



## **Pliant Therapeutics Receives FDA Orphan Drug Designation for Lead Program PLN-74809 in Primary Sclerosing Cholangitis**

### *Dr. Bertus Eksteen Joins Scientific Advisory Board*

**SOUTH SAN FRANCISCO, CA — November 20, 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 primary sclerosing cholangitis (PSC). In addition, Bertus Eksteen, Ph.D., MBChB, FRCP, a leading clinical researcher in PSC, has joined Pliant's scientific advisory board.

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 PSC.

PSC is a rare, chronic and progressive liver disorder of unknown origin, which frequently occurs in the setting of inflammatory bowel disease. It is characterized by inflammation, and eventually fibrosis, or scarring, of the liver and its bile ducts. While PSC affects nearly 45,000 patients in the U.S., there are currently no approved therapies to treat the disease, with more than 50 percent of patients requiring liver transplantation within 10 to 15 years after diagnosis. PLN-74809 targets the fibrotic process in both the liver cells and bile ducts, potentially slowing down the progression of disease.

"Our excitement for lead product candidate PLN-74809 continues to build as we have now received orphan drug designation in both PSC and idiopathic pulmonary fibrosis (IPF). We expect to initiate our first clinical trial to support our lead indication of IPF before year-end, followed by studies in PSC to further investigate our approach of inhibiting integrins as a way to impact key drivers of fibrosis," 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- $\beta$  pathway. The company's lead small molecule is a dual selective inhibitor of the  $\alpha_v\beta_1$  and  $\alpha_v\beta_6$  integrins. In preclinical studies, PLN-74809 modulates these fibrotic tissue-specific integrins, which selectively block activation of TGF- $\beta$ , preventing the growth of fibrotic tissue within the lung and liver. PLN-74809 received FDA Orphan Drug Designation for idiopathic pulmonary fibrosis (IPF) earlier this year.

Dr. Bertus Eksteen is director of the Aspen Woods Clinic, the founder of the Calgary Primary Sclerosing Cholangitis (PSC) Clinic and a member of the Calgary Liver Unit and the Southern Alberta Liver Transplant Clinic. His main interests are autoimmune liver and gastrointestinal diseases such as PSC, auto-immune hepatitis and inflammatory bowel disease. Dr. Eksteen's research has defined many of the

crucial immune pathways that underpin these diseases in the search for new therapies. He is part of the International PSC study group (IPSCSG) and runs one of the biggest PSC clinics in the world. Closely linked to Dr. Eksteen's clinical practice is his clinical research and clinical trials to develop novel drugs in PSC.

**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 develop novel therapeutics that seek to halt progression of fibrotic diseases, ultimately preserving organ function. Founded by a group of seasoned experts in fibrosis biology, medicinal chemistry and translational medicine, Pliant expects to initiate clinical trials with its lead product candidate PLN-74809 in idiopathic pulmonary fibrosis in late 2018, with additional programs to advance into the clinic in 2019. For more information, please visit [www.pliantrx.com](http://www.pliantrx.com).

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