Prelude Therapeutics Announces Clinical Collaboration with Merck to Evaluate PRT3789 in Combination with KEYTRUDA® (pembrolizumab) in Patients with SMARCA4-Mutated Cancers

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Combining a first-in-class, highly selective SMARCA2 degrader with an anti-PD-1 therapy may potentially enhance the anti-tumor activity of either agent because of the complementary nature of the two mechanisms.

Prelude will sponsor the clinical trial and Merck will provide KEYTRUDA.

WILMINGTON, Del., July 09, 2024 (GLOBE NEWSWIRE) -- Prelude Therapeutics Incorporated (Nasdaq: PRLD) ("Prelude" or the "Company"), a clinical-stage precision oncology company, today announced that it has entered into a clinical trial collaboration and supply agreement (the "Agreement") with Merck (known as MSD outside of the US and Canada). Under the terms of the Agreement, the Phase 2 clinical study will evaluate PRT3789, the Company's investigational, highly selective, first-in-class SMARCA2 degrader in combination with KEYTRUDA ® (pembrolizumab) Merck's anti-PD-1 therapy, in patients with SMARCA4-mutated cancers.

"We are excited for this opportunity to work together with Merck on this study combining our novel, highly selective SMARCA2 degrader with KEYTRUDA," stated Prelude's President and Chief Medical Officer Jane Huang, M.D. "Through this collaboration of potentially complementary mechanisms, we may have the potential to positively impact clinical outcomes in patients harboring a SMARCA4 mutation, who have previously been known to have limited treatment options."

PRT3789 is a potent and highly selective, first-in-class SMARCA2 degrader, in Phase 1 clinical development in biomarker selected SMARCA4 mutant patients. Enrollment remains on track, and the Company expects to conclude monotherapy dose escalation mid-2024 and identify recommended Phase 2 dose. In addition, enrollment of patients into back-fill cohorts enriched for NSCLC and SMARCA4 loss-of-function mutations is ongoing. Objectives for this first Phase 1 clinical study are to establish the safety and tolerability profile of PRT3789 as both monotherapy and in combination with docetaxel, evaluate activity, pharmacokinetics and pharmacodynamics and determine a dose and potential indications for advancement into a registrational clinical trial.

The mechanistic rationale and pre-clinical data to support the SMARCA2 and anti-PD-1 monoclonal antibody (mAb) combination was previously presented by the Company at the 2023 AACR International Conference on Molecular Targets and Cancer Therapeutics. In pre-clinical models, SMARCA2 degrader combined with an anti-PD-1 mAb in SMARCA4-mutated cancers enhanced anti-tumor immunity and demonstrated tumor regressions.

Under the terms of the Agreement, Merck will provide KEYTRUDA to Prelude, which will be the sponsor of the Phase 2 clinical combination trial. Prelude and Merck each retain all commercial rights to their respective compounds, including as monotherapy or as combination therapies.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About Prelude Therapeutics

Prelude Therapeutics is a clinical-stage precision oncology company developing innovative drug candidates targeting critical cancer cell pathways. The Company's diverse pipeline is comprised of highly differentiated, potentially best-in-class proprietary small molecule compounds aimed at addressing clinically validated pathways for cancers with selectable underserved patients. Prelude's pipeline includes three candidates currently in clinical development: an IV administered, potent and highly selective SMARCA2 degrader, PRT3789, a potent and highly selective CDK9 inhibitor, PRT2527, and a next generation CDK4/6 inhibitor, PRT3645. Prelude is also developing a potent, highly selective, orally bioavailable SMARCA2 degrader, PRT7732. The Company is also collaborating with AbCellera to jointly discover, develop and commercialize up to five precision, next generation antibody drug conjugate (ADC) products combining AbCellera's antibody discovery and development engine with Prelude's expertise in medicinal chemistry and drug development. 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 initial proof-of-concept data and clinical trial results for Prelude's product candidates, and the sufficiency of Prelude's cash runway into 2026. 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, 2023, 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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