Pliant Therapeutics Announces Successful Completion of PLN-1474 Phase 1 Study and Development Transition to Global Pharmaceutical Partner

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SOUTH SAN FRANCISCO, Calif., March 16, 2021 (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 the successful completion of a Phase 1 trial of PLN-1474, an oral, small-molecule selective inhibitor of the integrin $\alpha_v\beta_1$ in development for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis. Following the successful completion of this study, PLN-1474 has been transferred to Novartis.

The Phase 1 trial of PLN-1474 was a safety, tolerability, and pharmacokinetics dose-escalating first-in-human study that enrolled 84 healthy volunteers. PLN-1474 was rapidly absorbed and well tolerated with no dose- or treatment-limiting toxicities or severe/serious adverse events observed. In preclinical studies, PLN-1474 was observed to selectively block the $\alpha_v\beta_1$ integrin-mediated activation of TGF-β, reducing liver fibrosis in animal models.

“Our team’s successful Phase 1 development of PLN-1474 places this novel therapeutic in a strong position as we transfer it to Novartis,” said Éric Lefebvre, M.D., Chief Medical Officer of Pliant Therapeutics. “With these first-in-human study results in healthy volunteers showing that PLN-1474 was readily absorbed and generally well tolerated, we look forward to the program’s next steps under Novartis.”

Pursuant to the October 2019 Collaboration and License Agreement between the two companies, following Pliant’s completion of Phase 1, the PLN-1474 Investigational New Drug (IND) Application has been transferred to Novartis who will be responsible for all future development, manufacturing, and commercialization activities.

About the Collaboration and License Agreement

In October 2019, Pliant and Novartis entered into a Collaboration and License Agreement for the development and commercialization of PLN-1474 and up to three integrin research targets. Pliant received a $50 million upfront fee for a worldwide exclusive license on PLN-1474 as well as $30 million in equity investment commitments from Novartis. Pliant is expected to receive reimbursement for research and development activities under the collaboration. Pliant is eligible to receive milestone payments of up to $416 million on achievement of development, regulatory and commercialization milestones, as well as tiered royalties ranging from mid-single digit to low double-digit percentages.

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 our product candidates, including their development and therapeutic potential and our collaboration with Novartis for PLN-1474 and the potential and intended benefits of such collaboration. 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 our dependence on Novartis for future development of PLN-1474, 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, 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 prospectus dated June 3, 2020 as filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act 1933, as amended, and the Quarterly Report for the third quarter of 2020 filed with the SEC on Form 10-Q on November 10, 2020 which are available on the SEC's website at www.sec.gov.

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 for the treatment of idiopathic pulmonary fibrosis, or IPF, primary sclerosing cholangitis, or PSC, and COVID-19 related ARDS. 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 for the treatment of IPF and PSC. Pliant's second clinical stage product candidate, PLN-1474, is a small-molecule selective inhibitor of $\alpha_v\beta_1$ 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.

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