Pliant Therapeutics Provides Update on BEACON-IPF

06-27-2025 at 4:05 PM EDT

Bexotegrast development in IPF discontinued

Clinical oncology program and early-stage programs continue

Recent workforce and operational changes align with next steps

SOUTH SAN FRANCISCO, Calif., June 27, 2025 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX) today announced that following the review of data from the recently terminated BEACON-IPF Phase 2b/3 clinical trial, the Company has discontinued development of bexotegrast in idiopathic pulmonary fibrosis (IPF).

BEACON-IPF Trial Update

BEACON-IPF was a randomized, double-blind, placebo-controlled, global Phase 2b/3 clinical trial evaluating patients with IPF. In March of this year, Pliant announced the voluntary discontinuation of BEACON-IPF 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, citing an imbalance in IPF-related adverse events.

Following an analysis of the full safety and efficacy data from the BEACON-IPF trial, the Company is discontinuing development of bexotegrast in IPF. Results showed that at doses of 160 mg and 320 mg, bexotegrast demonstrated an unfavorable risk-benefit profile. Compared to placebo, bexotegrast-treated participants showed an increased risk of experiencing adverse events associated with IPF disease progression, defined as events of worsening of IPF and acute IPF exacerbation, respiratory-related hospitalization, and/or all-cause mortality. The average time to disease progression for bexotegrast-treated participants was 33 weeks, suggesting that the safety risk may not be apparent with shorter dosing duration as was the case in the prior INTEGRIS-IPF Phase 2a trial.

At Week 12, bexotegrast 160 mg and 320 mg treatment groups demonstrated improvements in forced vital capacity (FVC) decline of 72 mL ($p<0.05$) and 46 mL ($p>0.05$), respectively, compared to placebo. At Week 24, bexotegrast 160 mg and 320 mg treatment groups demonstrated improvements in FVC decline of 58 mL ($p>0.05$) and 8 mL ($p>0.05$), respectively, compared to placebo.

The full results from BEACON-IPF will be submitted for future publication.

"Although the decision to discontinue bexotegrast in IPF is disappointing for us and the many patients in need of new treatment options, we believe it is the right decision to protect patient safety," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant. "We sincerely thank all patients, their caregivers, the study investigators and their research teams who were part of the BEACON-IPF clinical program for their extensive efforts."

Oncology Phase 1 Enrollment Continues

PLN-101095 is an oral, small molecule, dual selective inhibitor of αvβ8 and αvβ1 integrins, designed to block TGF-β activation in the tumor microenvironment. PLN-101095 is currently undergoing a Phase 1 open-label trial as monotherapy and in combination with pembrolizumab in patients with solid tumors that are resistant to immune checkpoint inhibitors. In March, the Company announced interim results from this trial showing that PLN-101095 was generally well tolerated with confirmed partial responses in 50% of patients at highest dose tested to date, across multiple tumor types. The trial is currently enrolling the fifth of five planned dose cohorts.

Early Programs Supported by Proprietary Platform

The Company's drug discovery platform consists of a proprietary library of over 15,000 integrin binding molecules, a comprehensive screening assay system (binding, integrin confirmation, ligand-induced internalization) and an advanced live human tissue program. The Company believes in the broad applicability of the platform across multiple disease areas including delivery of drug payloads to cells utilizing integrin receptor-binding molecules as tissue-specific delivery and internalization mechanisms.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical-stage biopharmaceutical company and leader in the discovery and development of integrin-based therapeutics. Pliant is conducting a Phase 1 study for 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, 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. Pliant's early-stage platform includes preclinical research focused on tissue-specific delivery and internalization of drug payloads utilizing integrin receptor-binding molecules.

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 development plans for PLN-101095, PLN-101325 and the Company's proprietary platform; and the Company's efforts to align its workforce and operations for its next steps. 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, geopolitical and marketplace conditions on our business, operations, clinical supply and plans, our reliance on single-source third parties located in foreign jurisdictions, including China, 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 March 31, 2025 which are 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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