Pliant Therapeutics Presents Data from its Bexotegrast Program at the European Association for the Study of the Liver (EASL) International Liver Congress™

June 23, 2023

Presentations highlight preclinical and clinical advancements of bexotegrast program in primary sclerosing cholangitis

SOUTH SAN FRANCISCO, Calif., June 23, 2023 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), a clinical stage biotechnology company focused on discovering and developing novel therapeutics for the treatment of fibrosis, today announced that it presented Phase 2a clinical data and preclinical data of bexotegrast (PLN-74809) program this week as part of the European Association for the Study of the Liver (EASL) International Liver Congress™ 2023, held June 21- 24, 2023. Bexotegrast, is an oral, small molecule, dual-selective inhibitor of αvβ6 and αvβ1 integrins being developed for the treatment of idiopathic pulmonary fibrosis and primary sclerosing cholangitis (PSC).

“PSC is a rare chronic autoimmune disease with no effective therapy, representing a large unmet need for new treatments. Our presentations this week discuss the early non-clinical work that support our ongoing Phase 2a clinical program. We look forward to sharing interim data from this trial in the third quarter,” said Éric Lefebvre, M.D., Chief Medical Officer at Pliant Therapeutics.

INTEGRIS-PSC Phase 2a Study: Evaluating the Safety, Tolerability, and Pharmacokinetics of Bexotegrast (PLN-74809) in Participants with Primary Sclerosing Cholangitis

The study design and baseline demographics from the 85 participants randomized into the 40, 80 and 160 mg dose cohorts or placebo was presented from the ongoing INTEGRIS-PSC Phase 2a study. This study is evaluating the safety, tolerability, and pharmacokinetics of bexotegrast in PSC.

Twelve-week data from this study is expected in the third quarter of 2023. Following a positive independent Data Safety Monitoring Board (DSMB) safety review in the first quarter, enrollment commenced in a Phase 2a trial of bexotegrast at 320 mg dosed once daily for at least 24 weeks, and up to 48 weeks, in patients with PSC.

The following posters were selected for inclusion in EASL’s Session Poster Tours.

Dual alpha-v/beta-6 and alpha-v/beta-1 Integrin Inhibitor Bexotegrast Attenuates Profibrogenic Gene Expression of Myofibroblasts in Human Liver Explant Tissue with Biliary Fibrosis

The effects of bexotegrast on individual cell populations were evaluated in fibrotic PSC and primary biliary cholangitis (PBC) precision-cut liver slices. Treatment with bexotegrast resulted in clear reductions in profibrogenic gene expression across multiple pathologic cell populations with a similar degree of reduction in profibrogenic gene expression seen compared to a TGF-β receptor I kinase inhibitor. These results suggest an important role for the integrin-TGF-β activation pathway in fibrotic biliary diseases and are consistent with the anti-fibrotic mechanism of action of bexotegrast.

Non-invasive Imaging Method Demonstrates Anti-fibrotic Efficacy of a Dual Integrin alpha-v/beta-6 and alpha-v/beta-1 Inhibitor in a Rat Model of Biliary Fibrosis

PET and molecular MRI were used to non-invasively monitor the effects of αvβ6 and αvβ1 antagonism in a rat model of biliary fibrosis. Results showed changes in target expression and fibrosis in response to bile duct injury and treatment with a dual integrin αvβ6/αvβ1 antagonist that were confirmed by classic histological analysis. These data support the antifibrotic effect of dual αvβ6/αvβ1 integrin inhibition in biliary fibrosis.

Posters presented at the 2023 EASL Conference are available under the Publications section on Pliant’s website at https://pliantrx.com/publications.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those regarding future development of bexotegrast and timing of future data from our clinical programs. Because such statements deal with future events and are based on our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Pliant Therapeutics could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including those related to the development and commercialization of our product candidates, including any delays in our ongoing or planned preclinical or clinical trials, the impact of the COVID-19 pandemic on our business, operations, clinical supply and plans, our reliance on third parties for critical aspects of our development operations, the risks inherent in the drug development process, the risks regarding the accuracy of our estimates of expenses and timing of development, our capital requirements and the need for additional financing, and our ability to obtain and maintain intellectual property protection for our product candidates. These and additional risks are discussed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2022, as updated by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, which are available on the SEC's website at www.sec.gov. Unless otherwise noted, Pliant is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical stage biopharmaceutical company focused on discovering and developing novel therapies for the treatment of fibrosis. Pliant's lead product candidate, bexotegrast (PLN-74809), is an oral small molecule dual selective inhibitor of αvß6 and αvß1 integrins that is in development in the lead indications for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. Bexotegrast has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in IPF and PSC and Orphan Drug Designation from the European Medicines Agency in IPF and PSC. Pliant is currently conducting a Phase 2a trial of bexotegrast in the PSC and is planning a Phase 2b trial in IPF. Pliant has also developed PLN-1474, a small molecule, selective inhibitor of αvß1 for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis. Pliant is initiating a Phase 1 study for its third clinical program, PLN-101095, a small molecule, dual-selective inhibitor of αvß8 and αvß1 integrins, that is being developed for the treatment of solid tumors. In addition to clinical stage programs, Pliant currently has a preclinical program targeting muscular dystrophies. For additional information, please visit: www.PliantRx.com. Follow us on social media: Twitter, LinkedIn, Facebook and YouTube.

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