



Avalyn Completes Successful Phase 1 Clinical Trials of AP02, its Novel Inhaled Formulation of Nintedanib, Preparing for Phase 2 Development in Idiopathic Pulmonary Fibrosis

Apr 1, 2025

Topline data from the single- and multiple-ascending dose studies confirmed safety and favorable tolerability profile of AP02 at all dose levels

Full safety, tolerability, and pharmacokinetics data to be presented at the American Thoracic Society 2025 International Conference in May 2025

Company plans to advance AP02 into a Phase 2 clinical trial in patients with idiopathic pulmonary fibrosis (IPF)

CAMBRIDGE, Mass., April 01, 2025 (GLOBE NEWSWIRE) -- [Avalyn Pharma Inc.](#), a clinical-stage biopharmaceutical company developing inhaled therapies for the treatment of life-threatening pulmonary diseases, today announced that AP02 (inhaled nintedanib) was safe and well tolerated in multiple single-ascending dose (SAD) and multiple-ascending dose (MAD) Phase 1 clinical trials in healthy adult volunteers and patients with idiopathic pulmonary fibrosis (IPF).

IPF is largely untreatable and characterized by scarring of lung tissue, decline in lung function, and reduced exercise capacity and quality of life. There is a clear need to bring treatment options to patients that maximize therapeutic impact while minimizing systemic exposure and transform the disease from a fatal diagnosis into a manageable condition.

The most recently completed Phase 1 trial enrolled a total of 60 healthy adult volunteers and consisted of a single-ascending dose (SAD) portion, which assessed AP02 at 2.0 mg, 4.0 mg, and 8.0 mg once-daily (QD); a multi-ascending dose (MAD) portion that evaluated twice-daily (BID) dosing of AP02 at the same dose levels over a seven-day treatment period; and a bronchoalveolar lavage (BAL) portion, which assessed lung exposure following a single 4.0 mg AP02 dose across three timepoints.

"We are excited to complete this innovative set of clinical trials for AP02, where we assessed lung exposure in both studies of the inhaled compared to oral nintedanib," said Lyn Baranowski, Chief Executive Officer of Avalyn. "Through its enhanced drug delivery directly to the lungs, our approach allows us to address the underlying pathophysiology of the disease and positions AP02 as a potential future standard-of-care for patients with IPF."

The company expects to present full topline data from two Phase 1 studies, including safety, tolerability, and pharmacokinetics at the American Thoracic Society 2025 International Conference in May 2025. Based on these results, Avalyn plans to advance AP02 into a Phase 2 clinical program for patients with idiopathic pulmonary fibrosis (IPF).

About Avalyn Pharma

Avalyn is reimagining the future of pulmonary fibrosis treatment with a pipeline of new inhaled formulations of approved medicines designed to reduce systemic exposure and deliver medication directly to the site of disease. Pulmonary fibrosis is characterized by scarring of lung tissue, decline in lung function, and reduced exercise capacity and quality of life, and is associated with increased mortality. Currently approved therapeutic options slow pulmonary fibrosis progression but are associated with significant toxicities that restrict their use and dosing. Avalyn's [inhaled approach](#) tackles the underlying pathophysiology of pulmonary fibrosis at its source and is designed to reduce systemic exposure and deliver medication directly to the site of disease. Avalyn's lead program, AP01, is an optimized inhaled formulation of pirfenidone, currently being studied in the ongoing MIST Phase 2b study in progressive pulmonary fibrosis (PPF). AP01 has been assessed in over 150 individuals with different forms of pulmonary fibrosis and demonstrated clinical proof-of-concept with improved efficacy and safety compared to historical data with existing therapies. The company completed two Phase 1 studies for its second program, AP02, inhaled nintedanib, for the treatment of idiopathic pulmonary fibrosis (IPF). For more information, please visit avalynpharma.com and follow us on [LinkedIn](#).

Investor Contact:

Alex Straus, THRUST
alex@thrustsc.com
ir@avalynpharma.com

Media Contact:

media@avalynpharma.com