ForPatients
by Roche

Idiopathic Pulmonary Fibrosis (IPF)

A Study to Evaluate the Efficacy and Safety of PRM-151 in Patients With Idiopathic Pulmonary Fibrosis

A Study to Evaluate the Efficacy and Safety of Recombinant Human Pentraxin-2 (rhPTX-2; PRM-151) in Participants With Idiopathic Pulmonary Fibrosis

Trial Status	Trial Runs In	Trial Identifier
Terminated	35 Countries	NCT04552899 2020-000791-38 WA42293

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 Phase III Randomized, Double-blind, Placebo Controlled Trial to Evaluate the Efficacy and Safety of PRM-151 in Patients With Idiopathic Pulmonary Fibrosis

Trial Summary:

This phase III study will evaluate the efficacy, safety and pharmacokinetics (PK) of recombinant human pentraxin-2 (rhPTX-2; PRM-151) zinpentraxin alfa, compared with placebo in participants with idiopathic pulmonary fibrosis (IPF).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04552899 2020-000791-38 WA42293
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#40 Years & # 85 Years	No

Inclusion Criteria:

- Documented diagnosis of IPF per the 2018 American Thoracic Society (ATS)/European Respiratory Society (ERS)/Japanese Respiratory Society (JRS)/Latin American Thoracic Society (ALAT) Clinical Practice Guideline

- High-resolution computed tomography (HRCT) pattern consistent with the diagnosis of IPF, confirmed by central review of Chest HRCT and central review of any available lung biopsy (LB)
- Minimum 6 minute walk distance (6MWD) of 150 meters with maximum use of 6 L/min at sea-level and up-to 8 L/min at altitude of supplemental oxygen while maintaining oxygen saturation of greater than or equal to (>/=)83% during the 6 minute walk test (6MWT) during screening
- FVC >/= 45% predicted during screening as determined by the over-reader
- Forced expiratory volume in 1 second (FEV1)/FVC ratio greater than (>) 0.70 during screening determined by the over-reader
- Diffusing capacity for carbon monoxide (DLCO) >/= 30% and less than or equal to (</=) 90% of predicted at screening as determined by the over-reader
- If receiving pirfenidone or nintedanib treatment for IPF, the participant must have been on treatment for at least 3 months and a stable dose for at least 4 weeks prior to screening, and during screening
- If not currently receiving nintedanib or pirfenidone treatment (either treatment naïve or having previously taken and discontinued) must have discontinued such treatment >/= 4 weeks prior to screening and during screening
- Anticipated life expectancy of at least 12 months at baseline
- Participant and investigator considered all medicinal treatment options and/or possibly lung transplantation prior to considering participation in the study.
- For women of childbearing potential (excluding participant enrolling in Japan): agreement to remain abstinent or use contraception
- For men: agreement to remain abstinent or use a condom, and agreement to refrain from donating sperm
- Anticipated life expectancy of at least 12 months at baseline, according to the investigator's judgment
- For participant enrolled in the extended China enrollment phase: current resident of mainland China, Hong Kong, or Taiwan, and of Chinese ancestry

Exclusion Criteria:

- Evidence of other known causes of Interstitial Lung Disease (ILD)
- FVC% predicted value showing repeated increase in the 6 months period prior to screening and including screening value
- Emphysema present on greater than or equal to (>/=) 50% of the HRCT, or the extent of emphysema is greater than the extent of fibrosis, according to central review of the HRCT
- Receiving nintedanib in combination with pirfenidone
- Received cytotoxic, immunosuppressive, cytokine modulating, or receptor antagonist agents (including but not limited to methotrexate, azathioprine, mycophenolate mofetil, cyclophosphamide, cyclosporine or other steroid sparing agent) within 4 weeks prior to or during screening
- Receiving systemic corticosteroids equivalent to prednisone > 10 mg/day or equivalent within 2 weeks prior to or during screening
- Acute respiratory or systemic bacterial, viral, or fungal infection either during screening or prior to screening and not successfully resolved 4 weeks prior to screening visit
- Participants with active or latent tuberculosis (confirmed within the 6 months prior to or during screening, by a positive screening test [interferon gamma release assay])
- 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 meters] above sea level) during screening
- Class IV New York Heart Association chronic heart failure
- Historical evidence of left ventricular ejection fraction < 35%
- Presence of pulmonary hypertension that, in the investigator's opinion, would substantially limit the ability to comply with study requirements or may influence any of the safety or efficacy assessments included in the study
- Cardiopulmonary rehabilitation program based on exercise training that has been completed within 8 weeks prior to screening or planned to start during the participant enrollment in this trial

- History of smoking, alcohol or substance abuse disorder, or a malignancy
- Previous treatment with PRM-151
- Clinically significant abnormality on ECG during screening that, in the opinion of the investigator, may pose an additional risk in administering study drug to the participant including prolonged corrected QT interval > 450 ms (for men) or > 470 ms (for women) on ECG during screening based on the Fridericia correction formula
- Clinically significant laboratory test abnormalities during screening (hematology, serum chemistry, and urinalysis) that, in the opinion of the investigator, may pose an additional risk in administering study drug to the participant
- Pregnant or breastfeeding, or become pregnant during the study or within 8 weeks after the final dose of PRM-151
- Women of childbearing potential (Only for participants enrolling in Japan)