ASPIRE Study

Trial title	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Trial Evaluating the Efficacy and Safety of 2 Doses of a new therapy Over 52 Weeks in People with Idiopathic Pulmonary Fibrosis.
Trial synopsis	A clinical study is being conducted to see if a new therapy (study drug) is safe and effective for improving lung function and treating idiopathic pulmonary fibrosis (IPF). This study will compare the STUDY DRUG to a placebo (a non-active treatment) to determine how well it works.
Investigational medicinal product, comparator and randomisation	The study drug works by activating a specific receptor in the lungs called the AT2 receptor. This receptor is found in certain lung cells that help keep the lungs healthy and repair damage. In simpler terms, the study drug helps the lungs repair themselves and stay healthy by targeting these important cells. The study drug is taken orally, two times per day. The clinical study will have three groups: study drug dose A (50mg) / study drug dose B (100 mg) / matching placebo, randomized 1:1:1.
Disease target	Idiopathic Pulmonary Fibrosis (IPF)
Sponsor	Vicore Pharma AB
Duration	The trial consists of 3 consecutive periods: a screening period of up to 6 weeks, a 52-week treatment period, and a follow-up period of 2-4 weeks.
Trial Status	Recruiting
Trial phase	Phase II
Key inclusion criteria	1. Age ≥ 40 years. 2. Diagnosed with IPF within 7 years prior to visit 1. 3. HRCT scan within 36 months prior to visit 1 with central reading confirming either a or b, and c: a. A pattern consistent with usual interstitial pneumonia (UIP). b. A pattern indeterminate for UIP and a historical biopsy (surgical lung biopsy or transbronchial lung cryobiopsy) consistent with IPF. c. Extent of fibrosis > extent of emphysema. 4. FVC ≥50% predicted at visit 1.

	5. DLCO (corrected for hemoglobin) ≥30% predicted at visit 1. 6. Either: a. On a stable dose of licensed IPF therapy for at least 8 weeks prior to visit 1 and expected to remain on this background treatment after randomization. Due to the risk of DDIs, concomitant treatment with pirfenidone is not allowed in this trial. b. Not currently receiving treatment for IPF. Any such previous treatment must have been discontinued >8 weeks prior to visit 1. 7. Anticipated life expectancy of at least 12 months at visit 1 and not anticipated to require a lung transplant during the trial period (being on a transplant list does not exclude a participant from the trial). 8. Contraceptive use by women of childbearing potential (WOCBP). 9. Written informed consent.
Key exclusion criteria	1. Concurrent serious medical condition that in the opinion of the investigator constitutes a risk or a contraindication for participation in the trial or that could interfere with the trial objectives, conduct or evaluation. 2. Airways obstruction with a pre-bronchodilator forced expiratory volume in one second (FEV1)/FVC ratio <0.7 at visit 1. 3. Lower respiratory tract infection requiring antibiotics and not fully recovered according to investigator judgement within 4 weeks prior to V2. 4. Confirmed infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) requiring hospitalization and not fully recovered within 4 weeks prior to visit 2. 5. Known impaired hepatic function or clinically significant liver disease (Child-Pugh B or C hepatic impairment), or aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >3 times upper limit of normal (ULN) or total bilirubin >1.5 times ULN at visit 1. 6. Severe renal impairment (i.e., estimated glomerular filtration rate (eGFR) ≤35 ml/min/1.73 m2 at visit 1. 7. Prolonged QTcF (QT interval with Fridericia's correction) (>450 ms), AV-block II or III,

	uncontrolled arrhythmia, or other clinically significant abnormality in the resting ECG at visit 1. 8. Heart failure NYHA Class IV, acutely decompensated right heart failure, PH with syncopal episode, confirmed myocardial infarction, unstable angina or uncontrolled hypertension, within 6 months prior to visit 1. 9. Known hypersensitivity or intolerance to study drug or to any other components of the test product, including excipients. 10. Pregnant or breast-feeding female participants. 11. Acute IPF exacerbation within 3 months prior to visit 1 and/or during the screening period: a. Acute worsening or development of dyspnea typically <1 month duration. b. Computed tomography with new bilateral ground-glass opacity and/or consolidation superimposed on a background pattern consistent with usual interstitial pneumonia pattern. c. Deterioration not fully explained by cardiac failure or fluid overload. 12. Inability to generate spirometry data at least twice at visit 1. 13. Treatment with pirfenidone (substrate of CYP1A2) within 8 weeks prior to visit 1 or anticipated need for pirfenidone during participation in the trial. 14. Treatment with the medications listed below within 2 weeks prior to visit 2 or anticipated need for such medication during participation in the trial: a. Sensitive or moderately sensitive substrates of CYP1A2 (e.g., theophylline, tizanidine), CYP2C9 (e.g., warfarin, tolbutamide, gliclazide, glibenclamide, acenocoumarol, phenprocoumon, phenytoin, siponimod), CYP2C19 (e.g., mephenytoin, valproic acid, escitalopram), or CYP2C8 (e.g., paclitaxel) with a narrow therapeutic index. b. Fluvastatin or pitavastatin. c. Any immunosuppressive therapies other than: Inhaled, nasal and topical corticosteroids, corticosteroids for the treatment of acute exacerbations. 15. Current or previous participation in any other clinical trial where the participant has received a dose of IMP within 4 weeks or 5 half-lives of the IMP, whichever is longest, prior to visit 1.

	16. Previous participation in a clinical trial with the study drug and received at least one dose of the study drug.
Number of participants sought	270 participants (90 in each arm)
Lead site(s) in Australia	St Vincent's Hospital (NSW)
Lead site(s) in New Zealand	N/A
Additional sites	• Austin Health (VIC) • Lung Research Victoria (VIC) • Royal Prince Alfred Hospital (NSW) • Concord Repatriation Hospital (NSW) • Flinders Medical Centre (SA) • Queen Elizabeth Hospital (SA) • Prince Charles Hospital (QLD) • Townsville University Hospital (QLD)
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