Pliant Therapeutics Receives FDA Fast Track Designation for PLN-74809 for the Treatment of Idiopathic Pulmonary Fibrosis

May 3, 2022

SOUTH SAN FRANCISCO, Calif., May 03, 2022 (GLOBE NEWSWIRE) -- Pliant Therapeutics (NASDAQ: PLRX) announced today that PLN-74809, its oral, dual-selective $\alpha_v\beta_6/\alpha_v\beta_1$ integrin inhibitor, has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the potential treatment of idiopathic pulmonary fibrosis (IPF). PLN-74809, the Company's lead drug candidate, is currently being tested as part of the INTEGRIS-IPF Phase 2a clinical trial (NCT04396756). Pliant anticipates topline data from this randomized, double-blind, placebo-controlled trial in patients with IPF, in mid-2022.

"The Fast Track designation marks an important step in PLN-74809's clinical development in IPF. It underscores the urgent need for new therapeutic options to address this devastating disease," said Éric Lefebvre, M.D., Chief Medical Officer at Pliant Therapeutics. "We will continue to work closely with the FDA to support the future development of PLN-74809 beginning with data from the Phase 2a INTEGRIS-IPF trial, which is on track for readout in mid-2022."

FDA's Fast Track designation is intended to facilitate and expedite the development and review of new drugs to treat serious or life-threatening conditions. To qualify, available clinical and non-clinical data need to demonstrate the potential to address unmet medical need. The benefits of Fast Track designation include opportunities for frequent meetings with the FDA to discuss trial design, development plans and data needed to support drug approval, as well as the ability to submit a New Drug Application (NDA) on a rolling basis, and eligibility for priority review, if relevant criteria are met.

Background on Idiopathic Pulmonary Fibrosis

IPF is a deadly, age-related lung disease of unknown cause with few treatment options. IPF affects approximately 140,000 people in the United States with 30,000 to 40,000 new cases diagnosed each year. Approximately 60 to 80 percent of patients with IPF die within five years of diagnosis. Patients experience debilitating symptoms, including shortness of breath and difficulty performing routine functions, 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.

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, the anticipated benefits of receiving Fast Track designation and timing expectations for topline data from the INTEGRIS-IPF Phase 2a clinical trial. 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 subsequent filings with the SEC, 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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