ForPatients
by Roche

Idiopathic Pulmonary Fibrosis (IPF)

Efficacy, Safety, and Tolerability Study of Pirfenidone in Combination With Sildenafil in Participants With Advanced Idiopathic Pulmonary Fibrosis (IPF) and Risk of Group 3 Pulmonary Hypertension

Trial Status	Trial Runs In	Trial Identifier
Completed	13 Countries	NCT02951429 2015-005131-40 MA29957

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 IIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Sildenafil Added to Pirfenidone in Patients With Advanced Idiopathic Pulmonary Fibrosis and Intermediate or High Probability of Group 3 Pulmonary Hypertension

Trial Summary:

This Phase IIb, randomized, placebo-controlled, multicenter, international study will evaluate the efficacy, safety, and tolerability of sildenafil or placebo added to pirfenidone (Esbriet) treatment in participants with advanced IPF and intermediate or high probability of Group 3 pulmonary hypertension (PH) who are on a stable dose of pirfenidone with demonstrated tolerability. Participants will be randomized to receive 1 year of treatment with either oral sildenafil or matching placebo while continuing to take pirfenidone.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT02951429 2015-005131-40 MA29957
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 40 Years & # 80 Years	No

Inclusion Criteria:

- Diagnosis of IPF for at least 3 months prior to Screening
- Confirmation of IPF diagnosis by the investigator in accordance with the 2011 international consensus guidelines at screening
- Advanced IPF (defined as a measurable carbon monoxide diffusing capacity [DLCO] less than or equal to (<=)40% of predicted value at Screening) and intermediate or high probability of group 3 pulmonary hypertension (PH)
- Participants receiving pirfenidone for at least 12 weeks, at a dose in the range of 1602 to 2403 mg/day for at least 4 weeks prior to Screening and must not have experienced either a new or ongoing adverse event of National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) (version 4.03) Grade 2 or higher and considered by the investigator to be related to pirfenidone, or an interruption of pirfenidone treatment of greater than (>)7 days for any reason
- WHO Functional Class II or III at Screening
- 6MWD of 100 to 450 meters at screening
- Women of childbearing potential and for men who are not surgically sterile agreement to remain abstinent or use of contraceptive measures

Exclusion Criteria:

- History of any of the following types of PH: Group 1 (PAH); Group 1 (pulmonary veno-occlusive disease and/or pulmonary capillary hemangiomatosis); Group 2 (left-heart disease); Group 3 (due to conditions other than interstitial lung disease, including chronic obstructive pulmonary disease [COPD], sleep-disordered breathing, alveolar hypoventilation, high altitude, or developmental abnormalities); Group 4 (chronic thromboembolic pulmonary hypertension); Group 5 (other disorders)
- History of clinically significant cardiac disease
- History of coexistent and clinically significant COPD, bronchiectasis, asthma, inadequately treated sleep-disordered breathing, or any clinically significant pulmonary diseases or disorders other than IPF or PH secondary to IPF
- History of use of drugs and toxins known to cause PAH, including aminorex, fenfluramine, dexenfluramine, and amphetamines
- FEV1/FVC ratio less than (<) 0.70 post bronchodilator; SpO2 saturation at rest <92% with >= 6 liters (L) of supplemental oxygen at Screening
- Extent of emphysema greater than the extent of fibrotic changes (honeycombing and reticular changes) on any previous high-resolution computed tomography (HRCT) scan, in the opinion of the Investigator
- Smoked tobacco within 3 months prior to screening or is unwilling to avoid tobacco products (cigarettes, pipe, cigars) throughout the study
- Illicit drug or significant alcohol abuse
- Electrocardiogram (ECG) with a heart-rate corrected QT interval (corrected using Fridericia's formula [QTcF]) >=500 milliseconds (ms) at screening, or a family or personal history of long QT syndrome
- Exclusion criteria based on pirfenidone reference safety information: 1. participants with a history of angioedema due to pirfenidone; 2. concomitant use of fluvoxamine
- Exclusion criteria based on sildenafil reference safety information: 1. co-administration with nitric oxide donors or organic nitrates, phosphodiesterase-5 (PDE5) inhibitors, guanylate cyclase stimulators, and most potent of the Cytochrome P450 3A4 (CYP3A4) inhibitors; 2. loss of vision in one eye because of non-arteritic anterior ischemic optic neuropathy (NAION); 3. use of an alpha-blocker; 4. participants with bleeding disorders or active peptic ulceration; 5. known hereditary degenerative retinal disorders such as retinitis pigmentosa; 6. galactose intolerance