Oorja Bio Unveils Clinical Data for ORJ-001, a First-in-Class Therapeutic Targeting Alveolar Epithelial Type 2 (AEC2) Cells for Treatment of Idiopathic Pulmonary Fibrosis (IPF)

ORJ-001 achieved therapeutic exposure and was well tolerated in Phase 1 study, supporting company's plans to initiate Phase 2 clinical trial in IPF patients

Data from preclinical studies of ORJ-001 demonstrated durable tissue target engagement and lower levels of Tenascin-C, a biomarker for tissue remodeling, chronic inflammation, and fibrosis

Two poster presentations included at the American Thoracic Society 2026 International Conference

HOUSTON, Texas – May 19, 2026 – Oorja Bio, Inc., a clinical-stage biopharmaceutical company developing groundbreaking therapies for fibrotic and cardiopulmonary diseases, today announced the presentation of the first-in-human Phase 1 clinical data for ORJ-001, a first-in-class therapeutic to treat idiopathic pulmonary fibrosis (IPF), demonstrating therapeutically relevant exposure and favorable tolerability in healthy volunteers. The company also announced the presentation of data from preclinical studies of ORJ-001 in the therapeutic model of bleomycin-induced lung fibrosis showing durable target tissue engagement and biomarker activity. The two poster presentations are included at the American Thoracic Society (ATS) 2026 International Conference, taking place May 15-20 in Orlando, Florida.

ORJ-001 is a peptide therapeutic for subcutaneous administration 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. Oorja Bio plans to initiate a Phase 2 clinical trial this year for ORJ-001 in IPF patients. The data to support the Phase 2 trial includes multiple *in vivo* studies in the well-validated bleomycin model of pulmonary fibrosis to evaluate the dose range to show effectiveness of ORJ-001. *In vitro* studies in human-derived lung epithelial cells and fibroblasts have demonstrated target engagement in the nanomolar range, similar to the plasma concentrations achieved in Phase 1 studies.

"The clinical and preclinical results from our studies to date give us confidence that ORJ-001 represents a novel treatment approach with the potential to repair and reverse fibrosis and modify disease progression in IPF," said Janethe Pena, MD, Chief Medical Officer of Oorja Bio. "Our preclinical results support ORJ-001's AEC2-targeting mechanism and its disease modifying potential in IPF. In preclinical models, ORJ-001 showed a reversal of fibrosis and induced re-epithelialization of the alveoli, showing significantly better results than comparative treatments, nintedanib or pirfenidone."

The Phase 1 program include two studies that were single-center, prospective, randomized, double-blind, placebo-controlled, including a single-ascending dose (SAD) with four cohorts and a multiple-ascending dose (MAD) with four cohorts of ORJ-001 administered subcutaneously daily or weekly in a total of 64 adult healthy volunteers. Key findings from the single and multiple dose cohorts presented in the poster at the ATS International Conference include:

- The Phase 1 program's primary objective was to assess the clinical safety and tolerability of ORJ-001. No systemic toxicities were observed; injection site reactions were the most common adverse events and were mostly mild.
- The program also evaluated the pharmacokinetics to identify the active dosing range for future clinical development. Physiologically based pharmacokinetic (PBPK) modeling demonstrated that plasma exposure in humans was in the pharmacologically active range identified in the animal models.

Preclinical data for ORJ-001 presented at the ATS International Conference included results from studies in the therapeutic mouse model of bleomycin-induced lung fibrosis, including the following key findings:

- Target tissue engagement was sustained for up to 7 days following a single subcutaneous dose of ORJ-001.
- Levels of Tenascin-C (TNC) and Surfactant Protein-D (SP-D) declined steadily over four weekly doses of ORJ-001. TNC is a biomarker of tissue remodeling, chronic inflammation, and fibrosis, while SP-D is a specific biomarker of AEC2 damage. These biomarkers are correlated with long-term outcomes in IPF patients, and are included in a panel of biomarkers currently being qualified by the U.S. Food and Drug Administration as a scoring system for IPF.[1]

In additional preclinical studies in animal models of pulmonary fibrosis, ORJ-001 has demonstrated reversal of fibrosis and repair of lung tissue. These results were presented at the Pulmonary Fibrosis Foundation Summit in November 2025:

- Reversal of established fibrosis was demonstrated in multiple studies using therapeutic bleomycin models, in which fibrosis was induced for 7-28 days prior to treatment initiation.
- Regeneration of normal lung and alveolar morphology was demonstrated by re-epithelialization of lung alveoli evidenced by AEC1 cell staining with RAGE, Aquaporin-5 and T1α-podoplanin.

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 peptide 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 an agonist of β1 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. β1 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. is a clinical-stage biotechnology company developing groundbreaking therapies for idiopathic pulmonary fibrosis (IPF) and other fibrotic and cardiopulmonary diseases by targeting mechanisms underlying the 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 initial investment from Westlake BioPartners. The company is based in in Houston, TX. For more information about Oorja Bio, visit www.oorjabio.com and follow us on LinkedIn.

[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

Media Contact
Kathryn Morris
The Yates Network LLC
914-204-6412
kathryn@theyatesnetwork.com