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About Avalyn

Avalyn is dedicated to improve the care and outcomes of people with severe respiratory diseases by developing novel inhaled therapeutics that address significant unmet clinical needs.

Our lead asset is inhaled pirfenidone (Aerodone™) for the treatment of idiopathic pulmonary fibrosis (IPF). As an orphan-designated product, Aerodone offers the potential to show superior efficacy and safety to Roche/Genentech's oral pirfenidone (Esbriet®), a product expected to garner over \$2Bn of peak sales despite a limited therapeutic margin.

The company is backed by leading life science investors F-Prime Capital, Edmond de Rothschild Investment Partners, Novo A/S, RiverVest Venture Partners and TPG Biotech. With offices in Seattle and San Diego, Avalyn's experienced IPF and inhaled product development team is rapidly advancing Aerodone to Phase 2 proof-of-concept for IPF and additional pipeline candidates for IPF and other severe respiratory diseases.

Therapeutic Focus

Although two products are available to treat IPF, a substantial unmet need remains for highly tolerable medicines enabling improved effect stand-alone and add-on combination therapy.

IPF is a fatal lung disease characterized by progressive scarring, reduced exercise capacity and death due to respiratory failure or co-morbidities. With a 2-5 year survival period, IPF has more deaths per year than breast cancer and only lung cancer has a worse prognosis. Recently, the first drugs were approved for IPF treatment; oral pirfenidone (Esbriet®) and oral nintedanib (Ofev®). While these medicines are an important first step to treat IPF, a substantial unmet need remains for highly tolerable medicines enabling improved efficacy and compliance as stand-alone and add-on combination therapies.

Aerodone™ (Pirfenidone Solution for Inhalation)

Pirfenidone is a low potency drug that requires a very large oral dose to deliver effective lung levels. Unfortunately, blood-level safety limits and poor compliance due to oral dose-related adverse effects reduce the oral product's benefit. To maximize pirfenidone's potential, Avalyn has reformulated pirfenidone for nebulization and inhaled aerosol lung delivery. By this approach, small inhaled doses delivered directly to the lung hold promise to maximize pirfenidone's effect while avoiding adverse effects associated with oral delivery. Our data indicates that as stand-alone therapy, inhalation may substantially-reduce or eliminate oral adverse effects and may increase pirfenidone's efficacy through a greater lung dose and improved compliance. Moreover, as a safe and well-tolerated therapy, Aerodone may enable pirfenidone's use in combination regimens (e.g., with Ofev®) without increasing total adverse events.