



Avalyn Announces Multiple Presentations on AP01 and AP02 for Pulmonary Fibrosis at the American Thoracic Society 2025 International Conference

May 6, 2025

Topline Results from the AP02 (Inhaled Nintedanib) Phase 1 Clinical Trials Among the Company's Five Poster Presentations

4.5 Year Long-Term Safety and Efficacy Data Supporting AP01 (Inhaled Pirfenidone) from the ATLAS Open-Label Extension Trial to be Presented

Avalyn to be featured in ATS Industry Theater Program

CAMBRIDGE, Mass., May 06, 2025 (GLOBE NEWSWIRE) -- [Avalyn Pharma Inc.](#), a clinical-stage biopharmaceutical company focused on development of inhaled therapies for the treatment of life-threatening pulmonary diseases, today announced multiple presentations at the American Thoracic Society (ATS) 2025 International Conference being held May 16-21, 2025, at the Moscone Center in San Francisco, CA.

"We're proud to showcase a strong portfolio of presentations at the upcoming ATS conference, which reflects the dedication of our team and collaboration with physicians and medical professionals to meet the urgent therapeutic needs in the pulmonary fibrosis community," said Lyn Baranowski, CEO of Avalyn Pharma. "We look forward to reporting topline data from two Phase 1 clinical trials of AP02, which support its advancement into a Phase 2 trial, and up to 240 weeks of long-term clinical efficacy and safety data on AP01. Our presence at ATS will showcase our belief that we are well-positioned to transform how pulmonary fibrosis will be treated in the future through the advent of optimized inhaled formulations that offer improved safety, efficacy and long-term adherence – a critical must-have given the progressive, chronic nature of this disease."

Avalyn's presentations will include topline data from the single- and multiple-ascending dose [Phase 1 clinical trials of AP02](#) (inhaled nintedanib) in healthy adult volunteers and patients with idiopathic pulmonary fibrosis (IPF) and new long-term safety and efficacy data from the ATLAS open-label extension trial of AP01 (inhaled pirfenidone) in patients with IPF and progressive pulmonary fibrosis (PPF). Furthermore, the company, in collaboration with Qureight, will present results from two deep learning-based analyses of high-resolution computed tomography (HRCT) scans and patient data from the Phase 1b ATLAS trial of AP01, exploring the utility of novel imaging biomarkers and synthetic study arms in validating treatment efficacy in patients with IPF.

Avalyn will also be featured in the ATS Industry Theater program, where Joyce Lee, M.D., Professor of Medicine in Pulmonary Sciences and Critical Care Medicine, Director of the Interstitial Lung Disease Program, University of Colorado School of Medicine, an investigator in the Phase 2b clinical trial of AP01, and a steering committee member for AP02, will provide data highlights from the Phase 1 clinical trials of AP02.

Avalyn's abstracts for the conference are available on the ATS 2025 [online program](#) and the Company's event schedule is outlined as follows:

ATS 2025 Poster Presentations:

Thematic Poster Session A57: Late Breaking Abstracts in Clinical Problems, Sunday, May 18, 2025, 11:30 a.m.-1:15 p.m. PT:

Title: *A Double-blind, Placebo-controlled, Randomized Phase 1 Study to Evaluate Safety, Tolerability, and Pharmacokinetics After Single or Repeat Twice-daily Doses of AP02, a Nebulized Formulation of Nintedanib*

Authors: Michelle Palacios, Rebecca Boone, Stephen Pham, Howard M. Lazarus, Craig S. Conoscenti, Melissa Rhodes
Poster #: P1007

Title: *Monte Carlo External Control Arm Generation Utilizing Real-world Patient Data and Deep Learning-based Quantitative CT Metrics Demonstrates Treatment Effect in the ATLAS IPF Trial*

Authors: Kiril R. Kirov, Elliott Bussell, Muhunthan Thillai, Felix A. Woodhead, Howard M. Lazarus, Craig S. Conoscenti, Simon L.F. Walsh
Poster #: P1009

Thematic Poster Session A101: New Approaches to the Monitoring and Treatment of ILD, Sunday, May 18, 2025, 2:15 p.m.-4:15 p.m. PT:

Title: *Long-term Safety and Efficacy Data with Inhaled Pirfenidone (AP01) in the ATLAS Open-label Extension Study Up to 240 Weeks*

Authors: Tamera J. Corte, Sebastien Tilleux, Deepthi K. Nair, Felix A. Woodhead, Hao Bao, Craig S. Conoscenti, Howard M. Lazarus, Margaret L. Wilsher
Poster #: 103

Title: *Inhaled Nintedanib (AP02) for the Treatment of IPF: Safety, Tolerability, and Pharmacokinetics After Single Ascending Doses to Healthy Subjects and IPF Patients*

Authors: Michelle Palacios, Stephen Pham, Mark Surber, Deepthi K. Nair, Felix A. Woodhead
Poster #: 112

Thematic Poster Session C23: On the Horizon: Imaging and Molecular Biomarkers in Fibrotic ILD, Tuesday, May 20, 2025, 9:15 a.m.-11:15 a.m. PT:

Title: *Dose-Dependent Change of Inhaled Pirfenidone Seen in Lung Volume and Fibrosis Quantification in Patients With IPF: A Deep Learning Image-Based Analysis of Data from the ATLAS Phase 1b Trial*

Authors: Elliott Bussell, Miguel Monteiro, Fahdi Kanavati, Muhunthan Thillai, Simon L.F. Walsh, Felix A. Woodhead, Howard M. Lazarus, Craig S. Conoscenti
Poster #: 601

ATS 2025 Industry Theater Conference Event, Tuesday, May 20, 2025, 12:00 p.m.-12:30 p.m. PT:

Title: *Breathing New Life: Inhaled Nintedanib and the Future of Pulmonary Fibrosis Treatment*

Presenters: Joyce Lee, M.D., Professor of Medicine in Pulmonary Sciences and Critical Care Medicine, Director of the Interstitial Lung Disease Program, University of Colorado School of Medicine; Howard M. Lazarus, MD, FCCP, Chief Medical Officer, Avalyn Pharma

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](#).

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