



Pliant Therapeutics Presentations at The Liver Meeting® 2023 Highlight Bexotegrast, an Inhibitor of $\alpha v\beta 6$ and $\alpha v\beta 1$ Integrins, in Primary Sclerosing Cholangitis

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INTEGRIS-PSC interim results highlighted in an oral late-breaker presentation

SOUTH SAN FRANCISCO, Calif., Nov. 13, 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 the presentation of preclinical data and clinical data from the INTEGRIS-PSC Phase 2a trial of bexotegrast in patients with primary sclerosing cholangitis (PSC). These posters were presented at The Liver Meeting® 2023 of the American Association for the Study of Liver Diseases (AASLD). The meeting is being held November 10-14, 2023.

"Our presentations at the Liver Meeting feature preclinical and clinical work supportive of bexotegrast's antifibrotic mechanism of action in liver fibrosis," said Éric Lefebvre, M.D., Chief Medical Officer of Pliant. "A highlight of the conference was the late-breaker presentation of our recent positive interim data from the INTEGRIS-PSC trial, demonstrating the potential of bexotegrast in the unmet area of need of patients with PSC."

Late Breaker: [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](#)

Professor Gideon Hirschfield, M.D., Lily and Terry Horner Chair in Autoimmune Liver Disease Research, Toronto Centre for Liver Disease and INTEGRIS-PSC trial investigator presented interim data from the 40, 80, 160 mg dose cohorts from INTEGRIS-PSC, an ongoing, double-blind, dose-ranging, randomized, placebo-controlled Phase 2a trial of bexotegrast in participants with PSC. Bexotegrast was well tolerated over 12 weeks of treatment with no treatment-related severe or serious treatment emergent adverse events. At all doses tested, bexotegrast reduced changes in enhanced liver fibrosis (ELF) score and PRO-C3 levels from Baseline relative to placebo, with statistically significant differences for both parameters observed with the 160 mg dose. Twelve-week data from the INTEGRIS-PSC 320mg cohort is expected in the first quarter of 2024.

[Inhibition of Integrin \$\alpha v\beta 1\$ Attenuates Profibrogenic Gene Expression by Myofibroblasts in Fibrotic Human Liver Explants](#)

An $\alpha v\beta 1$ -selective integrin inhibitor was evaluated on fibrotic and non-fibrotic human liver tissue to assess the effects on cell populations present in fibrotic human liver tissue. The $\alpha v\beta 1$ integrin is a (myo)fibroblast-specific integrin that activates transforming growth factor (TGF)- β that promotes fibrogenesis, or wound healing and repair. Results showed that treatment of fibrotic human tissue with an $\alpha v\beta 1$ inhibitor resulted in clear reductions in profibrogenic gene expression by myofibroblasts. In addition, $\alpha v\beta 1$ and ALK5 (TGF- β receptor) inhibitors demonstrated similar effects on fibrogenic gene expression in myofibroblasts highlighting the significance of the $\alpha v\beta 1$ integrin-TGF- β activation pathway in fibrotic liver disease.

[Dual \$\alpha v\beta 6/\alpha v\beta 1\$ Integrin Inhibitor Bexotegrast Attenuates Profibrogenic Gene Expression Across Multiple Pathologic Cell Types in Human Liver Explant Tissue with Biliary Fibrosis](#)

The effects of bexotegrast (PLN-74809), a dual inhibitor of integrins $\alpha v\beta 6$ and $\alpha v\beta 1$, were assessed on human liver tissue to characterize the response of unique cell populations in fibrotic primary sclerosing cholangitis (PSC) and primary biliary cholangitis (PBC). Treatment with bexotegrast was shown to significantly decrease profibrogenic pathways in myofibroblasts and reduce gene expression in scar-associated endothelial cells. In addition, bexotegrast's anti-fibrotic effect was similar to ALK5i (TGF- β receptor inhibitor) demonstrating the importance the $\alpha v\beta 6/\alpha v\beta 1$ integrin-TGF- β activation pathway in fibrotic biliary disease. These data support the ongoing clinical study evaluating the anti-fibrotic activity of bexotegrast in PSC.

These posters and the late breaker presentation are also available on the Publications page of the Pliant's website at www.PliantRx.com.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical-stage biopharmaceutical company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases. Pliant's lead product candidate, bexotegrast (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. 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 $\alpha v\beta 1$ 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 $\alpha v\beta 8$ 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, please visit: www.PliantRx.com. Follow us on social media [X](#), [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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