# Pliant Therapeutics Highlights Recent Developments for Lead Program PLN-74809 and Expected 2022 Milestones

01-11-2022 at 8:03 AM EST

*Enrollment complete in INTEGRIS-IPF Phase 2a clinical trial with top-line data expected mid-2022*

*FDA has authorized evaluation of long-term treatment with PLN-74809 at doses up to 320 mg in IPF*

*Company will present updates at the 40th Annual J.P. Morgan Healthcare Conference*

SOUTH SAN FRANCISCO, Calif., Jan. 11, 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 provided an update on its PLN-74809 program. The Company will present these updates at the 40th Annual J.P. Morgan Healthcare Conference on Wednesday, January 12, 2022, at 9:45 a.m. ET/ 6:45 a.m. PT.

“The completion of enrollment of INTEGRIS-IPF and the FDA authorization of long-term dosing of PLN-74809 in idiopathic pulmonary fibrosis reflect our team’s unwavering commitment to executing against our clinical development plan for PLN-74809,” said Bernard Coulie M.D. Ph.D., President and CEO of Pliant. “Furthermore, this illustrates another step in the ongoing de-risking of PLN-74809 in IPF and positions the program for later stage development.”

**INTEGRIS-IPF Phase 2a Clinical Trial Enrollment Complete**

In December, the Company completed enrollment of its INTEGRIS-IPF Phase 2a clinical trial in patients with idiopathic pulmonary fibrosis (IPF). INTEGRIS-IPF is a 12-week randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability, and pharmacokinetics of PLN-74809 at doses of 40, 80 or 160 mg in 84 patients with IPF. Exploratory endpoints include quantitative lung fibrosis, or QLF, imaging, as well as pulmonary function tests, including forced vital capacity, or FVC. The Company maintains its previous guidance of topline data expected in mid-2022.

**FDA Authorized Evaluation of Long-term Treatment with PLN-74809 at Higher Doses in IPF**

The U.S. Food and Drug Administration (FDA) has authorized evaluation of long-term dosing of PLN-74809 up to 320 mg in patients with IPF. PLN-74809 has been administered to over 450 subjects, including healthy volunteers and patients, with no serious adverse events reported to date. This approval enables the evaluation of PLN-74809 in larger, long-term pivotal trials in IPF.

**2022 Expected Milestones**

- Data from a Phase 1b proof of biological mechanism study of PLN-74809 at doses of 80, 160 or 320 mg utilizing bronchoalveolar lavage fluid, or BAL, is expected in the first quarter 2022
- Initiation of a 6-month Phase 2a trial of PLN-74809 at 320 mg in IPF is expected in the first half of 2022
- INTEGRIS-IPF Phase 2a topline data expected mid-2022
- INTEGRIS-PSC Phase 2a trial enrollment expected to complete mid-2022 with topline data expected late 2022 / early 2023
- Oncology and muscular dystrophy programs on track with Investigational New Drug (IND) application submissions expected by the end of 2022

These updates are included in the most recent Pliant Corporate Presentation which can be accessed from the Events & Presentations section of Pliant’s website.

**Presentation at the 40th Annual J.P. Morgan Healthcare Conference**

Pliant will webcast its presentation at the 40th Annual J.P. Morgan Healthcare Conference on Wednesday, January 12, 2022, at 9:45 a.m. ET/ 6:45 a.m. PT. The live webcast of the presentation and will be accessible through the Events & Presentations section of Pliant’s website. An archived replay of the webcast will be available for 30 days following the presentation.

**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 recruiting 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. 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 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, 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.

**Investor and Media Contact:**
Christopher Keenan
Vice President, Investor Relations and Corporate Communications
Pliant Therapeutics, Inc.
IR@pliantrx.com