Prelude Therapeutics Announces IND Clearance for PRT2527, a Highly Selective CDK9 Inhibitor

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Phase 1 Clinical Trial in Patients with Selected Solid Tumors Anticipated to Begin by Year-End

WILMINGTON, Del., Nov. 08, 2021 (GLOBE NEWSWIRE) -- Prelude Therapeutics Inc. (Nasdaq: PRLD), a clinical-stage precision oncology company, today announced that the United States Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application for its precision oncology candidate, PRT2527, which is designed to be a potent and selective CDK9 inhibitor.

Prelude anticipates beginning a Phase 1 clinical trial of PRT2527 by year-end evaluating escalating doses of intravenous (IV) PRT2527 as a monotherapy in patients with selected solid tumors, including sarcoma, prostate cancer, breast cancer, and other cancers with genomic alterations that lead to *MYC* dependence.

In preclinical studies, PRT2527 was shown to reduce MCL1 and MYC protein levels and was highly active in preclinical models at well-tolerated doses. PRT2527 has demonstrated high potency and kinase selectivity which may offer improved efficacy and safety compared to less selective CDK9 inhibitors. Preclinical data presented in October 2021 at the annual *AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics* demonstrated that treatment with PRT2527 depleted oncogenic drivers with short half-lives, such as MYC and MCL1, and effectively induced apoptosis. PRT2527 treatment demonstrated robust efficacy in both hematological malignancies and solid tumor models with *MYC* dysregulation.

“Utilizing our internal discovery engine and expertise, we are focused on developing and advancing differentiated, optimal small molecule therapeutics to treat highly underserved patients with difficult to treat cancers. Our precision oncology approach seeks to identify those cancers vulnerable to mechanisms targeted by our product candidates, in the hopes of providing new options in the battle against these devastating diagnoses. I’m proud of the achievements of our Prelude team, as we now advance our fourth oncology candidate into clinical development. We look forward to providing updates on PRT2527 and our other clinical development programs in 2022,” said Kris Vaddi, PhD, Chief Executive Officer.

About Prelude Therapeutics

Prelude Therapeutics is a clinical-stage precision oncology company developing innovative, potential best-in-class molecules targeting critical cancer cell pathways involved in cancer pathogenesis. Prelude’s initial clinical candidates, PRT543 and PRT811, are potent, selective, oral PRMT5 inhibitors in Phase 1 development for the treatment of advanced solid tumors, primary and secondary CNS cancers and select myeloid malignancies. PRT1419, a potent and selective MCL1 inhibitor, is in Phase 1 development for patients with relapsed/refractory hematologic malignancies and solid tumors. The Company’s pipeline also includes PRT2527, a CDK9 inhibitor, and PRT-SCA2, a SMARCA2 protein degrader, PRT-K4, a highly selective kinase inhibitor, and additional discovery stage programs.

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, timing of availability and announcements of clinical results, the timing of the expansion portion for its Phase 1 clinical trial for PRT543, PRT811 and PRT1419, the timing of clinical and IND-related activities for PRT2527 and PRT-SCA2 and the potential benefits of the Company’s product candidates and platform. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company 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 the Company’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the Company’s ability to advance its product candidates, the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, the impact of the COVID-19 pandemic on the Company’s business, clinical trial sites, supply chain and manufacturing facilities, the Company’s ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical and clinical trials, the Company’s ability to fund development activities and achieve development goals, the Company’s ability to protect intellectual property, and other risks and uncertainties described under the heading “Risk Factors” in documents the Company 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 the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

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