

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	<p>This is a Phase 3, randomized, double-blind, placebo-controlled, multi-centre trial to evaluate the efficacy and safety of pamrevlumab in subjects with idiopathic pulmonary fibrosis (IPF).</p> <p>Approximately 340 eligible subjects will be randomized at a 1:1 ratio to IV pamrevlumab or matching placebo, dosed every 3 weeks.</p> <p>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:</p> <ul style="list-style-type: none"> • 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 <p>NOTE: No subject should discontinue an approved IPF therapy for the purpose of enrolling in this study.</p> <p>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.</p> <p>Subjects who complete the study will be eligible for an open-label, extension with pamrevlumab.</p>
Investigational medicinal product, comparator and randomisation	Pamrevlumab (FGCL-3019) or placebo. Infusion over 2 hours. Subsequent infusions could be tapered down to 30 minutes.
Disease target	Idiopathic Pulmonary Fibrosis
Sponsor	FibroGen Inc
Duration	<p>Screening: up to 6 weeks</p> <p>Treatment: 48 weeks</p> <p>Follow up period/final safety assessment 28 days post last dose and 60 days post last dose</p>
Trial Status	Recruiting as of 29 Jul 2020

Patient - PACT

New Clinical Trial and Research



Lead site(s) in Australia	Westmead Hospital, Sydney
Lead site(s) in New Zealand	Not applicable
Additional sites	<ol style="list-style-type: none">1. The Alfred Hospital, Melbourne2. Mater Health Services Adult Hospital, Brisbane3. Concord Repatriation General Hospital, Sydney4. Box Hill Hospital, Melbourne5. Royal Adelaide Hospital, Adelaide6. Princess Alexandra Hospital, Brisbane
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