Avalyn Publishes Phase 1 Data Highlighting AP02's Lung-Targeted Delivery and Encouraging Safety Profile

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Results validate Avalyn's approach of delivering established antifibrotic medicines directly to the lungs to maximize local exposure while limiting systemic exposure and improving tolerability

Findings support continued advancement of AP02 for idiopathic pulmonary fibrosis (IPF); enrollment is on track in AURA Phase 2 trial with topline data expected late 2027

BOSTON, Sept. 21, 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 that *Respiratory Research* has published detailed results from two Phase 1 clinical trials of AP02 (nebulized nintedanib) in healthy volunteers and patients with IPF. Topline data from the trials were previously presented at the American Thoracic Society (ATS) International Conference in May 2025.

"The publication of these Phase 1 data marks an important milestone for the AP02 program and reinforces the scientific rationale behind Avalyn's inhaled approach to treating IPF," said Melissa Rhodes, PhD, Chief Operating Officer of Avalyn Pharma. "Our goal has always been to address what many consider the central challenge of antifibrotic therapy: delivering more drug to the lungs, where it is needed, while reducing exposure throughout the rest of the body and improving tolerability. The data published today demonstrate substantially higher predicted lung exposure alongside significantly lower systemic exposure than oral nintedanib, supporting AP02's potential to improve the therapeutic profile of this important medicine. We believe this lung-targeted approach may ultimately help patients derive greater benefits from treatment, with fewer side effects that can limit adherence to long-term therapy and impact quality of life."

Dr. Rhodes continued, "We are encouraged by the continued progress of our AURA Phase 2 trial and the strong interest we have seen from investigators and patients across participating sites. We look forward to Phase 2 clinical data from AURA further evaluating AP02's potential to deliver meaningful benefit for people living with IPF."

Highlights from the *Respiratory Research* Publication

Data were generated in two randomized Phase 1 clinical studies. The first study evaluated AP02 in single ascending doses up to 2.0 mg in healthy volunteers (n=32) and patients with IPF (n=6) and included a healthy volunteer cohort receiving the approved 150mg oral dose of nintedanib (n=4). The second study evaluated AP02 in single (n=36) and multiple (n=24) ascending doses up to 8.0 mg twice daily for seven days in healthy volunteers. Safety, tolerability, and nintedanib plasma pharmacokinetics were evaluated, and AP02 and oral nintedanib bronchoalveolar lavage pharmacokinetics were assessed to evaluate lung exposure.

Published results show:

- AP02 was generally well tolerated across both Phase 1 studies, with no serious adverse events reported. The most common treatment-related adverse events were headache, nausea and mild cough in the first study, and dizziness in the second; no treatment-related adverse events led to withdrawal from studies.
- In all of the cohorts receiving multiple ascending doses, AP02 resulted in 10- to 56-fold lower systemic exposure than the mean steady-state exposure associated with the approved 150 mg BID oral nintedanib dose. Nintedanib systemic exposure generally increased with increasing AP02 dose.
- Lung exposure was substantially higher with AP02 than with oral nintedanib. At a 4.0 mg dose, AP02 achieved approximately 26-fold higher predicted nintedanib peak concentration (C_{max}) and overall exposure ($AUC_{0\text{-}12}$) in epithelial lining fluid versus oral nintedanib dosed at 150mg.

Together, these findings demonstrate AP02's potential to achieve substantially higher lung exposure and markedly lower systemic exposure, supporting its potential to deliver both enhanced efficacy and reduced side effects compared to oral nintedanib.

Based on these data, Avalyn advanced AP02 into the AURA clinical trial. AURA is a Phase 2 randomized, double-blind, placebo-controlled trial evaluating two doses of AP02 administered twice daily in patients with IPF. The 12-week study is designed to enroll 160 patients to assess safety and efficacy; topline data are anticipated in late 2027.

The paper, titled, "Nebulized nintedanib (AP02) for idiopathic pulmonary fibrosis demonstrates favorable safety and lung lining fluid exposures: Results from two Phase 1 safety, tolerability, and pharmacokinetics studies," was published in *Respiratory Research* on

September 21, 2026, and can be found here.

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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