Pliant Therapeutics Receives FDA Orphan Drug Designation for Lead Program PLN-74809 in Idiopathic Pulmonary Fibrosis

SOUTH SAN FRANCISCO, CA — August 6, 2018 — Pliant Therapeutics, Inc., a biotechnology company focused on discovering, developing and commercializing treatments for fibrotic diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for the company's anti-fibrotic lead compound, PLN-74809, for the treatment of idiopathic pulmonary fibrosis (IPF).

The FDA's Orphan Drug Designation program is designed to incentivize and facilitate the development of drugs for rare diseases that affect fewer than 200,000 people in the U.S. The designation provides Pliant with various development and commercial incentives, including market exclusivity and tax relief for clinical research costs, in order to address this unmet need for patients suffering from IPF.

IPF is a chronic and progressive fibrotic disease in which lung tissue becomes thickened, stiff and scarred, leading to increased difficulty in breathing and decreased quality of life. As lung fibrosis progresses, it becomes increasingly difficult for the lungs to transfer oxygen into the bloodstream—ultimately preventing vital organs from receiving the oxygen necessary to function properly. IPF currently affects approximately 140,000 people in the U.S.

"Achieving this important regulatory milestone provides Pliant an early vote of confidence as we prepare our investigational new drug application and plan the first-in-human trials for PLN-74809. We are eager to initiate clinical development of this product candidate early next year as a potential treatment option for patients with IPF," said Éric Lefebvre, M.D., chief medical officer of Pliant Therapeutics.

Pliant's therapeutic approach focuses on fibrotic tissue-specific inhibition of integrins and the TGF-β pathway. The company's lead small molecule is a dual selective inhibitor of the αVβ1 and αVβ6 integrins.

In preclinical studies, PLN-74809 modulates these fibrotic tissue-specific integrins, which selectively block activation of TGF-β, preventing the growth of fibrotic tissue within the lung and liver. Pliant also expects to evaluate PLN-74809 in patients with primary sclerosing cholangitis (PSC).

Pliant's prolific drug discovery engine is generating compounds that may address fibrosis in a variety of organs and conditions, including the muscle (Duchenne and other muscular dystrophies), liver (PSC, NASH and cirrhosis), kidney (renal fibrosis), skin (scleroderma) and the gastrointestinal tract (stricturing Crohn's disease).

About Pliant Therapeutics

Pliant Therapeutics is a biotechnology company unraveling and targeting the key biological pathways driving fibrosis. By leveraging its powerful product discovery engine, Pliant's mission is to halt progression and reverse disease, and ultimately to restore organ function. Founded by a group of seasoned experts in fibrosis biology and medicinal chemistry, Pliant was launched in 2016 by Third Rock Ventures and is headquartered in South San Francisco, California. For more information, please visit www.pliantrx.com.

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