Pliant Therapeutics Announces First Patient Dosed in FORTIFY, the Phase 1b Indication Expansion Trial Evaluating PLN-101095 in Patients with ICI-Refractory Solid Tumors

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SOUTH SAN FRANCISCO, Calif., April 30, 2026 (GLOBE NEWSWIRE) -- Pliant Therapeutics (Nasdaq: PLRX) today announced the dosing of the first participant in the FORTIFY Phase 1b open-label indication expansion clinical trial of PLN-101095 in combination with pembrolizumab, in patients with immune checkpoint inhibitor (ICI)-refractory advanced or metastatic solid tumors. PLN-101095 is an oral, small molecule, dual selective inhibitor of the integrins αvβ8 and αvβ1.

“We are pleased to announce this milestone for the FORTIFY trial and the expansion into solid tumor cohorts that we believe are supported by PLN-101095’s mechanism of action,” said Bernard Coulie, M.D., Ph.D.., Chief Executive Officer of Pliant. “As a leader in integrin drug development, we look forward to exploring the full potential of this novel drug candidate.”

FORTIFY - Phase 1b Clinical Trial Design

The primary objective of this trial is to evaluate the safety, tolerability, pharmacokinetics and preliminary evidence of anti-tumor activity of PLN-101095 when administered orally in combination with pembrolizumab in adult participants with advanced or metastatic solid tumors. The expansion trial is enrolling three cohorts of patients with NSCLC, clear cell renal cell carcinoma, or one of a subset of tumors with high tumor mutational burden. Patients will be treated for 14 days with PLN-101095 as monotherapy dosed at 1,000 mg twice daily, after which pembrolizumab will be added as combination therapy. Enrollment is underway with interim data expected in 2027.

PLN-101095 for the Treatment of Checkpoint Resistant Tumors

PLN-101095 is an oral, small molecule inhibitor of integrins αvβ8 and αvβ1. Activated transforming growth factor-β (TGF-β) has been shown to foster an immuno-suppressive tumor microenvironment (TME) that contributes to immune-checkpoint inhibitor (ICI) resistance and treatment failure in cancer.[1] Blocking integrins αvβ8 and αvβ1 has been shown to prevent the activation of TGF-β and is expected to stimulate immune activation by increasing immune cell infiltration into the tumor microenvironment.[2,3] PLN-101095 is currently being evaluated in Phase 1a/1b open-label, dose-escalation and indication expansion trial (NCT 06270706) to evaluate the safety, tolerability, pharmacokinetics, and preliminary evidence of antitumor activity of PLN-101095 in combination with pembrolizumab, in patients with immune checkpoint inhibitor (ICI)-refractory advanced or metastatic solid tumors. PLN-101095 in combination with an anti-PD-1 monoclonal antibody (mAb) elicited a dose-dependent reduction in tumor volume and increased CD8+ T cell tumor infiltration in the tumor microenvironment compared with anti-PD-1 mAb therapy alone.[4] In preclinical studies, PLN-101095 demonstrated monotherapy activity in reduction of tumor volume and increased cluster of differentiation (CD)8+ T cell infiltration.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical-stage biopharmaceutical company focused on the discovery and development of integrin-based therapeutics. Pliant’s lead program is 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 ICI-refractory advanced or metastatic solid tumors. PLN-101095 is being investigated in FORTIFY, a Phase 1b indication expansion trial of PLN-101095 enrolling patients with NSCLC, tumors with high tumor mutational burden or clear cell renal cell carcinoma. Pliant’s preclinical research is focused on tissue-specific delivery and internalization of drug payloads utilizing integrin receptor-binding molecules with programs focused on delivering siRNAs to skeletal muscle cells, adipocytes, and renal cells. For additional information, please visit: www.PliantRx.com. Follow Pliant on social media at 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 express or implied statements regarding ongoing clinical trial development of PLN-101095, including timing of enrollment and data; the potential benefits of PLN-101095; and Pliant’s plans for the continued development of PLN-101095 among others, including its integrin-based drug delivery platform. Because such statements deal with future events and are based on Pliant’s current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Pliant 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 Pliant’s product candidates, including any delays in Pliant’s ongoing or planned preclinical or clinical trials, the impact of current macroeconomic, geopolitical and marketplace conditions on Pliant’s business, operations, clinical supply and plans, Pliant’s reliance on single-source third parties located in foreign jurisdictions, including China, for critical aspects of Pliant development operations, the risks inherent in the drug development process, the risks regarding the accuracy of Pliant’s estimates of expenses and timing of development, its capital requirements and the sufficiency of its cash to support Pliant’s planned operations, and Pliant’s ability to obtain and maintain intellectual property protection for Pliant’s 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 Pliant’s Annual Report on Form 10-K for the period ended December 31, 2025, and subsequent filings with the Securities and Exchange Commission (SEC), 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.

Investor and Media Contact:
Christopher Keenan
Vice President, Investor Relations and Corporate Communications
Pliant Therapeutics, Inc.
ir@pliantrx.com

[1] Pickup M. et al. *Nat Rev Cancer*. 2013 Nov;13(11):788-99.

[2] Takasaka N. et al. *JCI Insight*. 2018 Oct 18;3(20).

[3] Reed NI. et al. *Sci Transl Med*. 2015 May 20;7(288):288ra79.

[4] Kothari V, et al. *J Immunother Cancer*. 2022;10(Suppl 2): A1403 abstract 1352 (SITC 2022)