Pliant Therapeutics Provides Update on BEACON-IPF, a Phase 2b/3 Trial in Patients with Idiopathic Pulmonary Fibrosis

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SOUTH SAN FRANCISCO, Calif., March 03, 2025 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX) today announced that following a prespecified data review and recommendation by the trial's independent Data Safety Monitoring Board (DSMB), as well as a secondary review and recommendation by an outside expert panel, Pliant has discontinued the BEACON-IPF Phase 2b trial evaluating bexotegrast in patients with idiopathic pulmonary fibrosis (IPF). While an imbalance in unadjudicated IPF-related adverse events between the treatment and placebo groups led to the discontinuation of the trial, early evidence of efficacy on the forced vital capacity (FVC) endpoint was also observed.

BEACON-IPF is the first late-stage IPF trial to be discontinued for safety while showing strong evidence of efficacy.

The mean exposure duration in BEACON-IPF was approximately 17 weeks. Overall, the percentage of IPF-related adverse events in both dose groups was comparable (approximately 10%). The imbalance between active and placebo appears to have been driven by a low (below 3%) IPF-related adverse event rate in the placebo group. In comparison, in the Phase 2a INTEGRIS-IPF trial (mean exposure duration of approximately 16 weeks), IPF-related adverse events were comparable in bexotegrast-treated (7%) across all doses and placebo-treated (10%) participants.

The Company plans to analyze the complete data from the BEACON-IPF trial and evaluate next steps for bexotegrast's development. Once the full analysis is completed, which should provide a better understanding of the benefit risk profile and therapeutic window of bexotegrast, the Company will consider additional dose-ranging Phase 2b studies with lower doses in pulmonary fibrosis and potentially, other non-respiratory indications, including liver diseases.

Pliant is committed to the development of its other clinical and pipeline assets including PLN-101095 in oncology. The Company is currently enrolling the fourth of five planned dose cohorts in a Phase 1 open label dose-escalation trial of PLN-101095 as monotherapy and in combination with pembrolizumab in patients with solid tumors that are resistant to immune checkpoint inhibitors. Interim data from the first three cohorts is expected in the first quarter of 2025.

Pliant would like to thank the BEACON-IPF investigators and their study teams, as well as the members of the Pliant team for their dedication in support of the execution of this trial. The Company also wants to give special thanks to the BEACON-IPF clinical trial participants, their families and support networks for their participation in, and support of BEACON-IPF.

About BEACON-IPF

BEACON-IPF is a 52-week, multinational, randomized, dose-ranging, double-blind, placebo-controlled trial evaluating bexotegrast at once-daily doses of 160 mg or 320 mg in patients with idiopathic pulmonary fibrosis (IPF).

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a late-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 α_Vß6 and α_Vß$_1$ integrins that is in development in the lead indication for the treatment of idiopathic pulmonary fibrosis, or IPF. Bexotegrast has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and Orphan Drug Designation from the European Medicines Agency in IPF. Pliant is conducting a Phase 1 study of, PLN-101095, a small molecule, dual-selective inhibitor of α_Vß$_8$ and α_Vß$_1$ integrins, that is being developed for the treatment of solid tumors. In addition, Pliant has received regulatory clearance for the conduct of a Phase 1 study of PLN-101325, a monoclonal antibody agonist of integrin $\alpha_7\beta_1$ targeting muscular dystrophies.

For additional information, please visit: www.PliantRx.com. Follow us on social media X, LinkedIn, and Facebook.

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 Company's preliminary analysis of data from the BEACON-IPF trial, the Company's intent to complete a more full analysis and potential next steps for bexotegrast development, as well as statements regarding the development of the Company's other clinical and pipeline assets. 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 analysis of the complete data from the BEACON-IPF trial, any delays in our ongoing or planned preclinical or clinical trials, the risks inherent in the drug development process, and our capital requirements and the need for additional financing, including the anticipated lack of availability of additional funds under the current terms of our loan facility. 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 September 30, 2024, which is available on the SEC's website at www.sec.gov, as updated by our

Annual Report on Form 10-K for the year ended December 31, 2024, which we expect to file with the SEC today. 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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