Clinician - PACT
New Clinical Trial and Research

Trial 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 synopsis	This phase III study will evaluate the efficacy, safety and pharmacokinetics (PK) of recombinant human pentraxin-2 (rhPTX-2; PRM-151) compared with placebo in participants with idiopathic pulmonary fibrosis (IPF).
Investigational medicinal product, comparator and randomisation	Placebo matching PRM-151 will be administered by IV infusion on Days 1, 3 and 5, followed by infusions Q4W to Week 48. Randomization 1:1
Disease target	Idiopathic pulmonary fibrosis (IPF)
Sponsor	F. Hoffmann-La Roche Ltd
Duration	Start (ANZ): April-2021 to March-2023 Participants will receive intravenous (IV) infusions of PRM-151 or placebo over 50-70 minutes on Days 1, 3 and 5, then followed by infusions every 4 weeks (Q4W) to Week 48.
Trial Status	Recruitment paused due to drug supply limitations – due to re-open June 2022
Trial phase	Phase III
Key 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 • Forced expiratory volume in 1 second (FEV1)/FVC ratio greater than (>) 0.70 during screening • Diffusing capacity for carbon monoxide (DLCO) >/= 30% and less than or equal to (</=) 90% of predicted at 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 • Patient and investigator considered all medicinal treatment options and/or possibly lung transplantation prior to considering participation in the study.
Key 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 of screening • Receiving systemic corticosteroids equivalent to prednisone > 10 mg/day or equivalent within 2 weeks prior to 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 patient's 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 including prolonged corrected QT interval > 450 ms (for men) or > 470 ms (for women) based on the Fridericia correction formula; or laboratory tests (hematology, serum chemistry, and urinalysis) that, in the opinion of the investigator, may pose an additional risk in administering study drug to the participant
Primary endpoint	Absolute Change in Forced Vital Capacity (FVC [mL]) [Time Frame: From Baseline up to Week 52]
Number of participants sought	658
Lead site(s) in Australia	Lung Research Queensland (private sites) and Princess Alexandra Hospital (public sites)
Lead site(s) in New Zealand	University of Otago, Christchurch
Additional sites	AUSTRALIA • WA Fiona Stanley Hospital, Michael Musk • VIC Monash Medical Centre Clayton, Xun Li • NSW Royal Prince Alfred Hospital, Tamera Corte • QLD Lung Research Queensland, Dan Chambers • VIC The Alfred Hospital, Ian Glaspole • QLD Princess Alexandra Hospital, Gregory Keir • Cairns Hospital QLD,Dr James Brown NEW ZEALAND • Tauranga Hospital, Suzanne Poole • NZ Respiratory and Sleep Institute, Andrew Veale • Auckland City Hospital, Margaret Wilsher • Waikato Hospital, Catherina Chang • Research and Enterprise University of Otago, Lutz Beckert
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