Pliant Therapeutics INTEGRIS-PSC Phase 2a Interim Data Evaluating Bexotegrast in Primary Sclerosing Cholangitis to be Highlighted in an Oral Late-Breaking Presentation at The Liver Meeting® 2023

10-19-2023 at 8:00 AM EDT

Interim results from INTEGRIS-PSC to be featured in an oral presentation on Monday, November 13

SOUTH SAN FRANCISCO, Calif., Oct. 19, 2023 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), a clinical-stage biotechnology company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases, today announced a late-breaking presentation of results from the INTEGRIS-PSC Phase 2a trial of bexotegrast in patients with primary sclerosing cholangitis (PSC) at The Liver Meeting® 2023 of the American Association for the Study of Liver Diseases (AASLD), in Boston, Massachusetts, November 10 – 14. Bexotegrast is an oral, small molecule, dual selective inhibitor of αvß6 and αvß1 integrins that is in development for the treatment of idiopathic pulmonary fibrosis (IPF) and PSC.

The oral presentation titled "Oral $\alpha_V\beta_6/\alpha_V\beta_1$ Integrin Inhibition in Primary Sclerosing Cholangitis: 12-week Interim Safety and Efficacy Analysis of INTEGRIS-PSC, A Phase 2a Trial of Bexotegrast," will be delivered by Professor Gideon Hirschfield, M.D., Lily and Terry Horner Chair in Autoimmune Liver Disease Research, Toronto Centre for Liver Disease.

"We are pleased to be sharing these positive interim results from the INTEGRIS-PSC trial with the scientific and medical communities as part of this leading hepatology conference," said Éric Lefebvre, M.D., Chief Medical Officer of Pliant. "Recognizing that no approved treatments are available for patients with PSC, we look forward to the further investigation of bexotegrast including 12 week data from the 320 mg dose in the first quarter of 2024 and 24 week safety data in mid-2024."

Late-Breaking Oral Presentation
Monday, November 13 5:00 PM EST
Oral $\alpha_V\beta_6/\alpha_V\beta_1$ Integrin Inhibition in Primary Sclerosing Cholangitis: 12-week Interim Safety and Efficacy Analysis of INTEGRIS-PSC, A Phase 2a Trial of Bexotegrast (Abstract #5008)
Gideon M. Hirschfield, Kris V. Kowdley, Michael Trauner, Palak J. Trivedi, Éric A. Lefebvre, Johanna Schaub, Annie Clark, Theresa Thuener, Hardean E. Achneck, Chris N. Barnes, Richard Pencek, Aldo J, Montano-Loza, Christopher L. Bowlus, Christoph Schramm, Cynthia Levy

The late-breaker poster will be made available on the Publications page of the Pliant website at the time of presentation.

Background on Primary Sclerosing Cholangitis

PSC is a rare, progressive liver disease of unknown origin, which frequently occurs in the setting of inflammatory bowel disease. PSC affects more than 30,000 patients in the United States and over 100,000 patients worldwide. The disease can occur in all ages, gender, and race. PSC is characterized by inflammation and fibrosis, with progressive liver and biliary damage leading to cirrhosis and liver failure. Currently there are no FDA or EMA-approved therapies for patients with PSC. Therefore, there is a high unmet need for new therapeutic options to address the symptoms and modify the disease progression of this grievous illness.

INTEGRIS-PSC Multinational Phase 2a Trial of Bexotegrast (NCT04480840)

INTEGRIS-PSC is a Phase 2a, randomized, dose-ranging, double-blind, placebo-controlled trial evaluating the safety, tolerability, and pharmacokinetics of bexotegrast 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 ursodeoxycholic acid (UDCA). The primary endpoint is the evaluation of bexotegrast safety and tolerability and the secondary endpoint is the assessment of pharmacokinetics across the range of doses. Exploratory endpoints will measure changes in liver fibrosis markers, ELF and PRO-C3, liver biochemistry and liver imaging.

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, bexotegrast (PLN-74809), is an oral, small molecule, dual selective inhibitor of αvß6 and αvß1 integrins that is in development in the lead indications for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. Bexotegrast 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 has initiated BEACON-IPF, a Phase 2b trial of bexotegrast in IPF. Pliant has also developed PLN-1474, a small molecule, selective inhibitor of αvß1 integrin for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis. Pliant has initiated a Phase 1 study for its third clinical program, PLN-101095, a small molecule, dual-selective inhibitor of αvß8 and αvß1 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, please visit: www.PliantRx.com. Follow us on social media 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 bexotegrast; our plans for the future development of bexotegrast; bexotegrast's potential to become a treatment for IPF or PSC; the anticipated timing of data and progress from our clinical studies; including the timing of 12-week and 24-week data from the 320 mg dose cohort of the INTEGRIS-PSC Phase 2a trial in the first quarter of 2024 and mid-2024, respectively. 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 current macroeconomic and marketplace conditions, 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, including the availability of additional term loans under our loan facility, 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 Quarterly Report on Form 10-Q for the period ended June 30, 2023 which is 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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