

Oorja Bio Announces Initiation of ORBIT-IPF Phase 2 Clinical Trial Evaluating ORJ-001 for the Treatment of Idiopathic Pulmonary Fibrosis

Randomized, placebo-controlled study to evaluate the safety, tolerability, and efficacy in a robust, two-part study

First-in-class therapeutic targets Alveolar Epithelial Type 2 (AEC2) cells with the aim to halt disease progression and promote repair of fibrotic damage in IPF

HOUSTON, Texas –October 13, 2026 – [Oorja Bio, Inc.](#), a clinical-stage biopharmaceutical company developing groundbreaking therapies for fibrotic and cardiopulmonary diseases, today announced that the first patient has been screened in its ORBIT-IPF Phase 2 clinical trial evaluating ORJ-001 for the treatment of idiopathic pulmonary fibrosis (IPF), a progressive and fatal lung disease with limited treatment options.

The ORBIT-IPF Phase 2 clinical trial ([NCT07869147](#)) is a randomized, double-blind, placebo-controlled multicenter study designed to evaluate the safety, tolerability, and efficacy of ORJ-001, a peptide therapeutic with a novel approach to treat IPF by restoring the function of alveolar epithelial type 2 (AEC2) cells, promoting alveolar repair and reducing the inflammatory and fibrotic signaling that drives pulmonary fibrosis. Preclinical studies in animal models of IPF have shown that ORJ-001 can repair damaged lung tissue and improve markers of lung function.

“The initiation of our ORBIT-IPF Phase 2 clinical trial represents a major step toward our goal of pioneering novel therapies that repair and reverse fibrosis,” said Sujay Kango, Chief Executive Officer of Oorja Bio. “Our \$34 million Series A financing raised from Westlake BioPartners and Andreessen Horowitz (a16z) enables us to advance Oorja’s commitment of developing disease modifying therapies, like ORJ-001, that can define a new future of IPF treatment for patients, physicians, and caregivers.” “It is exciting to see ORJ-001, a new therapeutic approach with the potential to repair damaged lung tissue in IPF, advance in clinical trials. To date, available therapies can slow the rate of decline in lung function, yet this challenging disease continues to progress and patients often struggle with side effects linked to standard-of-care medications,” said Toby Maher, MD, PhD, Professor of Medicine at University of Southern California. “IPF is a devastating disease with limited treatment options. We look forward to insights the ORBIT-IPF study will provide about ORJ-001 potential to deliver meaningful clinical benefits for patients suffering from IPF.”

The ORBIT-IPF Phase 2 study uses an adaptive study design, comprised of two parts: Part A will assess the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of two dose levels of ORJ-001 administered subcutaneously twice weekly compared with placebo over 12 weeks of treatment. In Part B, the primary efficacy endpoint will be change from baseline in forced vital capacity (FVC) as compared with placebo. In addition to continued safety monitoring, biomarkers of fibrosis (tenascin-C) and epithelial damage (SP-D) that are correlated with long-term outcomes in IPF patients, are being evaluated. These biomarkers are part of a panel of biomarkers currently being reviewed by the U.S. Food and Drug Administration as a scoring system for IPF.¹ The study will enroll IPF patients with moderate disease who are receiving standard-of-care therapy or who have discontinued standard-of-care therapy due to tolerability issues or inadequate response.

“The initiation of ORBIT-IPF clinical trial represents important progress as we advance ORJ-001 as a first-in-class treatment to address the urgent needs of patients living with IPF,” said Janethe Pena, MD, Chief

Medical Officer of Oorja Bio. “We believe that ORJ-001’s AEC2-targeting mechanism addresses the central role of the alveolar epithelium in IPF pathology, and therefore offers the potential to repair the alveoli and reverse fibrosis to modify the progression of disease for IPF patients. We look forward to working with clinical sites as we continue to enroll the ORBIT-IPF Phase 2 program.”

The ORBIT-IPF is a multi-country clinical trial with currently active study sites in the United States. More information about the ORBIT-IPF Phase 2 clinical trial can be found by visiting [ClinicalTrials.gov](https://clinicaltrials.gov).

About Idiopathic Pulmonary Fibrosis

Idiopathic pulmonary fibrosis (IPF) is a chronic, progressive, and life-threatening lung disease affecting more than 150,000 adults in the United States. It is characterized by progressive fibrosis of lung tissue, leading to declining lung function, respiratory failure, and ultimately death. Although the biological triggers of IPF onset remain incompletely understood, impaired epithelial regeneration following lung injury is recognized as a key driver of disease pathogenesis. In particular, the central role of alveolar epithelial type 2 (AEC2) cells in maintaining and repairing the lung epithelium has been well established. IPF remains an area of significant unmet medical need. Currently approved therapies can slow disease progression but do not prevent the continued decline in lung function. As a result, prognosis remains poor, with an average life expectancy of three to five years after diagnosis.

About ORJ-001 and Targeting Alveolar Epithelial Type 2 (AEC2) Cells

ORJ-001 is a first-in-class therapeutic for subcutaneous administration designed to treat idiopathic pulmonary fibrosis (IPF) by restoring the function of alveolar epithelial type 2 (AEC2) cells, promoting alveolar repair and reducing the inflammatory and fibrotic signaling that drives pulmonary fibrosis. It is a peptide agonist of $\beta 1$ integrin, a transmembrane protein that plays a critical role in AEC2 function within its cellular niche by transducing biochemical and mechanical signals from the extracellular matrix. $\beta 1$ integrin activity is essential for regulating AEC2 cell fate, including senescence and differentiation into mature alveolar epithelial type 1 (AEC1) cells, which line the majority of the alveolar surface and are key to epithelial function. It also influences inflammatory signaling pathways implicated in fibrosis. Through these multimodal effects, ORJ-001 has the potential to both halt disease progression and promote repair of the fibrotic damage characteristic of IPF.

About Oorja Bio

[Oorja Bio, Inc.](https://www.oorjabio.com) is a clinical-stage biotechnology company developing groundbreaking therapies for idiopathic pulmonary fibrosis (IPF) and other fibrotic and cardiopulmonary diseases by targeting mechanisms that drive the underlying pathophysiology of disease. ORJ-001, its lead drug candidate, is designed to restore function of alveolar epithelial type 2 (AEC2) cells to promote cellular repair and remodel fibrotic tissue. Oorja Bio was founded with investment from Westlake BioPartners and has raised \$34 million in Series A financing from investors including Westlake BioPartners and Andreessen Horowitz (a16z). The company is based in Houston, TX. For more information about Oorja Bio, visit www.oorjabio.com and follow us on [LinkedIn](https://www.linkedin.com/company/oorjabio).

¹ *Haelio*, “FDA accepts IPF biomarker panel into qualification program,” Feb. 3, 2026. <https://www.healio.com/news/pulmonology/20260203/qa-fda-accepts-ipf-biomarker-panel-into-qualification-program>