Avalyn Announces Publication Demonstrating Correlation Between Imaging, Improved Lung Function, and Quality of Life with AP01 in Patients with Idiopathic Pulmonary Fibrosis

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Findings provide early evidence supporting potential disease-modifying activity of AP01 (inhaled pirfenidone) in patients with IPF

BOSTON, March 25, 2026 (GLOBE NEWSWIRE) -- Avalyn Pharma Inc., ("Avalyn" or the "Company"), a clinical-stage biopharmaceutical company pioneering inhaled therapies to transform the treatment paradigm of serious, rare respiratory diseases, today announced the peer-reviewed publication of data demonstrating that improvements in quantitative lung imaging correlate with lung function and quality of life in patients with idiopathic pulmonary fibrosis (IPF) treated with AP01 in the company's Phase 1b ATLAS trial.

The finding on AP01 in *BMC Pulmonary Medicine* represents the first dataset for an antifibrotic therapy that shows a correlation between quantitative high-resolution computed tomography (HRCT) imaging, changes in measures of lung function, and patient-reported quality of life (QOL) outcomes. The analysis is based on post-hoc data from the company's ATLAS trial and incorporates advanced quantitative imaging in collaboration with the Department of Radiology at the University of California, Los Angeles (UCLA).

"Our quantitative CT imaging analysis suggest that inhaled AP01 may help stabilize lung fibrosis, and the results show early signals consistent with potential improvement of interstitial lung disease, alongside with encouraging trends in lung function and patients' daily lives," said Jonathan Goldin, M.D., Ph.D., senior author and Professor-in-Residence of Radiological Science, Medicine & Physics and Biology in Medicine Program at UCLA. "The ability to visualize and precisely measure distinct patterns of fibrosis and their response to treatment represents a new paradigm in pulmonary fibrosis research and future patient care."

Key findings as reported in the publication include:

- More than 70% of patients who received AP01 100 mg twice daily and had imaging data at both baseline and Week 24 achieved stabilization or improvement in fibrosis score on HRCT at week 24, with some demonstrating reductions in fibrotic volume (as measured by Quantitative Lung Fibrosis), and increases in whole lung volume.
- Dose-dependent reductions in quantitative ground glass (QGG), a marker associated with early fibrosis or potentially reversible lung injury, supporting the opportunity for AP01 for earlier intervention and broader patient impact.
- Quantitative analysis further confirmed patients with HRCT-documented fibrosis improvement experienced the greatest and most rapid QOL gains, with clinically meaningful benefits seen as early as Week 8 and sustained through Week 48.

"The findings from this seminal analysis mark a true trifecta of potential benefits for people living with IPF," said Howard Lazarus, M.D., FCCP, Chief Medical Officer of Avalyn. "This can mean not only slowing the progression of fibrosis but improving how patients feel and function in their daily lives. We are committed to addressing the major gaps left by oral therapies today and paving the way for better outcomes for patients living with these challenging diseases."

"This publication is a testament to Avalyn's commitment to advancing the field's understanding of pulmonary fibrosis and unlocking new possibilities for disease management," said Lyn Baranowski, Chief Executive Officer of Avalyn. "By demonstrating that these physiologic fibrosis and quality-of-life improvements can occur together with AP01, we are providing the kind of multi-dimensional insights that clinicians have been seeking. These findings, along with similar forced vital capacity stabilization trends observed in progressive pulmonary fibrosis, reinforce our strategy to incorporate quantitative imaging into our Phase 2 trials and accelerate the development of innovative treatments for patients in need.

The ongoing global MIST Phase 2b trial of AP01 in patients with progressive pulmonary fibrosis (PPF) and AURA Phase 2 trial of AP02 (inhaled nintedanib) in patients with IPF will prospectively incorporate HRCT imaging to further validate these findings. Additional data, including longitudinal findings from the company's ongoing open-label extension trial, are expected in mid-2026.

About AP01
AP01 is an optimized inhaled formulation of pirfenidone, being developed as a potential next-generation standard-of-care treatment for patients with PPF. Pirfenidone is a small molecule inhibitor that has anti-inflammatory and anti-fibrotic effects through

modulation of cytokines and growth factors involved in the pathogenesis of pulmonary fibrosis, resulting in reduced fibroblast proliferation, collagen production, and anti-inflammatory and antioxidative effects. AP01 is administered using the PARI eFlow® Nebulizer System that delivers the medication to the lungs in less than 10 minutes. AP01 has been extensively studied in over 150 clinical trial participants. In the completed ATLAS, Phase 1b clinical trial, AP01 was generally well-tolerated with meaningfully low rates of gastrointestinal and skin-related side effects. AP01 continues to demonstrate long-term tolerability and clinical activity in the ongoing open label extension trial, with some patients surviving more than four and a half years. AP01 is currently being evaluated in MIST, a global Phase 2b clinical trial in patients with progressive pulmonary fibrosis (PPF). AP01 is an investigational therapy and is not approved by the U.S. Food and Drug Administration (FDA), and its safety and efficacy have not been established.

About Avalyn Pharma
Avalyn aims to transform the treatment paradigm for pulmonary fibrosis and other serious, rare respiratory diseases. The company is advancing optimized inhaled formulations of established antifibrotic medicines designed to deliver drug directly to the lungs, enhance local efficacy, and reduce systemic side effects. Avalyn's AP01 program is an optimized inhaled formulation of pirfenidone currently being evaluated in MIST, a global Phase 2b clinical trial in patients with progressive pulmonary fibrosis (PPF). AP01 has demonstrated encouraging tolerability and clinical activity across Phase 1b and an ongoing, multi-year open-label extension trial, with long-term data supporting the potential to preserve lung function while improving tolerability relative to historical oral pirfenidone. Avalyn's AP02 program is an optimized inhaled formulation of nintedanib currently being evaluated in AURA, a global Phase 2 clinical trial in patients with idiopathic pulmonary fibrosis (IPF). Avalyn is also advancing AP03, an inhaled fixed-dose combination of pirfenidone and nintedanib, designed to deliver dual antifibrotic mechanisms through a single lung-targeted platform. By leveraging its proprietary drug-device approach and deep expertise in rare respiratory disease development, Avalyn aims to establish a new standard of care in pulmonary fibrosis through inhaled, lung-targeted therapies. For more information, please visit avalynpharma.com and follow the company on LinkedIn.

Investor Contact:
Cassie Saitow, Avalyn Pharma Inc.
Sr. Director, IR and Corporate Communications
ir@avalynpharma.com

Media Contact:
Kat Lippincott, Deerfield Group
kat.lippincott@deerfieldgroup.com
media@avalynpharma.com