

Introduction to GALACTIC-1

Idiopathic pulmonary fibrosis (IPF) is a severe, progressive lung disease that causes damage and scarring to the lungs, which makes it harder to breathe and often has a big impact on patients' quality of life.

Although there are treatments available for IPF, more can be done to improve the lives of patients. The GALACTIC-1 study will research a potential study drug that could offer benefit to patients with IPF. Thank you for considering participation in this trial.

What is the purpose of this study?

GALACTIC-1 is studying an investigational drug for patients who have IPF. The purpose of this study is to find out if the investigational drug works and to determine its safety.



**Thank you for
your interest in the
GALACTIC-1 trial.**

For more information, please visit Galactic1IPFStudy.com or contact:

Exploring new options for
idiopathic pulmonary fibrosis (IPF)



**A guide for patients
about the GALACTIC-1
study for idiopathic
pulmonary fibrosis (IPF)**

Protocol number: GALACTIC-1



How long will the trial last?

This study will consist of 10 visits over a period of up to 104 weeks.

The study is divided into four time periods:

- Screening visit (1 day)
- Baseline visit (1 day)
- Treatment period (up to week 52)
- Follow-up period (up to week 104)

You may be eligible to enroll regardless of whether you are currently taking pirfenidone or nintedanib.

What can I expect if I decide to participate?

If enrolled in the study, you will be randomly assigned to one of three treatment groups of daily inhaled treatment. Patients in all treatment groups will continue to receive their standard of care (pirfenidone, nintedanib, or another treatment if not prohibited) in addition to TD139 or placebo. Neither you nor your study doctor will know which treatment group you are assigned. The treatment groups are:

- TD139 (2 capsules) (10 mg) (+ pirfenidone or nintedanib, if applicable)
- TD139 (2 capsules) (3 mg) (+ pirfenidone or nintedanib, if applicable)
- Placebo (2 capsules) (+ pirfenidone or nintedanib, if applicable)

The study site staff will instruct you on how to take the drug (two inhalations will be performed on each capsule), including the number of capsules to be inhaled each day and the timing of doses. You will be given inhaler devices to last until your next visit.

After your Screening visit and your Baseline visit (week 0), you will visit the study site at six time points (weeks 4, 8, 12, 26, 40, and 52). Contact the study doctor/nurse/hospital if you have an issue while using the inhaler and be sure to bring back used and unused medication to these visits.

Lab tests, a physical exam, and other assessments and questionnaires will be conducted at the in-clinic visits. Not all activities will occur at every visit.

What are my costs to take part in this trial?

You will receive all study-related procedures and the investigational drug at no cost.

How large is this study?

Approximate recruitment for this study will be 450 patients in 100 sites in 11 countries.

What risks are involved if I decide to participate?

There are possible risks involved with any clinical study. Your study doctor will review the risks with you, and you will be closely monitored throughout the study.

What is a clinical trial?

A clinical trial is a scientific study in which participants are assigned to one or more investigational drugs to answer questions about the treatment to see if it works, works better than other treatments, and has side effects.

What is an investigational drug?

An investigational drug is a substance that is being tested in clinical trials. It has been reviewed by an ethics committee for testing in people but has not been approved by the government health agency for treatment for this condition.

Why should I take part in this study?

Clinical trials or studies are important for medical advances. Current treatments for diseases are only available because of research study volunteers.

Who can participate in this study?

You may qualify for this study if:

- You are 40 years of age or older
- You have been diagnosed with IPF in the past three years

Your doctor will go over other study requirements to confirm if you qualify.