

ALOFT IPF Study

Trial title	A Multicentre, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of BMS-986278 in Participants with Idiopathic Pulmonary Fibrosis (IM027-068).
Trial synopsis	<p>The purpose of this study is to evaluate the efficacy, safety, and tolerability of BMS-986278 in participants with Idiopathic Pulmonary Fibrosis.</p> <p>Primary Outcome Measure in Cohort 2</p> <p>Change in lung function (measured in absolute forced vital capacity (FVC)) from baseline at week 52.</p> <p>Key Secondary Outcome Measures in Cohort 2</p> <p>Disease progression measured by the time to first disease progression event up to approximately 3 years.</p> <p>Change from baseline score of patient questionnaire, Living with Pulmonary Fibrosis (patient reported outcomes) (at week 52 and up to approximately 3 years).</p> <p>Change from baseline in walking distance measured in 6-minute walk test (6MWT) (At week 52).</p>
Investigational medicinal product, comparator and randomization	Active / oral; Matching placebo / oral; 1:1:1
Disease target	Idiopathic Pulmonary Fibrosis (IPF)
Sponsor	Bristol-Myers Squibb Company
Duration	Minimum of 52 weeks up to 156 weeks
Trial Status	Recruiting
Trial phase	Phase 3
Key inclusion criteria	<ul style="list-style-type: none"> • ≥ 40 years of age • Diagnosis of Idiopathic Pulmonary Fibrosis (IPF) within 7 years prior to screening.



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Key exclusion criteria	<ul style="list-style-type: none">• Interstitial Lung Disease (ILD) associated with known primary causes (e.g., hypersensitivity pneumonitis, autoimmune associated ILD, sarcoidosis, etc.).• Acute exacerbation of pulmonary fibrosis within 4 weeks prior to or during screening• History of lung reduction surgery or lung transplant (being on transplantation list is allowed).
Number of participants sought	47
Lead site(s) in Australia	<ul style="list-style-type: none">• Westmead Hospital (NSW)• Gallipoli Medical Research (QLD)
Lead site(s) in New Zealand	N/A
Additional sites	Public: <ul style="list-style-type: none">• Royal Prince Alfred Hospital (NSW)• Prince Charles Hospital (QLD)• Royal Adelaide Hospital (SA)• Fiona Stanley Hospital (WA)• Peninsula Health (VIC)• Box Hill Hospital (VIC) Private: <ul style="list-style-type: none">• Institute for Respiratory Health (WA)• Mater Misericordiae Limited (QLD)
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