Prelude Therapeutics Announces Clinical Trial Collaboration with BeiGene to Evaluate PRT2527 in Combination with Zanubrutinib in Hematologic Cancers

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WILMINGTON, Del., March 15, 2023 (GLOBE NEWSWIRE) -- Prelude Therapeutics Incorporated (Prelude) (Nasdaq: PRLD), a clinical-stage precision oncology company, today announced a clinical trial collaboration with BeiGene, for future evaluation of its investigational CDK9 inhibitor, PRT2527, in combination with BeiGene's BTK inhibitor, zanubrutinib, in hematologic malignancies.

Inhibition of BTK is an active therapeutic approach in several B cell malignancies and the combination of CDK9 inhibition with BTK inhibition has demonstrated, in recent data publications, synergistic clinical efficacy over BTK inhibition alone; hence, there is a strong rationale for studying the combination in patients with certain hematologic malignancies.

"The opportunity to combine Prelude's potent, selective and potentially best-in-class CDK9 inhibitor with BeiGene's next-generation highly efficacious and tolerable BTK inhibitor, zanubrutinib, reflects our commitment to bringing the most promising options to patients," said Jane Huang, MD, President and Chief Medical Officer, Prelude Therapeutics.

Under terms of the clinical trial collaboration agreement, BeiGene will provide zanubrutinib to Prelude, and Prelude will retain all global operational, development and commercialization rights and responsibilities for PRT2527.

About PRT2527

PRT2527 was designed to be a potent and selective Cyclin-dependent kinase 9, or CDK9, inhibitor. 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, allowing for rapid development in combinations. PRT2527 is currently being studied as monotherapy in a Phase 1 dose-escalation study in advanced solid tumors, as well as in relapsed/refractory hematologic malignancies.

About Prelude Therapeutics

Prelude Therapeutics is a clinical-stage precision oncology company developing innovative drug candidates targeting critical cancer cell pathways. Prelude's diverse pipeline is comprised of highly differentiated, potentially best-in-class and first-in-class proprietary small molecule compounds aimed at addressing clinically validated pathways for cancers with selectable underserved patients. Prelude's pipeline includes four candidates currently in clinical development: PRT1419, a potent, selective inhibitor of MCL1, PRT2527, a potent and highly selective CDK9 inhibitor, PRT3645, a next-generation CDK4/6 inhibitor, and PRT3789 a first-in-class SMARCA2/BRM protein degrader.

For more information, visit our website and follow us on LinkedIn and Twitter.

About zanubrutinib

Zanubrutinib is a small-molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated globally in a broad clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Zanubrutinib was specifically designed to deliver targeted and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, zanubrutinib has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease-relevant tissues.

Zanubrutinib is supported by a broad clinical program which includes more than 4,700 subjects in 35 trials in more than 30 geographies. To date, zanubrutinib (BRUKINSA®) is approved in over 60 markets, including the United States, China, the European Union, Great Britain, Canada, Australia, South Korea, Iceland, Norway and Switzerland.

About BeiGene

BeiGene is a global biotechnology company that is developing and commercializing innovative and affordable oncology medicines to improve treatment outcomes and access for far more patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more than 9,000 colleagues spans five continents, with administrative offices in Beijing, China; Cambridge, U.S.; and Basel, Switzerland. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

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 for PRT2527, the timing of reporting expected findings related to PRT2527, the potential benefits of Prelude's product candidates, alone or in combination, and the sufficiency of cash and cash equivalents to fund operating expenses and capital expenditures into the fourth quarter of 2024. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. 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, the impact of the COVID-19 pandemic on Prelude's business, clinical trial sites, 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 documents 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.

Investor Contact:
Lindsey Trickett
Vice President, Investor Relations
240.543.7970
ltrickett@preludetx.com

Media Contact:
Helen Shik
Shik Communications
617.510.4373
Helen@ShikCommunications.com