Clinician - PACT
New Clinical Trial and Research

Trial title	A Phase 3, Randomized, Double-blind, Parallel-group, Placebo-controlled, Multi-center Study to Evaluate the Efficacy and Safety of Two Doses of GLPG1690 in Addition to Local Standard of Care for Minimum 52 Weeks in Subjects With Idiopathic Pulmonary Fibrosis
Trial synopsis	This clinical phase 3 study is a randomized, double blind, parallel-group, placebo-controlled multicentre study designed to evaluate the efficacy and safety of two doses of orally administered GLPG1690 in addition to local standard of care for at least 52 weeks in adult subjects with centrally confirmed diagnosis of IPF. Local standard of care for IPF is defined as receiving either pirfenidone or nintedanib, or neither prifenidone nor nintedanib (for any reason).
Investigational medicinal product, comparator and randomisation	Active dose A GLPG1690 / oral; Active dose B GLPG1690/oral; Matching placebo / oral; 1:1:1
Disease target	Idiopathic Pulmonary Fibrosis
Sponsor	Galapagos NV
Duration	4 weeks of screening followed by at least 52 weeks of treatment and 1 month follow up.
Trial Status	Recruiting
Trial phase	III
Key inclusion criteria	• Male or female subject aged ≥ 40 years on the day of signing the ICF. • A diagnosis of IPF within 5 years prior to the screening visit, as per applicable ATS/ERSI RS/ALAT guidelines. • Chest HRCT historically performed within 12 months prior to the screening visit and according to the minimum requirements for IPF diagnosis by central review based on subject's HRCT only (if no LB available), or based on both HRCT and LB (with application of the different criteria in either situation). If an evaluable HRCT<12 months prior to screening is not available, an HRCT can be performed at screening to determine eligibility, according to the same requirements as the historical HRCT. • Subjects receiving local standard of care for the treatment of IPF, defined as either pirfenidone or nintedanib, or neither pirfenidone nor nintedanib (for any reason).

	• The extent of fibrotic changes is greater than the extent of emphysema on the most recent HRCT scan (investigator determined). • Meeting all of the following criteria during the screening period: FVC ≥ 45% predicted of normal, Forced expiratory volume in 1 second (FEVI)/ FVC ≥ 0.7, DLCO corrected for Hb ≥ 30% predicted of normal. • Estimated minimum life expectancy of at least 30 months for non IPF related disease in the opinion of the investigator. • Male subjects and female subjects of childbearing potential agree to use highly effective contraception/preventive exposure measures from the time of first dose of IMP (for the male subject) or the signing of the ICF (for the female subject), during the study, and until 90 days (male) or 30 days (female) after the last dose of IMP. • Able to walk at least 150 meters during the 6MWT at screening Visit 1; without having a contraindication to perform the 6MWT or without a condition putting the subject at risk of falling during the test (investigator's discretion). The use of a cane is allowed, the use of a stroller is not allowed at all for any condition. At Visit 2, for the oxygen titration test, resting SpO2 should be ≥ 88% with maximum 6 L O2/minute; during the walk, SpO2 should be ≥ 83% with 6 L O2/minute or ≥ 88% with ≤4 L O2/minute.
Key exclusion criteria	• History of malignancy within the past 5 years (except for carcinoma in situ of the uterine cervix, basal cell carcinoma of the skin that has been treated with no evidence of recurrence, prostate cancer that has been medically managed through active surveillance or watchful waiting, squamous cell carcinoma of the skin if fully resected, and Ductal Carcinoma In Situ). • Acute IPF exacerbation within 6 months prior to screening and/or during the screening period. • Lower respiratory tract infection requiring antibiotics within 4 weeks prior to screening and/or during the screening period. • Interstitial lung disease associated with known primary diseases (e.g. sarcoidosis and amyloidosis), exposures (e.g. radiation, silica, asbestos, and coal dust), or drugs (e.g. amiodarone). • Diagnosis of severe pulmonary hypertension (investigator determined). • Unstable cardiovascular, pulmonary (other than IPF), or other disease within 6 months prior to screening or

	during the screening period (e.g. acute coronary disease, heart failure, and stroke). • Underwent major surgery within 3 months prior to screening or have major surgery planned during the study period. • Abnormal LFT at screening, defined as AST, and/or ALT, and/or total bilirubin ≥ 1.5xULN, and/or GGT ≥ 3xULN. Retesting is allowed once. • Abnormal renal function defined as estimated creatinine clearance, calculated according to Cockcroft-Gault calculation (CCr) <30 mL/min. Retesting is allowed once. • Use of any of the following therapies within 4 weeks prior to screening and during the screening period, or planned during the study: warfarin, imatinib, ambrisentan, azathioprine, cyclophosphamide, cyclosporine A, bosentan, methotrexate, sildenafil (except for occasional use), prednisone at steady dose >10 mg/day or equivalent.
Primary endpoint	Rate of decline of forced vital capacity (FVC) in mL. [Time Frame: From baseline through week 52]
Number of participants sought	750 per study
Lead site(s) in Australia	Lung Research Qld Royal Adelaide Hospital, SA
Lead site(s) in New Zealand	Christchurch Hospital, Christchurch
Additional sites	Flinders Medical Centre SA, Respiratory Clinical Trials Pty Ltd SA, St Vincent's Hospital NSW, Royal Prince Alfred Hospital NSW, Concord Repatriation General Hospital NSW, Austin Health VIC, The Alfred Hospital VIC, Box Hill Hospital VIC, Greenlane Clinical Centre Auckland, NZ Respiratory & Sleep Institute Auckland, Waikato Hospital Hamilton
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