Pliant Therapeutics Announces Positive DSMB Safety Review and Commencement of Enrollment of Phase 2a Trial of PLN-74809 at 320 mg Dose in Idiopathic Pulmonary Fibrosis

February 24, 2022

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

Trial initiation follows the FDA authorization of evaluation of long-term dosing of PLN-74809 at doses up to 320 mg in IPF patients

SOUTH SAN FRANCISCO, Calif., Feb. 24, 2022 (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 PLN-74809 at 320 mg dosed once daily for at least six months in patients with idiopathic pulmonary fibrosis (IPF). PLN-74809, is an oral, small molecule, dual-selective inhibitor of αvβ6 and αvβ1 being developed for the treatment of IPF and primary sclerosing cholangitis (PSC). PLN-74809 has been administered to over 450 study participants, including healthy volunteers and patients, with no drug-related serious adverse events or drug-related severe adverse advents reported to date.

“We are pleased that the favorable safety and tolerability profile seen with PLN-74809 to date supports the advancement of our Phase 2a program to evaluate a higher dose at a longer treatment duration,” said Bernard Coulie M.D. Ph.D., President and CEO of Pliant. “It is noteworthy that our sub-chronic and chronic GLP toxicology studies have revealed no on-target or off-target safety concerns across all doses tested. Moreover, throughout Phase 1 and Phase 2 trials, PLN-74809 has been well tolerated with no drug-related safety concerns identified to date.”

About the Phase 2a Trial

This Phase 2a trial is a randomized, double-blind, placebo-controlled study evaluating PLN-74809 at 320 mg administered daily over at least six months, and up to 48 weeks, in approximately 28 patients with IPF. The primary endpoint is the evaluation of PLN-74809 safety and tolerability and the secondary endpoint is the assessment of pharmacokinetics. Exploratory endpoints will measure change in forced vital capacity (FVC), HRCT-based Quantitative Lung Fibrosis score (QLF), and selected biomarkers over 6 months of treatment.

This trial is leveraging the same sites and protocol as the INTEGRIS-IPF Phase 2a trial, which recently competed enrollment at doses of 40 mg, 80 mg and 160 mg. Topline data from the INTEGRIS-IPF trial is expected to be released in mid-2022.

DSMB Recommends Continuation of INTEGRIS-IPF Phase 2a Trial Without Modifications

Following the full enrollment of the INTEGRIS-IPF Phase 2a trial, a February 17, 2022 meeting of the PLN-74809 independent DSMB, recommended that the INTEGRIS-IPF trial continue without modification. This review included all patients enrolled in all dose cohorts of the trial and allowed commencement of enrollment of the Phase 2a 320 mg trial. To date, no safety concerns have been identified by the DSMB.

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, PLN-74809, is an oral small molecule dual selective inhibitor of $\alpha_v\beta_6$ and $\alpha_v\beta_1$ integrins that is in development in the lead indications for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. PLN-74809 has received Orphan Drug Designation from the U.S. Food and Drug Administration for both IPF and PSC. Pliant is currently conducting Phase 2a trials of PLN-74809 in the lead indications of IPF and PSC. Pliant has also developed PLN-1474, a small molecule selective inhibitor of $\alpha_v\beta_1$ for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis, which Pliant has transferred to Novartis pursuant to our development partnership. In addition to clinical stage programs, Pliant currently has two preclinical programs targeting oncology and muscular dystrophies. For additional information about Pliant Therapeutics, visit www.pliantrx.com and follow us on Twitter, LinkedIn, Facebook and YouTube.

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 the anticipated progress of our clinical trials and timing of enrollment and data disclosures, the efficacy and safety profile of our product candidates; our expectations regarding our interactions with regulators, including the FDA, and anticipated progress of our pre-clinical programs, including timing expectations for regulatory filings. 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 filed for the year ended December 31, 2020 with the SEC on March 16, 2021, as updated by our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021,

filed with the SEC on November 9, 2021, 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.

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