ForPatients
by Roche

Idiopathic Pulmonary Fibrosis (IPF)Systemic Sclerosis With Lung Involvement

A Study Evaluating the Efficacy and Safety of Vixarelimab in Participants With Idiopathic Pulmonary Fibrosis and in Participants With Systemic Sclerosis-Associated Interstitial Lung Disease

Trial Status	Trial Runs In	Trial Identifier
Recruiting	20 Countries	NCT05785624 2022-502828-42 GB44496

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Two-Cohort, Phase II, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating the Efficacy and Safety of Vixarelimab Compared With Placebo in Patients With Idiopathic Pulmonary Fibrosis and in Patients With Systemic Sclerosis-Associated Interstitial Lung Disease

Trial Summary:

The main purpose of the study is to evaluate the efficacy of vixarelimab compared with placebo on lung function in participants with idiopathic pulmonary fibrosis (IPF) and in participants with systemic sclerosis-associated interstitial lung disease (SSc-ILD). Participants who complete 52-weeks of treatment in the Double-blind Treatment (DBT) period can choose to enroll in the optional Open-label Extension (OLE) period to receive treatment with vixarelimab for another 52 weeks.

Genentech, Inc. Sponsor	**Phase 2** Phase

NCT05785624 2022-502828-42 GB44496
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 85 Years	No

Inclusion Criteria:

Inclusion Criteria for all Participants:

- FVC #45% predicted during screening as determined by the over-reader
- Forced expiratory volume in 1 second (FEV1)/FVC ratio >0.70 during screening as determined by the over-reader
- DLco #30% and #90% of predicted during screening (Hgb corrected) as determined by the over-reader
- Minimum 6-MWT distance of 150 m with maximum use of 6 liters per minute (L/min) at sea-level and up to 8 L/min at altitude (> 5000 feet [1524 m] above sea level) of supplemental oxygen while maintaining oxygen saturation of >83% during the 6MWT during screening
- Participant and investigator consideration of all medicinal treatment options and/or possibly lung transplantation prior to consideration of participation in the study

Inclusion Criteria for Cohort 1:

- Age 40-85 years
- Documented diagnosis of IPF or IPF (likely)
- HRCT pattern consistent with the diagnosis of IPF, confirmed by central review of chest HRCT and central review of any available lung biopsy
- For participants receiving pirfenidone or nintedanib treatment for IPF: treatment for #3 months with a stable dose for #4 weeks prior to screening and during screening, with plans to continue treatment during the study period

Inclusion Criteria for Cohort 2:

- Age 18-85 years
- Diagnosis of SSc as defined using the American College of Rheumatology/European Alliance of Associations for Rheumatology (EULAR) criteria
- HRCT demonstrating #10% extent of fibrosis, confirmed by central review of Chest HRCT
- Evidence of progression of pulmonary fibrosis
- For participants receiving tocilizumab treatment for SSc-ILD: treatment for #3 months with a stable dose for #4 weeks prior to screening and during screening, with no contraindications according to local prescribing information, and no intention to change or modify their treatment regimen for the duration of the study
- For participants receiving nintedanib treatment for SSc-ILD: treatment for # 3 months with a stable dose for # 4 weeks prior to screening and during screening, with no contraindications according to local prescribing information, and no intention to change or modify their treatment regimen for the duration of the study
- Availability of skin for biopsy preferably on proximal forearms having Modified Rodnan Skin Score (mRSS) #2 at the biopsy location

Inclusion Criteria for OLE Period:

- Completion of 52 weeks of treatment in the double-blinded treatment period
- Investigator determination of a favorable benefit-risk for the individual participant, i.e., the expectation of reasonable likelihood for therapeutic benefit and tolerability of the study drug after evaluation of the preceding 52 weeks of double-blinded treatment

Exclusion Criteria:

Exclusion Criteria for all Participants:

- Percentage of predicted FVC value showing improvement in the 6-month period prior to screening and including screening value
- Known post-bronchodilator response in FEV1 and/or FVC (defined as an increase in percent predicted values by # 10)
- Resting oxygen saturation of <89% using up to 4 L/min of supplemental oxygen at sea level and up to 6 L/min at altitude (5000 feet [1524 m] above sea level) during screening
- History of lung transplant
- Previous treatment with vixarelimab
- Acute respiratory or systemic bacterial, viral, or fungal infection either during screening or prior to screening not successfully resolved by 4 weeks prior to screening visit
- Presence of pulmonary hypertension requiring treatment
- History of malignancy within the 5 years prior to screening
- Positive hepatitis C virus (HCV) antibody test result accompanied by a positive HCV ribonucleic acid (RNA) test at screening
- Known immunodeficiency
- Known evidence of active or untreated latent tuberculosis

Exclusion Criteria for Cohort 1:

- Evidence of other known causes of ILD
- Emphysema present on #50% of the HRCT, or the extent of emphysema is greater than the extent of fibrosis, according to central review of the HRCT

Exclusion Criteria for Cohort 2:

- Evidence of other known causes of ILD
- Rheumatic autoimmune disease other than SSc
- Receiving pirfenidone treatment within 4 weeks prior to screening
- Receipt of nintedanib in combination with tocilizumab

Exclusion Criteria for OLE Period:

- Significant non-compliance in the double-blinded treatment period, per investigator's judgment
- Any new clinically significant pulmonary disease other than IPF or SSc-ILD since enrolling in the double-blinded treatment period