Prelude Therapeutics Receives FDA Clearance of Investigational New Drug Application (IND) for PRT12396, a Mutant-selective JAK2V617F Inhibitor

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Phase 1 study of PRT12396 in patients with polycythemia vera and myelofibrosis anticipated to initiate by Q2 2026

WILMINGTON, Del., Feb. 03, 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 PRT12396, a mutant-selective JAK2V617F inhibitor being developed for the treatment of patients with certain myeloproliferative neoplasms (MPNs). The Company anticipates dosing the first patient by Q2 of 2026.

“The FDA's clearance of our IND for PRT12396 marks a pivotal first milestone in the strategic transformation and development focus on our JAK2 and KAT6 programs that we outlined last quarter,” stated Kris Vaddi, Chief Executive Officer of Prelude. “This achievement demonstrates our ability to translate high-quality science rapidly into clinical progress and our clear focus on executing these programs that represent the potential to reshape the treatment landscape for the target patient populations. We look forward to advancing PRT12396 into the phase 1 study in patients with polycythemia vera and myelofibrosis in parallel.”

The Phase 1 study of PRT12396 is an open-label, multi-center, safety and efficacy study in patients with high-risk polycythemia vera (PV) and intermediate and high-risk myelofibrosis (MF). The primary endpoints of the study include safety, efficacy and PK profile.

The JAK2V617F inhibitor program is subject to an exclusive option agreement with Incyte announced in November 2025.

Mutant selective JAK2V617F JH2 inhibitor program
JAK2V617F is the primary driver mutation responsible for disease progression in the majority of patients living with myeloproliferative neoplasms (MPNs). The mutation impacts approximately 95% of patients with polycythemia vera (PV), 60% of patients with essential thrombocythemia (ET) and 55% of patients with myelofibrosis (MF). Identifying JAK2 JH2 inhibitors that selectively target V617F+ cells has long been the goal for advancing the treatment of MPNs. Prelude has designed and identified novel allosteric inhibitors that bind into the JAK2 JH2 “deep pocket” where the V617F mutation resides. These candidates demonstrate mutant specific inhibition in multiple preclinical models of MPNs. Prelude believes this approach may have the potential to reduce mutant allele burden, slow or even reverse disease progression, and transform treatment outcomes for MPN patients.

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, 2024, 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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