Pliant Therapeutics Receives FDA Fast Track Designation for PLN-101095 in Combination with Pembrolizumab for the Treatment of ICI-Refractory Solid Tumors

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SOUTH SAN FRANCISCO, Calif., Aug. 18, 2026 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX) today announced the receipt of Fast Track designation from the U.S. Food and Drug Administration (FDA) for PLN-101095, an oral, small molecule, dual selective inhibitor of αvβ8 and αvβ1 integrins, in combination with pembrolizumab for the potential the treatment of solid tumors that are resistant to immune checkpoint inhibitors (ICIs). PLN-101095 is currently being evaluated in the Phase 1a/1b FORTIFY trial (NCT06270706) with data expected in 2027.

“While immune checkpoint inhibitors have fundamentally changed the oncology treatment landscape, primary or acquired resistance remains a significant barrier for the majority of patients,” said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant. “This Fast Track designation underscores the urgent need for innovative therapies for immune checkpoint inhibitor-refractory solid tumors and recognizes the potential of PLN-101095. We look forward to working closely with the FDA as we advance this program.”

FDA’s Fast Track designation is intended to facilitate and expedite the development and review of new drugs to treat serious or life-threatening conditions. To qualify, available clinical and non-clinical data need to demonstrate the potential to address unmet medical need. The benefits of Fast Track designation include opportunities for frequent meetings with the FDA to discuss trial design, development plans and data needed to support drug approval, as well as the ability to submit a New Drug Application (NDA) on a rolling basis, and eligibility for priority review, if relevant criteria are met.

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 αvß8 and αvß1 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 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; receipt of Fast Track designation and implications thereof; 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 risks inherent in the drug development process, including obtaining regulatory approval, even with Fast Track Designation; 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; 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 planned operations; and Pliant’s ability to obtain and maintain intellectual property protection for Pliant’s product candidates; among others. These and additional risks are discussed in the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" in Pliant’s Quarterly Report on Form 10-Q for the period ended June 30, 2026, as filed with the Securities and Exchange Commission (SEC) and available on the SEC's website, as may be amended or supplemented with future SEC filings. 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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