Avalyn Announces First Patient Dosed in AURA Phase 2 Clinical Trial Evaluating AP02, Inhaled Nintedanib, for the Treatment of Idiopathic Pulmonary Fibrosis

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AURA Phase 2 clinical trial designed to evaluate the safety and efficacy of AP02 compared to placebo in patients with idiopathic pulmonary fibrosis (IPF)

BOSTON, March 23, 2026 (GLOBE NEWSWIRE) -- Avalyn, a clinical-stage biopharmaceutical company pioneering inhaled therapies to transform the treatment paradigm of serious, rare respiratory diseases, today announced the initiation of the AURA Phase 2 clinical trial evaluating the safety and efficacy of AP02, inhaled nintedanib administered via nebulization, in patients with idiopathic pulmonary fibrosis (IPF).

AP02 is a novel formulation of nintedanib delivered using the PARI eFlow® nebulizer, which has been developed to optimize the distribution of the medication to the distal lung. Topline results from the Phase 1 single- and multiple-ascending dose clinical trials of AP02 in both healthy adult volunteers and patients with IPF demonstrated favorable safety and tolerability at all dose levels evaluated. Higher lung exposure following AP02 delivery relative to oral dosing was observed while maintaining lower systemic exposures, highlighting the targeted delivery of nintedanib to the lung.

“The initiation of our AURA Phase 2 clinical trial represents a significant step toward our goal of providing patients with pulmonary fibrosis with an urgently needed innovative treatment option that is well-tolerated and suitable for long-term use,” said Lyn Baranowski, Chief Executive Officer of Avalyn. “AURA builds on our robust Phase 1 program, where AP02 delivered via nebulization demonstrated preferential exposure in the lungs at substantially lower doses relative to oral administration, with a favorable safety profile including no cough or bronchospasm following repeat dosing. Importantly, there was no diarrhea reported, which is particularly notable given the profile of oral nintedanib. This indicates that inhaled delivery has the potential to achieve clinically meaningful lung exposure with signs supportive of a well-tolerated safety profile. We look forward to working closely with patients, investigators, and the broader pulmonary fibrosis community as we advance this important program.”

The randomized, double-blind, placebo-controlled AURA Phase 2 clinical trial will evaluate the safety and efficacy of AP02 in patients with IPF. The trial is expected to enroll 160 patients with IPF, who are not currently on treatment, and will evaluate two dose levels of AP02 compared to placebo. The primary endpoint is the change from baseline in forced vital capacity (FVC) at Week 12. Key secondary and exploratory endpoints include time to disease progression, lung fibrosis scores based on quantitative high-resolution computed tomography (HRCT), and quality of life measurements.

“Based on the encouraging Phase 1 findings for AP02, my colleagues and I are confident Avalyn’s AURA clinical trial will provide valuable insights into AP02’s potential ability to deliver meaningful clinical benefit for patients living with this devastating disease,” said 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 and a steering committee member for AP02. “For too long, many patients have struggled with the challenging side effects linked to standard-of-care oral medications and often discontinue treatment, despite the serious and progressive nature of the disease. By delivering therapy directly to the lungs, AP02 has the potential to offer antifibrotic benefits with improved tolerability.”

More information about the AURA Phase 2 clinical trial (NCT07194382) can be found by visiting ClinicalTrials.gov.

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 safety 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.

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