitial lung disease (PF-ILD)
Sponsor	Bristol-Myers Squibb
Duration	Approximately 34 weeks, with the option of another 26 weeks of study treatment extension.
Trial Status	Recruiting
Trial phase	Phase 2
Key inclusion criteria	For the idiopathic pulmonary fibrosis (IPF) cohort <ul style="list-style-type: none"> • Diagnosed within the past 7 years • Female or male \geq 40 years of age For the progressive fibrotic-interstitial lung disease (PF-ILD) cohort <ul style="list-style-type: none"> • Diagnosed within the past 7 years • Female or male \geq 21 years of age
Key exclusion criteria	Exclusion Criteria for both cohorts: <ul style="list-style-type: none"> • Women of childbearing potential (WOCBP) • Active smokers • Patients with current malignancy • History of allergy to BMS-986278 or related compounds Other protocol-defined Inclusion/Exclusion Criteria apply.
Primary endpoint	Rate of change in percent predicted forced vital capacity [ppFVC (%)] from baseline to Week 26 in IPF participants.
Number of participants sought	26 randomised participants in Australia

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Lead site(s) in Australia	Not applicable
Lead site(s) in New Zealand	No sites in New Zealand
Additional sites	<ul style="list-style-type: none">• Fiona Stanley Hospital, Murdoch WA• Royal Adelaide Hospital, Adelaide SA• Austin Hospital, Heidelberg VIC• Westmead Hospital, Westmead NSW• The Prince Charles Hospital, Chermside QLD• Institute of Respiratory Health, Nedlands WA• Royal Prince Alfred Hospital, Camperdown NSW• Greenslopes Private Hospital, Greenslopes QLD
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