



Pliant Therapeutics Announces FDA Clearance of Investigational New Drug Application for PLN-101095, A Novel Integrin Inhibitor for the Treatment of Solid Tumors

February 2, 2023

Phase 1 clinical study initiation expected in the second quarter of 2023

SOUTH SAN FRANCISCO, Calif., Feb. 02, 2023 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), a clinical stage biotechnology company focused on discovering and developing novel therapeutics for the treatment of fibrosis, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for PLN-101095, an oral, small molecule, dual selective inhibitor of integrins $\alpha v\beta 8$ and $\alpha v\beta 1$. A Phase 1 first-in-human study evaluating PLN-101095 in patients with solid tumors that are resistant to immune checkpoint inhibitors (ICIs) is expected to initiate in the second quarter of 2023.

"PLN-101095 represents our third program to advance into clinical development, this time targeting significant unmet need of cancer patients with a suboptimal response to immune checkpoint inhibitors," said Éric Lefebvre, M.D., Chief Medical Officer at Pliant Therapeutics. "Based on the compelling preclinical activity seen in tumor models with PLN-101095 in combination with immune checkpoint inhibitors, we look forward to evaluating this combination in patients with solid tumors."

PLN-101095 is an oral, small molecule, dual selective inhibitor of $\alpha v\beta 8$ and $\alpha v\beta 1$ integrins in development for the treatment of solid tumors resistant to immune checkpoint inhibitors. TGF- β plays an important anti-inflammatory role in the tumor micro-environment, promoting fibrosis, preventing T-cell infiltration and inhibiting the release of pro-inflammatory cytokines. Increased TGF- β signaling is recognized as a potential cause of resistance to checkpoint inhibitors, such as anti-PD-(L)1 therapies, seen in many tumors. PLN-101095 targets $\alpha v\beta 8$ and $\alpha v\beta 1$ integrins expressed in the tumor microenvironment, regulating TGF- β activation with the goal of re-sensitizing tumors to PD(L)-1 inhibitors.

Phase 1 Study of PLN-101095

The Phase 1 study will assess the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of PLN-101095. Additional details will be disclosed upon trial initiation.

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, bexotegast (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. Bexotegast 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 IPF and PSC. Pliant is currently conducting Phase 2a trials of bexotegast 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. Pliant is initiating a Phase 1 study for its third clinical program, PLN-101095, a small molecule, dual-selective inhibitor of $\alpha v\beta 8$ and $\alpha v\beta 1$ integrins, that is being developed for the treatment of solid tumors. In addition to clinical stage programs, Pliant currently has a preclinical program targeting 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 development of PLN-101095, and our other 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 which we filed with the SEC on March 1, 2022, as updated by our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, which we filed with the SEC on November 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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