

# LEARN ABOUT WHISTLE-PF

A NEW CLINICAL TRIAL FOR PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS



#### **ENV-101**

ENV-101 is a Hedgehog (Hh) signaling pathway inhibitor. By binding to and inhibiting a key receptor in the Hh pathway, ENV-101 stops the abnormal accumulation of the myofibroblasts that cause fibrosis. Endeavor BioMedicines believes that this may resolve the excessive wound-healing process seen in idiopathic pulmonary fibrosis (IPF), creating the potential to reverse fibrosis and improve lung volume and function.

Endeavor BioMedicines previously completed a Phase 2a randomized, double-blind, placebo-controlled trial of ENV-101 in 41 patients with IPF. Patients were randomized 1:1 to receive a 200 mg oral dose of ENV-101 once a day for 12 weeks or placebo. Findings shared in an oral, late-breaking presentation at the American Thoracic Society (ATS) 2024 International Conference support further clinical evaluation of ENV-101 in IPF.

## **WHISTLE-PF Trial Objectives**

## **Primary Objective**

To characterize the efficacy of a range of doses of ENV-101 in patients with IPF at 24 weeks

## **Secondary Objectives**

- To characterize the safety of ENV-101 in patients with IPF
- To characterize the effects of ENV-101 on patient reported outcomes in patients with IPF
- To characterize the effects of ENV-101 on lung capacity and lung fibrosis as measured by chest high-resolution computed tomography (HRCT) in patients with IPF

#### **Trial Medication**

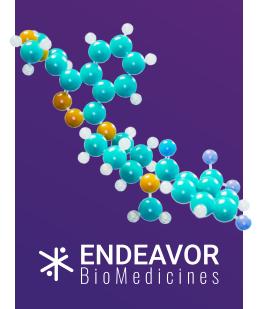
- Low, medium or high dose of ENV-101, or placebo, once daily
- Patients are allowed to be on standard of care (SoC) of antifibrotics (i.e., nintedanib or pirfenidone) provided they are on a stable regimen for at least three months prior to Day 1

# What is the WHISTLE-PF Clinical Trial?

The Wound-remodeling
Hedgehog-inhibitor ILD
Study Testing Lung Function
Endpoints (WHISTLE)-PF
clinical trial is a randomized,
placebo-controlled, Phase 2b
trial for patients with idiopathic
pulmonary fibrosis.

## **ENV-101**

ENV-101 is an investigational medication being developed by Endeavor BioMedicines, Inc., to treat fibrotic lung diseases, starting with IPF.



#### **Trial Duration**

Four-week screening period, 24 weeks of treatment and a two-week follow-up visit after treatment.

#### **WHISTLE-PF Trial Primary Inclusion Criteria**

- Patients ≥ 40 years old with an IPF diagnosis within the last five years based on 2022 international guidelines as confirmed by the investigator
- A qualifying chest HRCT scan taken within 30 days of the screening visit must be consistent with the diagnosis of IPF, as confirmed by central read/review

#### **Planned Trial Locations**

# Join the Trial

Endeavor BioMedicines is currently seeking additional clinical trial sites for the WHISTLE-PF trial.

## Learn More

whistle-pftrial.com



