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New Clinical Trial and Research

Trial title	Zephyrus - FGCL-3019-091 – A Phase 3, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Pamrevlumab in Subjects with Idiopathic Pulmonary Fibrosis (IPF)
Trial synopsis	This is a Phase 3, randomized, double-blind, placebo-controlled, multi-center trial to evaluate the efficacy and safety of pamrevlumab in subjects with idiopathic pulmonary fibrosis (IPF). Approximately 340 eligible subjects will be randomized at a 1:1 ratio to IV pamrevlumab or matching placebo, dosed every 3 weeks. Subjects who are not being treated with approved IPF therapies (i.e., nintedanib or pirfenidone) may be eligible for screening. Examples of reasons subjects may not be treated with approved IPF therapies include but are not limited to: • Intolerant or not responsive to approved IPF therapies • Ineligible to receive these therapies • Subject voluntarily declines to receive approved IPF therapies after being fully informed of the potential benefits/risks NOTE: No subject should discontinue an approved IPF therapy for the purpose of enrolling in this study. During the treatment period, co-administration of an approved IPF therapy (i.e., pirfenidone or nintedanib) is acceptable if clinically indicated in the Investigator's opinion with Pamrevlumab.
Investigational medicinal product, comparator and randomisation	Pamrevlumab (FGCL-3019) or placebo. Infusion over 2 hours. Subsequent infusions could be tapered down to 30 minutes. Randomization ratio 1:1 During the treatment period, co-administration of an approved IPF therapy (i.e., pirfenidone or nintedanib) is acceptable if clinically indicated in the Investigator's opinion, provided that the Investigator assesses the potential risks/benefits of combining approved IPF therapies with blinded study treatment (patient's own cost).
Disease target	Idiopathic Pulmonary Fibrosis
Sponsor	FibroGen Inc

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Duration	Screening: up to 6 weeks Treatment: 48 weeks Follow up period/final safety assessment 28 days post last dose and 60 days post last dose
Trial Status	Recruiting as of 29 Jul 2020
Trial phase	Phase III
Key inclusion criteria	1. Diagnosis of IPF as defined by ATS/ERS/JRS/ALAT guidelines (Raghu 2018) within the past 7 years prior to study participation. 2. HRCT scan at Screening consistent with UIP/probable UIP, with ≥10% to <50% parenchymal fibrosis (reticulation) and <25% honeycombing. 3. FVCpp value >45% and <95% 4. Diffusing capacity of the lungs for carbon monoxide (DLCO) percent predicted, corrected by Hb, ≥25% and ≤90% at screening (determined locally). 5. Not currently receiving treatment for IPF with an approved therapy (i.e., pirfenidone or nintedanib) for any reason.
Key exclusion criteria	1. Previous exposure to pamrevlumab. 2. Evidence of significant obstructive lung disease, evidenced on spirometry and/or HRCT. 3. Female subjects who are pregnant or nursing. 4. Smoking within 3 months of Screening and/or unwilling to avoid smoking throughout the study. 5. Interstitial lung disease other than IPF. 6. Sustained improvement in the severity of IPF during the 12 months prior to screening. 7. Other types of respiratory diseases including diseases of the airways, lung parenchyma, pleural space, mediastinum, diaphragm, or chest wall, that would impact the primary protocol endpoint or otherwise preclude the subject's participation in the study. 8. Medical conditions (e.g. MI/stroke, cancer or logistical challenges that in the opinion of the Investigator preclude the subject's adequate participation in the study. 9. Acute IPF exacerbation, including hospitalization due to acute IPF exacerbation, within 4 weeks prior to or during screening. 10. Recent use of any investigational drugs or unapproved therapies, or approved or participation in any clinical trial. 11. History of allergic or anaphylactic reaction to human, humanized, chimeric or murine monoclonal antibodies.
Primary endpoint	Change in FVC (L) from baseline at Week 48
Number of participants sought	340 globally

Lead site(s) in Australia	Westmead Hospital, Sydney
Lead site(s) in New Zealand	Not Applicable
Additional sites	1. The Alfred Hospital, Melbourne 2. Mater Health Services Adult Hospital, Brisbane 3. Concord Repatriation General Hospital, Sydney 4. Box Hill Hospital, Melbourne 5. Royal Adelaide Hospital, Adelaide 6. Princess Alexandra Hospital, Brisbane
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