Prelude Therapeutics Announces Fourth Quarter and Full Year 2020 Financial Results and Provides Operational Update

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– Dose Escalation Portion of Phase 1 Trial of PRT543 Complete; Additional Expansion Cohorts Set to Initiate Early in the Second Quarter –

– Clinical Data Readouts Expected in 2H21 for Lead PRMT5 Inhibitors PRT543 and PRT811 –

– Phase 1 Dose-Escalation Study of Oral PRT1419 Ongoing –

– Preclinical Data from Multiple Programs to be Presented at the Upcoming 2021 AACR Annual Meeting –

WILMINGTON, Del., March 16, 2021 (GLOBE NEWSWIRE) -- Prelude Therapeutics Inc. ("Prelude", "the Company", "we", "our") (Nasdaq: PRLD), a clinical-stage precision oncology company, today announced its financial results for the fourth quarter and full year ended December 31, 2020 and provided an update on recent developments.

"2020 marked a highly transformational year for Prelude with the successful completion of an initial public offering and progress across our three clinical-stage programs," said Kris Vaddi, PhD, Chief Executive Officer of Prelude Therapeutics. "We are firmly committed to bringing novel therapies to patients in areas of high unmet need, and we have entered 2021 with both the momentum and resources that we believe will carry us through several key milestones. Notably, we are pleased to announce the completion of dose escalation activities in our ongoing Phase 1 trial of PRT543, our lead PRMT5 inhibitor, in patients with advanced solid tumors and hematologic malignancies, and that we will soon begin initiating additional expansion cohorts. We look forward to sharing clinical data for this program, as well as for our second PRMT5 inhibitor, PRT811, in the second half of this year."

Dr. Vaddi added, "The ongoing Phase 1 trial of our third clinical candidate, PRT1419, an MCL1 inhibitor, also continues to progress, with the addition of dose expansion cohorts expected in the second half of the year. Finally, the continued advancement of our preclinical programs remains a high priority for us in 2021, with the anticipated submission of an IND application for PRT2527, our CDK9 inhibitor, in the second half of this year."

Recent Highlights and Upcoming Milestones

PRT543

- **Phase 1 Dose Escalation Complete; Additional Expansion Cohorts to Open in the Second Quarter.** The Company today announced that the dose escalation portion of the Phase 1 trial of its lead product candidate, PRT543, is now complete, and that a recommended expansion dose with adequate safety, pharmacokinetics, and target engagement profile has been established. PRT543 is designed to be a potent, selective, and oral inhibitor of PRMT5. The dose expansion portion of the Phase 1 trial is currently open for the patient cohort with adenoid cystic carcinoma, and will be open for additional patient cohorts with solid tumor and hematologic malignancies early in the second quarter. As previously announced, preliminary data from the dose escalation portion of the trial demonstrated early signs of clinical activity and tolerability. The Company anticipates presenting initial clinical data from the Phase 1 trial at medical meetings in the second half of 2021.

- **Preclinical Data to be Featured at the 2021 AACR Annual Meeting.** Three preclinical presentations on PRT543 will be featured at the upcoming American Association for Cancer Research (AACR) Annual Meeting being held April 10-15, 2021 in a virtual setting. A copy of the posters, titled "PRMT5 inhibition downregulates MYB and NOTCH1 signaling, key molecular drivers of adenoid cystic carcinoma" (abstract 1138), "PRMT5 inhibition epigenetically regulates DNA damage response pathways in cancer cells and sensitizes to chemotherapy and PARP inhibition" (abstract 1185), and "PRMT5 inhibition regulates alternative splicing and DNA damage repair pathways in SF3B1 R625C expressing uveal melanoma cells" (abstract 1137), will be available in the Publications section of the Prelude Therapeutics website following the conclusion of the meeting.

PRT811

- **Phase 1 Dose Expansion Cohorts Expected to Commence in Mid-2021.** The dose escalation portion of the Company's Phase 1 trial of its second clinical product candidate, PRT811, which is designed to be a potent, selective, and brain penetrant PRMT5 inhibitor, in patients with advanced solid tumors, including glioblastoma multiforme (GBM), remains ongoing. As previously reported, the trial has demonstrated early signs of clinical activity and tolerability. Prelude remains on track to establish the recommended expansion dose and commence the dose expansion portion of the trial in mid-2021 in patients with central nervous system cancers including GBM, with initial clinical data expected by the end of 2021.

PRT1419

- **Oral Formulation: Dose Expansion and Combination Cohorts Expected to be Added to Ongoing Phase 1 Trial in the Second Half of 2021**. The dose escalation portion of the Company's first-in-human Phase 1 open-label, multicenter, dose-escalation study of oral PRT1419 in patients with relapsed/refractory hematologic malignancies, including acute myeloid leukemia and high-risk myelodysplastic syndromes, remains ongoing. PRT1419, which is the Company's third clinical candidate, is designed to be an orally available, potent, and selective MCL1 inhibitor. The Company expects to add dose expansion and combination cohorts to the Phase 1 clinical trial in the second half of 2021.

- **IV Formulation: IND Application Cleared.** Prelude today announced the recent U.S. Food and Drug Administration (FDA) clearance of the Company's Investigational New Drug (IND) application for an intravenous (IV) formulation of PRT1419. A Phase 1 trial of the IV formulation, which leverages the optimized physicochemical properties of PRT1419, is expected to commence in the first half of 2021 in patients with solid tumors.

- **Data on Preclinical Characterization to be Featured at the 2021 AACR Annual Meeting.** Data on the preclinical characterization of PRT1419 will be featured during a poster session at the 2021 AACR Annual Meeting. A copy of the poster, titled "Preclinical characterization of PRT1419, a potent, selective and orally available inhibitor of MCL1" (abstract 983), will be available in the Publication section of the Prelude Therapeutics website following the conclusion of the meeting.

Discovery Programs

- **Advancement of Earlier-Stage Candidates Expected in 2021.** Prelude remains on track to submit an IND application for PRT2527, which is designed to be a potent and selective CDK9 inhibitor, in 2021. The Company also continues to expect to initiate IND-enabling studies for PRT-SCA2, which is designed to be a SMARCA2 protein degrader, in 2021.

- **Preclinical Data on SMARCA2 Protein Degradation to be Featured at the 2021 AACR Annual Meeting.** A poster presentation on Prelude's SMARCA2 protein degradation program, titled "Potent SMARCA2 targeted degraders induce genetic synthetic lethality in SMARCA4 deleted cancer" (abstract 1139), will be presented at the 2021 AACR Annual Meeting. A copy of the poster will be available in the Publications section of the Prelude Therapeutics website following the conclusion of the meeting.

Corporate

- **Completed Successful Upsized Public Offering of $172.5 Million.** In January 2021, the

Company announced the closing of its upsized public offering of 2,583,334 shares of its voting common stock and 291,666 shares of its non-voting common stock, each at a public offering price of $60.00 per share, which includes the exercise in full of the underwriters' option to purchase an additional 375,000 shares of its voting common stock. The aggregate gross proceeds from this offering were $172.5 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by Prelude.

Fourth Quarter and Full Year 2020 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of December 31, 2020 were $218.3 million.

- **Research and Development (R&D) Expenses**: For the fourth quarter of 2020, R&D expense increased to $14.6 million from $8.8 million for the prior year period, and for the full year increased to $48.2 million compared to $24.3 million for 2019. The fourth quarter and full year increases were primarily due to increased clinical research costs for the PRT543 and PRT811 clinical trials and increased costs associated with the initiation of the clinical trial for PRT1419, which began in the third quarter of 2020. The Company also incurred an increase in chemistry, manufacturing, and other costs for those trials.

- **General and Administrative (G&A) Expenses**: G&A expenses for the fourth quarter of 2020 increased to $4.9 million from $1.2 million for the prior year period, and for the full year increased to $10.6 million compared to $3.8 million for 2019. The fourth quarter and full year increases were primarily due to an increase in personnel related expense due to increased employee headcount and an increase in professional fees as the Company expanded its operations to support R&D efforts and incurred additional costs associated with operating as a public company.

- **Net Loss:** For the fourth quarter of 2020, net loss was $19.3 million, or $0.45 per share, compared with a net loss of $10.0 million, or $5.56 per share, for the same period in 2019. Net loss for the year ended December 31, 2020 was $56.9 million, or $4.56 per share, compared with a net loss of $27.6 million, or $16.52 per share, for the year ended December 31, 2019.

- **Financial Guidance:** The Company believes that its current cash and cash equivalents will be sufficient to fund operating expenses and capital expenditure requirements into 2023.

About Prelude Therapeutics

Prelude Therapeutics is a clinical-stage precision oncology company developing innovative drug candidates targeting critical cancer cell pathways. The Company's lead product candidates are designed to be oral, potent, and selective inhibitors of PRMT5. Prelude's first clinical candidate, PRT543, is in Phase 1 development for advanced solid tumors and select myeloid malignancies. Prelude is also advancing PRT811, a second PRMT5 inhibitor optimized for high brain exposure, in a Phase 1 clinical trial including glioblastoma multiforme (GBM). The Company's pipeline also includes its third clinical candidate, PRT1419, an orally available MCL1 inhibitor in Phase 1 development for patients with relapsed/refractory hematologic malignancies, and its two most advanced preclinical candidates, PRT2527, a CDK9 inhibitor, and PRT-SCA2, a SMARCA2 protein degrader.

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 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.

	Year ended December 31,	
(in thousands, except share and per share data)	**2020**	**2019**
Operating expenses:		
Research and development	$ 48,177	$ 24,279
General and administrative	10,586	3,830
Total operating expenses	58,763	28,109
Loss from operations	(58,763)	(28,109)
Other income, net	1,834	539
Net loss	$ (56,929)	$ (27,570)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (4.56)	$ (16.52)
Weighted average common shares outstanding, basic and diluted	12,478,463	1,668,549

	December 31,	
(in thousands, except share and per share data)	**2020**	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 218,309	$ 18,879
Prepaid expenses and other current assets	2,500	1,345
Total current assets	220,809	20,224
Property and equipment, net	2,480	1,647
Deferred offering costs	301	—
Total assets	$ 223,590	$ 21,871
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Capital lease obligation	$ —	$ 258
Accounts payable	3,920	1,974
Accrued expenses and other current liabilities	7,455	2,603
Total current liabilities	11,375	4,835
Other liabilities	32	5
Total liabilities	11,407	4,840
Convertible preferred stock, $0.0001 par value:		
Series A convertible preferred stock: No shares and 13,574,008 shares authorized at December 31, 2020 and 2019, respectively; No shares and 11,736,119 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	36,595
Series B convertible preferred stock: No shares and 18,500,000 shares authorized at December 31, 2020 and 2019, respectively; No shares and 7,628,846 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	29,848
Series C convertible preferred stock: No shares authorized, issued or outstanding at December 31, 2020 and 2019	—	—
Total convertible preferred stock	—	66,443
Stockholders' equity:		
Voting common stock, $0.0001 par value: 487,149,741 and 42,000,000 shares authorized at December 31, 2020 and 2019, respectively; 32,595,301and 3,161,653 shares issued and outstanding at December 31, 2020 and 2019, respectively	3	—
Non-voting common stock, $0.0001 par value: 12,850,259 and no shares authorized at December 31, 2020 and 2019, respectively; 11,110,371 and no shares issued and outstanding at December 31, 2020 and 2019, respectively	1	—
Additional paid-in capital	319,605	1,085
Accumulated deficit	(107,426)	(50,497)
Total stockholders' equity (deficit)	212,183	(49,412)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 223,590	$ 21,871

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