Pliant Therapeutics Announces Positive DSMB Safety Review and Initiation of Enrollment of Phase 2a Trial of Bexotegrast (PLN-74809) at 320 mg Dose in Primary Sclerosing Cholangitis

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Recent independent Data Safety Monitoring Board (DSMB) review recommended the INTEGRIS-PSC Phase 2a trial continue without modification and proceed to evaluate 320 mg dose

SOUTH SAN FRANCISCO, Calif., March 13, 2023 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), a clinical-stage biopharmaceutical company focused on discovering and developing novel therapies for the treatment of fibrosis, today announced that, following a positive independent Data Safety Monitoring Board (DSMB) safety review, enrollment has 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 primary sclerosing cholangitis (PSC). Bexotegrast, is an oral, small molecule, dual-selective inhibitor of αvβ6 and αvβ1 integrins being developed for the treatment of PSC and idiopathic pulmonary fibrosis (IPF). Bexotegrast has been administered to over 600 study participants to date, including healthy volunteers and patients, with no drug-related severe or serious adverse events reported to date.

“We are pleased to see the continued favorable safety and tolerability profile exhibited by bexotegrast, allowing us to evaluate a higher dose at a longer treatment duration in patients with PSC,” said Éric Lefebvre M.D. Chief Medical Officer of Pliant Therapeutics. “We recognize the high unmet medical need in PSC, as there are no FDA approved therapies for the indication and look forward to sharing 12-week interim data from our Phase 2a trial in the third quarter.”

DSMB Recommends Continuation of INTEGRIS-PSC Phase 2a Trial Without Modifications
Following the completion of enrollment of the 40, 80 and 160 mg dose groups in the INTEGRIS-PSC Phase 2a trial, a meeting of the bexotegrast independent DSMB was held earlier this month to review safety data from all patients enrolled in the trial to date. The DSMB recommended that the INTEGRIS-PSC trial continue without modification, enabling the initiation of enrollment of the 320 mg dose group.

About the INTEGRIS-PSC Phase 2a Trial
This Phase 2a trial is a randomized, double-blind, dose-ranging, placebo-controlled study evaluating bexotegrast at doses ranging from 40 to 320 mg, administered daily in approximately 112 patients with PSC. The initiation of the 320 mg dose group coincides with the FDA authorization to evaluate long-term dosing of bexotegrast in PSC patients, who will therefore be treated for at least 24 weeks and up to 48 weeks. The primary endpoint is the evaluation of the safety and tolerability of bexotegrast, and the secondary endpoint is the assessment of pharmacokinetics. The trial is also evaluating exploratory pharmacodynamic endpoints including fibrosis biomarkers such as PRO-C3 and enhanced liver fibrosis (ELF) score, changes in alkaline phosphatase (ALP), and liver imaging. Interim 12-week data from the 40, 80, and 160 mg dose groups of this trial [NCT04480840] is expected in the third quarter of 2023.

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 in PSC and anticipated timing of clinical data. 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 ongoing 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 which is 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 Phase 2a trials of bexotegrast in the lead indications of IPF and PSC. 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 about Pliant Therapeutics, visit www.PliantRx.com and follow us on Twitter, LinkedIn, Facebook and YouTube.

Investor and Media Contact:

Christopher Keenan
Vice President, Investor Relations and Corporate Communications
Pliant Therapeutics, Inc.
ir@pliantrx.com