Clinician - PACT
New Clinical Trial and Research

Trial title	An Open Label Study of the Efficacy, Safety and Tolerablity of Np-120 on Idiopathic Pulmonary Fibrosis and its Associated Cough
Trial synopsis	NP-120 has been shown to mediate anti-inflammatory responses and reduce pulmonary fibrosis in a murine model of IPF. In addition, NP-120 significantly reduced both cough frequency and onset in a guinea pig tussive model. The purpose of this proof-of-concept trial is to determine the efficacy of NP-120 in the treatment of IPF and its associated cough. PRIMARY OBJECTIVES: To investigate the ability of NP-120 (20 mg TID) to reduce cough frequency and/or maintain FVC in patients with IPF.
Investigational medicinal product, comparator and randomisation	Open Label Oral Tablet
Disease target	Idiopathic pulmonary fibrosis and its associated cough
Sponsor	Algernon Pharmaceuticals, Inc.
Duration	Last Patient First Visit assumed March 2021, to include all follow up and close out 18 months
Trial Status	Recruiting
Trial phase	2

Key inclusion criteria	• Male and female subjects with a diagnosis of IPF established during the previous seven years according to ATS/ERS/Fleischner criteria.
	• Score ≥ 40 mm on the Cough Severity VAS at Screening
	• Lung function parameters as follows:
	  ○ Forced Vital Capacity (FVC) ≥ 45% of the predicted value at screening.
	  ○ Diffusion lung capacity for carbon monoxide (DLCO) (corrected for Hb) of 30% to 79% of the predicted value at screening.
	• Any existing Standard of Care (SoC) treatment (e.g. pirfenidone or nintedanib) must be deemed as stable (minimum three months) before enrollment.

	• Subjects must sign and date a written, informed consent form and any required authorization prior to initiation of any study procedures.
Key exclusion criteria	• Currently has significant airways obstruction: Forced Expiratory Volume in 1 s (FEV1)/Forced Vital Capacity (FVC) ratio of < 0.7 at screening. • Has clinical evidence of active infection, including, but not limited to, bronchitis, pneumonia, sinusitis, urinary tract infection, and cellulitis. • Has a history of malignancy within the last 2 years with the exception of basal cell carcinoma, chronic lymphocytic leukaemia (under observation),prostate cancer requiring anti-androgens, localised treatment (minor surgery, radiotherapy) and/or managed by observation, and squamous cell carcinoma if diagnosed and successfully treated more than 6 months prior to the study. SCC diagnosed within the past 6 months will be exclusionary. • Patients experiencing cerebral hemorrhage or cerebral infarction at screening/baseline. • 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. • 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 patient at risk when participating in this trial. • Is likely to receive lung transplantation within the next 12 months. • Currently receiving high dose corticosteroid, cytotoxic (e.g., chlorambucil, azathioprine, cyclophosphamide, methotrexate), vasodilator therapy for pulmonary hypertension (e.g., bosentan), and or investigational therapy for idiopathic pulmonary fibrosis (IPF) or administration of such therapeutics within 4 weeks of initial screening (or 5 half-lives, whichever is longer). 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.

	• 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:
	  ○ Unstable angina pectoris or myocardial infarction, or percutaneous coronary intervention within the last 6 months,
	  ○ Congestive heart failure requiring hospitalization,
	  ○ Uncontrolled clinically significant arrhythmias.
	• If female, the subject is pregnant or lactating or intending to become pregnant before participating in this study during the study and within (5 half- lives plus 30 days) after last dose of the study drug; or intending to donate ova during such time period.
	• Women considered to be of childbearing potential who do not use highly effective birth control methods during the study.

Primary endpoint	• A ≥50% reduction in the average number of coughs per hour over 24 hours comparing baseline to treatment period using an ambulatory cough monitor during baseline and week 12 (≥11 weeks of treatment) and/or • No worsening of force vital capacity (FVC) in either mL or % predicted after 12 weeks of treatment.
Number of participants sought	20
Lead site(s) in Australia	Cairns Hospital (public) / Vale Medical Practice (private)
Lead site(s) in New Zealand	Waikato Hospital
Additional sites	Concord Repatriation General Hospital NSW, Westmead Hospital NSW, University of Otago
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