Clinician - PACT
New Clinical Trial and Research

Trial title	GALACTIC-1 - A randomised, double-blind, multicentre, parallel, placebo-controlled Phase 2b study in participants with idiopathic pulmonary fibrosis (IPF) investigating the efficacy and safety of GB0139, an inhaled galectin-3 inhibitor administered via a dry powder inhaler (DPI) over 52 weeks
Trial synopsis	This is a multicentre, randomised, double-blind, placebo-controlled phase 2b trial in participants diagnosed with IPF. The study is designed to evaluate the efficacy and safety of GB0139 in patients with IPF. GB0139 works by binding to and inhibiting Galectin-3, which is thought to be responsible for the scarring of tissue in the lungs. GB0139 is administered as a dry powder inhaler over 52 weeks of dosing. The primary efficacy measure of the study will be the rate of decline in Forced Vital Capacity (FVC) or lung volume over 52 weeks. Secondary outcomes look at the efficacy of GB0139 on acute exacerbations, lung function parameters: diffusion capacity for carbon monoxide (DLCO) and oxygen saturation (SpO2), 6-minute walk test (6MWT) distance, dyspnoea and health-related quality of life. Exploratory outcomes of the study include measurements of serum inflammatory and fibrotic biomarkers.
Investigational medicinal product, comparator and randomisation	Randomisation is 2:1 ratio into GB0139 3mg once a day by inhalation or Placebo once a day by inhalation
Disease target	Idiopathic Pulmonary Fibrosis
Sponsor	Galecto
Duration	52 weeks
Trial Status	Recruiting
Trial phase	Phase IIb
Key inclusion criteria	1. Male and female participants aged ≥ 40 years of age with a diagnosis of IPF established during the previous five (5) years according to ATS/ERS/Fleischner criteria. A historical diagnostic HRCT scan assessed according to the ATS/ERS/Fleischner criteria must be available from within the 12 months prior to screening. Diagnostic HRCTs will be subject to central reading for confirmation. 2. Lung function parameters as follows: a. FVC > 45% of the predicted value at screening b. DLCO (corrected for Hb) of 30% to 79% of the predicted value at screening.

	3. Participants who currently are not being treated with nintedanib or pirfenidone; or cannot tolerate nintedanib or pirfenidone.
Key exclusion criteria	1. Currently has significant airways obstruction: FEV1/FVC ratio of < 0.7 at screening 2. Has clinical evidence of active infection, including, but not limited to, bronchitis, pneumonia, sinusitis, urinary tract infection, and cellulitis. 3. Has a history of malignancy within the last 2 years with the exception of basal cell carcinoma, squamous cell carcinoma of the skin (localised, treated or cured), chronic lymphocytic leukaemia (under observation) and prostate cancer requiring anti-androgens, localised treatment (minor surgery, radiotherapy) and/or managed by observation. 4. Has any condition other than IPF that, in the opinion of the investigator, is likely to result in the death of the subject within the next 2 years. 5. Presence of other disease that may interfere with testing procedures or in the judgement of the Investigator may interfere with trial participation or may put the participants at risk when participating in this trial. 6. Is likely to receive lung transplantation within the next 12 months. 7. Currently receiving nintedanib, pirfenidone, high dose corticosteroid, cytotoxic (e.g., chlorambucil, azathioprine, Page 3 of 10 PACT Endorsement Policy Version 3.0, 19 Oct 2020 cyclophosphamide, methotrexate), vasodilator therapy for pulmonary hypertension (e.g., bosentan). A current dose of less than or equal to 15 mg/day of prednisone or its equivalent is acceptable if the dose is anticipated to remain stable during the study. 8. Prior use of nintedanib or pirfenidone within 7 days of initiation of screening. 9. Prior use of investigational drugs within 30 days (or 5 half-lives, whichever is longer) of initiation of screening. 10. Participating in another clinical trial, either interventional or observational. 11. Has a history of unstable or deteriorating cardiac or pulmonary disease (other than IPF) within the previous six months, including, but not limited to, the following: a. Unstable angina pectoris or myocardial infarction, or percutaneous coronary intervention within the last 6 months b. Congestive heart failure requiring hospitalization c. Uncontrolled clinically significant arrhythmias. 12. If female, the subject is pregnant or lactating or intending to become pregnant before participating in this study during the study and within 33 days after last dose of

	the study drug; or intending to donate ova during such time period. 13. Woman considered to be of childbearing potential who do not use highly effective birth control methods during the study and for 33 days after last administration of study drug. 14. Male partners of women of child bearing potential not committing to using condoms during the course of the study and 90 days after last administration of study drug, unless they have undergone male sterilization. 15. Known hypersensitivity to lactose or any other excipients in the GB0139 formulation and/or a history of severe milk protein allergy.
Primary endpoint	Efficacy of GB0139 by assessing the annual rate of decline in Forced Vital Capacity (FVC; expressed in mL over 52 weeks).
Number of participants sought	An additional 169 worldwide, 6-15 in Australia
Lead site(s) in Australia	TrialsWest, Spearwood, WA Flinders Medical Centre, Bedford Park, SA
Lead site(s) in New Zealand	Not applicable
Additional sites	Respiratory Clinical Trials, SA
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