

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	IPF cohort closed; PF-ILD cohort 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">• Austin Hospital, Heidelberg VIC• Westmead Hospital, Westmead NSW• Institute of Respiratory Health, Nedlands WA• Royal Prince Alfred Hospital, Camperdown NSW
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