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

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Recent independent Data Safety Monitoring Board (DSMB) review recommended the INTEGRIS-IPF Phase 2a trial continue without modification

Interim 12-week data expected in early 2023

SOUTH SAN FRANCISCO, Calif., Sept. 01, 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 a positive safety review of the ongoing INTEGRIS-IPF Phase 2a trial of PLN-74809 at 320 mg once-daily dose in patients with idiopathic pulmonary fibrosis (IPF) from a regularly scheduled meeting of its independent Data Safety Monitoring Board (DSMB). The DSMB recommended the INTEGRIS-IPF trial continue without modification.

The DSMB review was held after completion of enrollment of the 320 mg cohort of the INTEGRIS-IPF trial and examined the safety data from all patients enrolled, approximately half of whom had completed at least 12 weeks of treatment. Interim 12-week data from the 320 mg dose cohort from this Phase 2a, randomized, double-blind, placebo-controlled trial are expected in early 2023.

“This positive safety review marks an important milestone in the development of PLN-74809. Given 320 mg is the highest dose planned to be tested in the PLN-74809 program, the positive DSMB review significantly builds on the favorable safety profile seen to date,” said Éric Lefebvre, M.D., Chief Medical Offer at Pliant. “In addition to the accumulating patient safety database, we have completed all necessary sub-chronic and chronic GLP toxicology studies of PLN-74809, with no on-target or off-target safety concerns noted to date across all doses tested.”

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.

About the INTEGRIS-IPF Trial

INTEGRIS-IPF is a randomized, double-blind, placebo-controlled study evaluating PLN-74809 at once-daily doses across multiple doses. The current patient cohort is testing 320 mg of PLN-74809 administered daily over at least six months, and up to 48 weeks, in approximately 28 patients with IPF (NCT04396756). The primary endpoint is the evaluation of PLN-74809 safety and tolerability. 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. In July, Pliant announced positive topline data from the INTEGRIS-IPF trial of 40 mg, 80 mg and 160 mg 12-week dose cohorts.

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 αvß6 and αvß1 integrins that is currently in development for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. PLN-74809 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 PSC. Pliant is currently conducting Phase 2a trials of PLN-74809 in IPF and PSC. Pliant has also developed PLN-1474, a Phase 2-ready small molecule selective inhibitor of αvß1 for the treatment of nonalcoholic steatohepatitis, or NASH, with liver fibrosis, which Pliant has partnered with Novartis. 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 derisking of our ongoing and potential future clinical programs; anticipated progress of our clinical trials and timing of regulatory, enrollment and data disclosures; and the efficacy and safety profile of our product candidates. 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, 2021 with the SEC on March 1, 2022, as updated by our Quarterly Report on Form

10-Q filed for the quarter ended June 30, 2022 with the SEC on August 8, 2022, each 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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