Avalyn Presents New Data at ERS Congress 2026 Supporting AP01 Lung Distribution and Patient-Centered Trial Design in Pulmonary Fibrosis

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In silico modeling predicts robust AP01 distribution in healthy and fibrotic lungs, even in severe disease

Patient survey findings suggest that clear communication, transparent discussions of potential benefits and risks, and efforts to reduce logistical burden may support engagement in future pulmonary fibrosis clinical studies

BOSTON, Sept. 08, 2026 (GLOBE NEWSWIRE) -- Avalyn Pharma Inc. (Nasdaq: AVLN), a clinical-stage biopharmaceutical company pioneering inhaled therapies to transform the treatment paradigm of serious, rare respiratory diseases, today announced new data demonstrating predicted aerosol distribution of AP01 and survey data highlighting patient perspectives on participation in clinical studies for idiopathic pulmonary fibrosis (IPF). The findings were presented at the European Respiratory Society (ERS) International Congress 2026, being held September 5-9, 2026, in Barcelona, Spain.

“At Avalyn, our mission is not only to redefine the standard of care for respiratory diseases, but to ensure patients help guide the way those therapies are developed. The most meaningful innovations are driven by a deep understanding of both the underlying disease biology and the patient experience,” said Lyn Baranowski, Chief Executive Officer of Avalyn Pharma. “The data presented at ERS reinforce that philosophy from both perspectives. The AP01 modeling data support the potential to deliver medication throughout the lung, including to the areas most impacted by active fibrotic disease. And the patient insights provide important guidance for designing studies that reflect the needs, experiences and priorities of people living with pulmonary fibrosis. Together, these findings highlight the opportunity to both deliver meaningful therapeutic impact and advance clinical development in a way that elevates the patient experience.”

AP01 Modeling Demonstrates Robust Delivery to Sites of Active Fibrotic Disease

To evaluate the pulmonary distribution of AP01, Avalyn used the validated Ebenbuild Twinhale® *in silico* modeling platform, combining AP01 eFlow® Nebulizer System and aerosol performance characteristics with three-dimensional lung models derived from high resolution computed tomography (HRCT) scans of healthy, mild IPF, and severe IPF lungs. These patient-specific *in silico* simulations were designed to predict aerosol deposition in key regions of the lung and assess how nebulized AP01 may distribute in individuals with different degrees of fibrotic disease involvement.

Data show that:

- AP01 achieved broad distribution throughout the lung, including in severely fibrotic lungs, with consistent deposition patterns observed across healthy, mild IPF and severe IPF models.
- Alveolar and thoracic tissues accounted for the majority of deposited aerosol mass in all models, demonstrating robust delivery to the primary sites of fibrotic remodeling and active disease, even in the case of advanced fibrosis.
- Video visualization of deposition pattern reinforced that simulated tidal breathing of nebulized AP01 delivered particles throughout the lung.

Patients with IPF Express Strong Interest in Clinical Trial Participation and Clear Preferences for Patient-Focused Study Design

To better understand factors influencing clinical trial engagement in IPF, Avalyn conducted a quantitative and qualitative survey of individuals living with IPF to assess prior clinical trial experience and preferences. Participants provided perspectives on communication needs, logistical barriers, and motivations for engaging in research, with the goal of informing more patient-focused clinical trial design.

Results show that:

- Individuals living with IPF demonstrated a strong willingness to participate in clinical research, including long-distance travel and extended participation in placebo-controlled studies.
- Clear communication regarding study goals, risks, and potential benefits, along with recognition of prior patient experience and attention to logistical barriers, emerged as key factors supporting engagement in clinical research and informing more patient-focused trial design.

See the ERS online program for more details. The presentations are accessible on the company's website.

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 indicated encouraging safety and clinical activity across Phase 1b and multi-year open-label extension trials, 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 multiple 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.

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