ForPatients
by Roche

Idiopathic Pulmonary Fibrosis (IPF)

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

Trial Status	Trial Runs In	Trial Identifier
Terminated	28 Countries	NCT04594707 2020-001429-30 WA42294

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 Open-label Extension Study to Evaluate Long-term Safety and Efficacy of PRM-151 in Patients With Idiopathic Pulmonary Fibrosis (IPF)

Trial Summary:

This study will evaulate the long-term safety, efficacy and pharmacokinetics (PK) of recombinant human pentraxin-2 (rhPTX-2; PRM-151) zinpentraxin alfa, administered by intravenous (IV) infusion to participants with idiopathic pulmonary fibrosis (IPF).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT04594707 2020-001429-30 WA42294
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All		No

Inclusion Criteria:

- Taken part in either of the prior PRM-151 studies: PRM-151-202 or WA42293.
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception.
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm.

Exclusion Criteria:

- Acute respiratory or systemic bacterial, viral, or fungal infection at the first visit of the OLE, or within 2 weeks of the first visit for patients joining Cohort A (from Study PRM-151-202).
- History of smoking within 3 months prior to the first visit in the OLE.
- History of alcohol or substance use disorder within 2 years prior to the first visit of the OLE or known or suspected active alcohol or substance-use disorder.
- History of severe allergic reaction or anaphylactic reaction to PRM-151.
- Clinically significant abnormality on ECG during eligibility assessment that, in the opinion of the investigator, may pose an additional risk in administering study drug to the participant.
- Prolonged corrected QT interval > 450 ms (for men) or > 470 ms (for women) based on the Fridericia correction formula.
- Clinically significant laboratory test abnormalities (hematology, serumchemistry, and urinalysis) that, in the opinion of the investigator, may pose an additional risk in administering study drug to the participant.