Avalyn Pharma Reports Results of Phase 1 Study of AP02 in Healthy Volunteers and Participants with Idiopathic Pulmonary Fibrosis

March 30, 2023 – SEATTLE -- Avalyn Pharma Inc., a clinical-stage biopharmaceutical company focused on development of targeted therapies for life-threatening pulmonary diseases, today reported top-line results from the company's Phase 1 trial for AP02 (inhaled nintedanib). AP02 was generally well tolerated, with no serious adverse events (SAEs) reported among the participants who were administered AP02.

"We were especially excited to see the tolerability results of AP02 in those participants with idiopathic pulmonary fibrosis (IPF), an underserved interstitial lung disease with survival rates between 3 and 5 years from diagnosis," explained Lyn Baranowski, Avalyn's CEO. "With a nebulized solution that is formulated to be easier to tolerate than the oral systemic therapies, we are hopeful that patients can stay on treatment longer, potentially improving outcomes."

The open-label Phase 1 trial enrolled 38 participants, 32 of whom were healthy volunteers and 6 of whom had IPF. Four healthy volunteers were administered oral nintedanib. Each of the 34 remaining participants were administered a single dose of AP02 (either 0.5 mg, 1 mg, or 2 mg) or placebo using an optimized eFlow Technology Nebulizer (PARI GmbH, Germany). Participants were monitored for safety, tolerability, and pharmacokinetics. The most common adverse events (AEs) observed in the study and deemed related to AP02 were cough and headache followed by nausea and dizziness. With the exception of one case of headache, which was moderate and resolved in an individual with IPF, all AEs were mild. Avalyn plans to present more detailed findings at a medical meeting later this year.

About AP02

AP02 (inhaled nintedanib), an investigational drug in development for pulmonary fibrosis, is the second candidate Avalyn has advanced through a Phase 1 clinical trial. The company's inhalation development expertise has been applied to AP02 to enable targeted delivery of nintedanib directly to the lungs at potentially much lower doses than would be effective in its oral form. With this novel formulation, AP02 may offer the reduction in fibrosis characteristic of nintedanib without the adverse events attributable to its systemic delivery. These include diarrhea, hyperbilirubinemia (increased serum bilirubin, which can lead to jaundice), and drug-induced liver injury.

About Avalyn Pharma

Avalyn is a biopharmaceutical company developing targeted therapeutics for the treatment of rare respiratory diseases including idiopathic pulmonary fibrosis (IPF) and other interstitial lung diseases (ILD). ILDs are characterized by scarring, decline in lung function, reduced exercise capacity and quality of life, and are associated with increased mortality. Currently approved therapeutic options slow ILD progression but are associated with significant toxicities, which restrict their use and dosing. Avalyn is developing a pipeline of inhaled therapeutics designed to reduce systemic exposure and deliver medication to the site of disease. AP01, Avalyn's lead candidate, is an inhaled formulation of pirfenidone

optimized for delivery via inhalation. In a recent clinical study of two doses assessed in 91 individuals with IPF, AP01 demonstrated the potential to improve both efficacy and safety over existing therapy. More information can be found at www.avalynpharma.com.

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