Prelude Therapeutics Receives FDA Clearance of Investigational New Drug (IND) Application for PRT13722, Its First-in-Class Oral KAT6A Selective Degrader

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Phase 1 study of PRT13722 in patients with HR+ breast cancer anticipated to begin enrolling patients in the fourth quarter of 2026.

WILMINGTON, Del., Sept. 10, 2026 (GLOBE NEWSWIRE) -- Prelude Therapeutics Incorporated (Nasdaq: PRLD), a precision oncology company, today announced that the U.S. Food and Drug Administration (FDA) cleared the Company to proceed with a Phase 1 study under its Investigational New Drug Application (IND) for PRT13722, an oral KAT6A selective degrader being developed for the treatment of patients with HR+/HER2- breast cancer. The Company expects to begin enrolling patients in the fourth quarter of 2026.

"Recent clinical data validated KAT6 as a targetable mechanism in the treatment of HR+/HER2- breast cancer, including those with actionable mutations," stated Charles Morris, MBChB, MRCP, Chief Medical Officer of Prelude. "Dual KAT6A/B inhibitors, however, demonstrated overlapping toxicities with current backbone therapies that may limit the utility in earlier lines of treatment. Our approach of selectively degrading KAT6A has the potential to address this challenge by maximizing the therapeutic window with enhanced efficacy and improved hematological safety, as supported by our preclinical data. We look forward to advancing PRT13722 into the clinic with the ultimate goal of providing a new therapeutic option for patients with HR+/HER2- breast cancer."

The Phase 1 study is a first-in-human, open-label, multicenter study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and antitumor activity of PRT13722 as monotherapy and in combination with endocrine and targeted therapies in adults with locally advanced or metastatic HR-positive, HER2-negative breast cancer.

Highly selective KAT6A oral degrader program
KAT6 is an emerging and clinically validated target in the treatment of ER+ breast cancer. Prelude discovered and is developing first-in-class, highly potent, highly selective and orally bioavailable KAT6A degraders. Prelude believes that selectively degrading KAT6A and sparing KAT6B has the potential for improved efficacy, tolerability and combinability with other agents relative to dual inhibitors of KAT6A/B.

About Prelude Therapeutics
Prelude Therapeutics is a leading precision oncology company developing innovative medicines in areas of high unmet need for cancer patients. Our pipeline features highly selective KAT6A degraders and JAK2V617F mutant selective inhibitors -- new approaches to clinically validated targets with transformative potential for patients. We are leveraging our expertise in targeted protein degradation to create and develop next generation degrader antibody conjugates (DACs) with novel payloads. We are on a mission to extend the promise of precision medicine to every cancer patient in need. For more information, visit preludetx.com.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, anticipated discovery, preclinical and clinical development activities for Prelude's product candidates, the potential safety, efficacy, benefits and addressable market for Prelude's product candidates, the expected timeline for clinical trial results for Prelude's product candidates, and the sufficiency of Prelude's cash runway. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," "schedule," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are predictions based on the Company's current expectations and projections about future events and various assumptions. Although Prelude believes that the expectations reflected in such forward-looking statements are reasonable, Prelude cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause Prelude's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to Prelude's ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, clinical trial sites and our ability to enroll eligible patients, supply chain and manufacturing facilities, Prelude's ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, Prelude's ability to fund development activities and achieve development goals, Prelude's ability to protect intellectual property, and other risks and uncertainties described under the heading "Risk Factors" in Prelude's Annual Report on Form 10-K for the year ended December 31, 2025, its Quarterly Reports on Form 10-Q and other documents that Prelude files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and Prelude undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof, except as may be required by law.

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