Avalyn Completes Target Enrollment in Phase 2b MIST Trial of AP01 (Inhaled Pirfenidone) for Patients with Progressive Pulmonary Fibrosis

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Company expects to report topline 12-month clinical results in the second half of 2027

BOSTON, June 17, 2026 (GLOBE NEWSWIRE) -- Avalyn Pharma Inc. (Nasdaq: AVLN) (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 it has completed target enrollment of 375 patients in the Phase 2b MIST clinical trial of AP01 (inhaled pirfenidone) in patients with progressive pulmonary fibrosis (PPF). Additional patients currently in screening remain eligible for randomization and may be enrolled in the trial over the next several weeks.

“PPF is a serious and progressively debilitating condition that can lead to a steady decline in lung function, increasing symptom burden, and reduced quality of life,” said Tim Whelan, MD, Professor of Medicine at the Medical University of South Carolina and investigator in the Phase 2b MIST trial. “Even with today's treatments, the prognosis remains poor, with median survival of just three to five years after diagnosis. We urgently need options that can meaningfully alter the course of this disease and improve outcomes for patients. Completing target enrollment in this trial is an exciting milestone as we assess the therapeutic potential of AP01.”

MIST is a global, randomized, double-blinded, placebo-controlled Phase 2b clinical trial evaluating the safety and efficacy of two doses of AP01 in patients with PPF. MIST was designed to enroll 375 patients with PPF, randomized 2:1:2 into three cohorts: AP01 100 mg twice-daily, AP01 50 mg twice-daily, and placebo. The primary endpoint is the change from baseline in lung function, as measured by forced vital capacity (FVC), at 52 weeks.

“We are energized to have completed target enrollment in MIST,” said Lyn Baranowski, Chief Executive Officer of Avalyn. “Strong enthusiasm from investigators and patients enabled us to reach this milestone ahead of schedule, underscoring the demand for new treatment options in PPF. Based on data from the ATLAS Phase 1b trial and our ongoing open-label extension study, we believe AP01’s tolerability profile may enable patients to remain on treatment longer. We expect MIST to help inform the full impact of AP01 on preserving lung function and improving quality of life for people living with PPF, and we look forward to reporting topline data in the second half of 2027.”

About AP01

AP01 is an optimized formulation of pirfenidone administered using the investigational eFlow® Nebulizer System (PARI Pharma GmbH). AP01 is currently in clinical development for the treatment of progressive pulmonary fibrosis. In the ATLAS Phase 1b study comparing 100 mg twice-daily and 50 mg once-daily doses of AP01, results showed low rates of side effects, including gastrointestinal toxicities and liver enzyme elevations, and suggested a trend toward stability in lung function at the higher dose. AP01 is currently being evaluated in the MIST Phase 2b trial in patients with PPF. For more information, please visit www.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 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.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995,

as amended. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, without limitation, implied and express statements about Avalyn’s beliefs and expectations regarding the possibility that additional patients may be enrolled in the Phase 2b MIST trial; the timing of topline 12-month clinical results in the Phase 2b MIST clinical trial of AP01 in the second half of 2027; the interpretation and significance of the Phase 2b MIST trial and Phase 1b ATLAS clinical data; and the therapeutic potential of its product candidates.

Any forward-looking statements in this press release are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: the risk that earlier results may not be indicative of future results; risks related to clinical trial site activation, delays in enrollment generally or enrollment rates that are lower than expected; delays related to assessment of clinical trial results; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to volatile market and economic conditions; risks related to our ability to protect and maintain our intellectual property position or relationships with third-parties; the initiation, timing, progress and results of our current and future research and development programs, preclinical studies and clinical trials; our ability to successfully complete our clinical trials; our ability to advance any product candidates that we may identify and successfully complete any clinical studies, including the manufacture of any such product candidates; the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates; and risks related to needs for additional financing. These and other risks and uncertainties are described in greater detail in the section entitled “Risk Factors” in Avalyn’s current and future filings with the Securities and Exchange Commission, including those described from time to time under the caption “Risk Factors.” In addition, any forward-looking statements represent Avalyn’s views only as of today and should not be relied upon as representing its views as of any subsequent date. Avalyn explicitly disclaims any obligation to update any forward-looking statements subject to any obligations under applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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