Pliant Therapeutics Announces Positive Safety and Efficacy Data from Phase 2a INTEGRIS-IPF Clinical Trial of PLN-74809 in Patients with Idiopathic Pulmonary Fibrosis

July 10, 2022

PLN-74809 demonstrated a dose-dependent treatment effect on FVC and QLF versus placebo over 12 weeks of treatment

PLN-74809 treatment effect was observed on top of standard of care therapy and as monotherapy

PLN-74809 was well tolerated over 12 weeks of treatment with no drug related SAEs and no treatment discontinuations due to adverse events

Company to host webcast and conference call tomorrow, Monday July 11 at 8:00 a.m. ET

SOUTH SAN FRANCISCO, Calif., July 10, 2022 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), today announced positive data from INTEGRIS-IPF, a multinational, randomized, double-blind, placebo-controlled Phase 2a clinical trial of PLN-74809 in patients with idiopathic pulmonary fibrosis (IPF). The trial met its primary and secondary endpoints demonstrating that PLN-74809 was well tolerated over a 12-week treatment period and displayed a favorable pharmacokinetic profile. The trial's exploratory efficacy endpoints assessing changes in forced vital capacity (FVC) and Quantitative Lung Fibrosis (QLF) imaging, demonstrated a dose-dependent treatment effect on FVC and QLF versus placebo over 12 weeks in PLN-74809 treated patients.

INTEGRIS-IPF is a randomized, double-blind, placebo-controlled Phase 2a multinational study evaluating PLN-74809 at once-daily doses of 40 mg, 80 mg, 160 mg or placebo for 12 weeks in 90 patients with IPF. 67 patients were enrolled in the active arms and 23 patients were enrolled in the placebo arm. Approximately 80% of enrolled patients were on standard of care and were equally distributed between nintedanib and pirfenidone.

PLN-74809 Was Well Tolerated Across All Doses

The primary endpoint of the INTEGRIS-IPF trial is the evaluation of the safety and tolerability of PLN-74809. The secondary endpoint is an assessment of its pharmacokinetics.

PLN-74809 was well tolerated at all three doses tested. Of the 67 patients treated with PLN-74809, 65 (97%) completed 12 weeks of treatment with no discontinuations due to adverse events. No deaths or drug-related serious adverse events (SAE) were reported. Most treatment emergent adverse events (TEAEs) were mild or moderate in severity.

PLN-74809 exhibited dose-proportional increases in plasma concentrations, consistent with prior studies.

PLN-74809 Demonstrated Dose-Dependent Treatment Effects on FVC and QLF Versus Placebo over 12 Weeks

The exploratory endpoints of the INTEGRIS-IPF trial measured changes in forced vital capacity (FVC), high-resolution CT (HRCT)-based QLF, and serum biomarkers over 12 weeks of treatment.

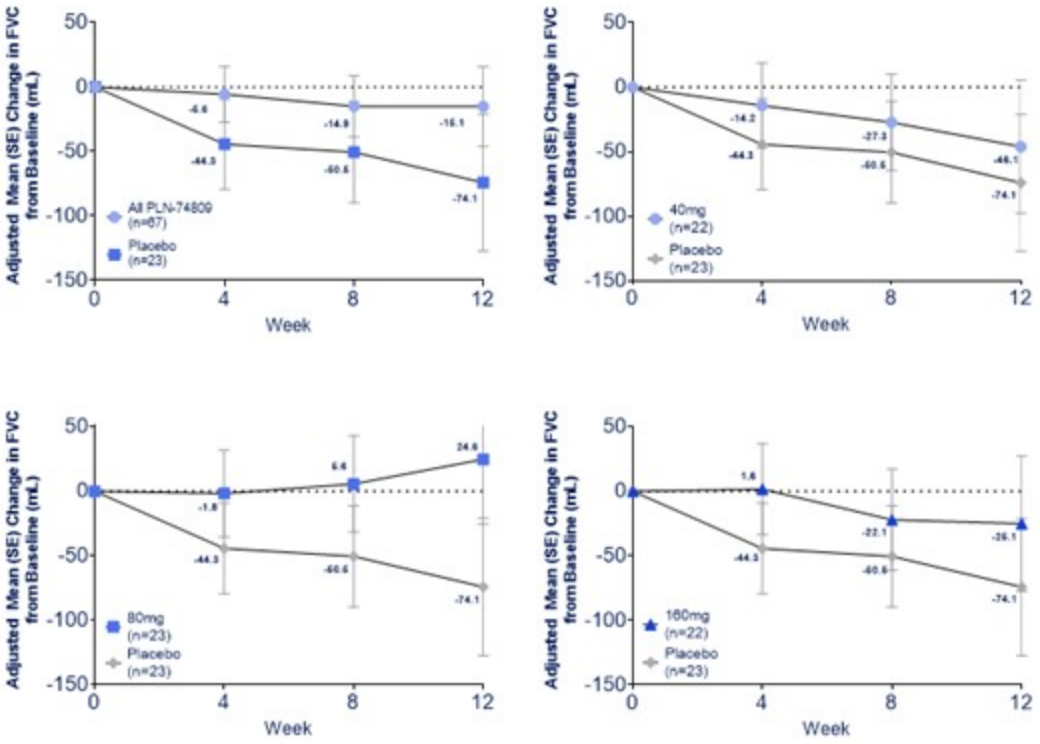

Figure 1. Change in FVC Over 12 Weeks in INTEGRIS-IPF; Mixed Model Repeat Measures Analysis – Intent to Treat Population

A treatment effect was observed in all PLN-74809 dose groups, with and without standard of care therapy. A pooled analysis of PLN-74809 treated patients showed an 80% reduction in FVC decline at 12 weeks versus placebo (-15.1 mL for PLN-74809 pooled groups versus -74.1 mL for placebo). The 40 mg and 160 mg dose groups demonstrated 38% (-46.1 mL) and 66% (-25.1 mL) reductions in FVC decline relative to placebo, respectively. Importantly, in the 80 mg treatment group, a +24.6 mL increase in FVC was observed relative to baseline.

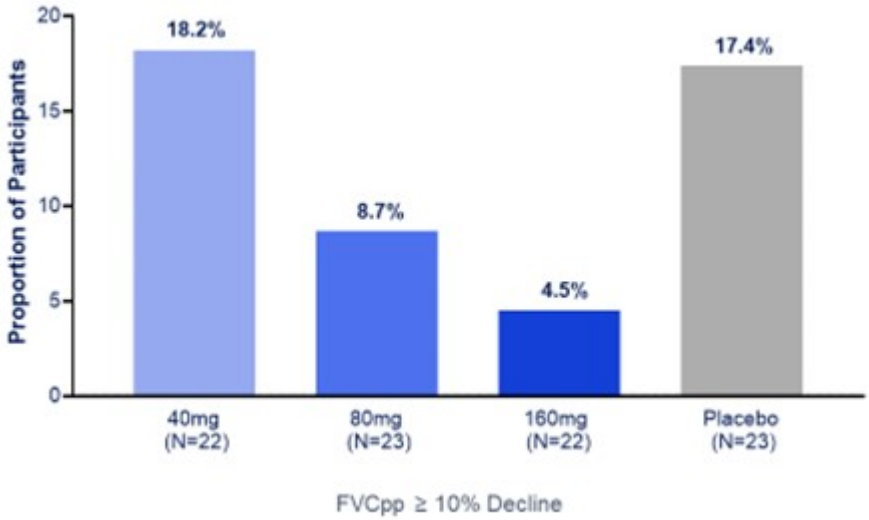

Figure 2. Proportion of Participants with FVCpp Decline ≥10% - Intent to Treat Population

A dose-dependent reduction in the proportion of patients with percent predicted FVC(FVCpp) decline of ≥10% was observed across treatment groups: 18.2%, 8.7% and 4.5% of patients experienced a ≥10% decline in FVCpp in the 40 mg, 80 mg and 160 mg treatment groups, respectively, versus 17.4% in the placebo group. A decline of ≥10% in FVCpp at 12 weeks is associated with an increased risk of death in IPF patients over a two-year period.[1]

An increase in QLF score is associated with an increase in pulmonary fibrosis. The mean percentage change in QLF at 12 weeks was 3.15%, 0.70%

and 0.00% in the 40 mg, 80 mg and 160 mg treatment groups, respectively, versus 1.15% in the placebo group. These findings suggest a dose-dependent antifibrotic effect of PLN-74809, consistent with its mechanism of action and preclinical findings.

“Data from the INTEGRIS-IPF trial exceeded our expectations exhibiting a favorable safety and tolerability profile and a treatment effect on FVC, the current registrational endpoint in IPF. Importantly, the treatment effect was also observed on top of standard of care therapy,” said Éric Lefebvre, M.D., Chief Medical Offer at Pliant Therapeutics. “Additionally, the dose-dependent reduction observed in the proportion of patients experiencing a decline in percent predicted FVC of ≥10% underscores the potential of this novel investigational therapy to advance the treatment of IPF.”

“I am very encouraged by the Phase 2 results from INTEGRIS-IPF. IPF studies are challenging, as large samples sizes are usually required to detect a treatment effect,” said Lisa H. Lancaster, M.D., Professor of Medicine, Vanderbilt School of Medicine and INTEGRIS-IPF Principal Investigator. “The results from INTEGRIS-IPF are impressive, with PLN-74809 demonstrating a favorable safety profile and treatment effect both on and off standard of care therapy. The IPF patient community is in desperate need of new drugs given the limited treatment options currently available.”

INTEGRIS-IPF Next Steps

Pliant has recently completed enrollment in the 320 mg cohort of the INTEGRIS-IPF Phase 2a trial. The 12 week interim data from the 320 mg cohort is anticipated in early 2023. Today’s data is intended to be shared with regulatory authorities in the near term to discuss the late-stage development of PLN-74809.

We would like to thank our INTEGRIS-IPF investigators and their study teams as well as the members of the Pliant team for their dedication in support of the successful execution of this trial. Special thanks to the INTEGRIS-IPF clinical trial participants, their families and support networks for helping us advance this promising program.

INTEGRIS-IPF Multinational Phase 2 Trial of PLN-74809 (NCT04396756)

INTEGRIS-IPF is a Phase 2a, randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability, and pharmacokinetics of PLN-74809 administered over 12 weeks in patients with IPF. Patients were enrolled in doses of 40 mg, 80 mg, 160 mg or 320 mg, with a 3:1 randomization ratio (active:placebo) and stratification based on use of standard of care therapy. The primary endpoint is the evaluation of PLN-74809 safety and tolerability and the secondary endpoint is the assessment of pharmacokinetics across a dose range. Exploratory endpoints will measure change in Forced Vital Capacity (FVC), HRCT-based Quantitative Lung Fibrosis (QLF) score and selected biomarkers**.**

Background on Idiopathic Pulmonary Fibrosis

IPF is a chronic, progressive, fibrosing lung disease of unknown cause with few treatment options and a poor prognosis. Patients experience debilitating symptoms, including shortness of breath and difficulty performing daily activities, such as walking and talking. Currently, there is no pharmacological cure for IPF with neither of the approved two therapies demonstrating an ability to stop the progression of IPF. Therefore, there is a high unmet need for new therapeutic options to address the symptoms and modify the disease progression of this grievous illness.

Conference Call and Webcast

The Company will host a conference call and webcast with a slide presentation tomorrow, Monday, July 11 at 8:00 a.m. ET to discuss this update. Interested parties may access the conference call live via webcast on Pliant’s website at https://edge.media-server.com/mmc/p/5rrtxipc or may participate via telephone by registering using this online form. Upon registration, all telephone participants will receive the dial-in number along with a unique PIN number that can be used to access the call. A replay of the conference call webcast will be available in the Events & Presentations section of the Investors & Media page of the Pliant website for 30 days following completion of the event.

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 (IPF), and primary sclerosing cholangitis (PSC). PLN-74809 has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in IPF and Orphan Drug Designation from the FDA and European Medicines Agency in 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 (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 safety, tolerability, pharmacodynamics and therapeutic potential of PLN-74809; our plans for the future development of PLN-74809; PLN-74809’s potential to become a treatment for IPF; the anticipated timing of the interim analysis of the 320 mg cohort of the INTEGRIS-IPF Phase 2a trial; discussions with regulatory authorities; and the efficacy and safety profile and potential 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 March 31, 2022 with the SEC on May 9, 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.

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

[1] Paterniti MO, et al. *Ann Am Thorac Soc*. 2017 Sep;14(9):1395-1402.

Photos accompanying this announcement are available at:

https://www.globenewswire.com/NewsRoom/AttachmentNg/44b22797-8e66-4b4d-b277-df3cd869d0cf

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