Prelude Therapeutics Announces First Quarter 2021 Financial Results and Operations Update

May 11, 2021

- Enrollment Now Underway in Multiple Solid Tumor and Hematologic Malignancy Expansion Cohorts in Phase 1 Trial of Oral PRMT5 Inhibitor PRT543 -

- Initial Clinical Data Readouts for Lead Oral PRMT5 Inhibitors PRT543 and PRT811 Expected in 2H21 -

- Dose Escalation Ongoing in Phase 1 Trial of Oral MCL1 Inhibitor PRT1419, with Dose Expansion Cohorts on Track to be Added in 2H21 -

WILMINGTON, Del., May 11, 2021 (GLOBE NEWSWIRE) -- Prelude Therapeutics Inc. (Nasdaq: PRLD), a clinical-stage precision oncology company, today announced its financial results for the first quarter ended March 31, 2021 and provided an update on recent clinical and development pipeline progress.

"With several novel, internally discovered therapeutics now advancing in clinical trials, our pipeline products are off to a strong start in 2021 and we expect this momentum to carry us through multiple key inflection points," said Kris Vaddi, PhD, Chief Executive Officer. "We initiated numerous expansion cohorts for PRT543, our novel PRMT5 inhibitor, in the ongoing Phase 1 trial in patients with advanced solid tumors and hematologic malignancies. We expect to present initial clinical data for both PRT543 and PRT811, our brain penetrant PRMT5 inhibitor, in the second half of the year."

Dr. Vaddi added, "We continue to enroll the dose escalation portion of our Phase 1 trial of oral PRT1419, our MCL1 inhibitor, and plan to initiate dose expansion and combination cohorts in the second half of the year. Beyond our clinical pipeline, we remain focused on the advancement of our preclinical programs, and expect to submit an IND application for PRT2527, our CDK9 inhibitor, by year end. We are steadfast in our mission to develop novel therapeutic options for several cancers with high unmet need, and we look forward to providing updates on our continued progress as these programs mature."

Recent Highlights and Upcoming Milestones

PRT543

- **Enrollment Ongoing in Phase 1 Dose Expansion Cohorts.** Patient enrollment is underway in additional solid tumor and hematologic malignancy expansion cohorts of the Company's Phase 1 trial of PRT543, which is designed to be a potent and selective inhibitor of PRMT5. 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 Featured at the 2021 AACR Annual Meeting.** Three preclinical presentations on PRT543 were featured at the American Association for Cancer Research (AACR) Annual Meeting in April 2021. A copy of each poster is available in the Publications section of the Prelude Therapeutics website.

PRT811

- **Phase 1 Dose Expansion Cohorts Remain on Track to Begin 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, remains ongoing in patients with advanced solid tumors, including gliomas. As previously reported, the trial has demonstrated early signs of clinical activity and tolerability. Prelude remains on track to establish a recommended expansion dose and commence the dose expansion portion of the trial in mid-2021 in patients with central nervous system cancers, including glioblastoma multiforme (GBM), with initial clinical data expected by the end of 2021.

PRT1419

- **Oral Formulation: Planned 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 study of oral PRT1419 in patients with relapsed/refractory hematologic malignancies, including acute myeloid leukemia and high-risk myelodysplastic syndromes, is 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.

- **IND Application Cleared.** In March 2021, the Company announced that the U.S. Food and Drug Administration (FDA)

cleared its 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 coming months in patients with solid tumors.

- **Data on Preclinical Characterization Featured at the 2021 AACR Annual Meeting.** Data on the preclinical characterization of PRT1419 was featured at the AACR Annual Meeting in April 2021. A copy of the poster is available in the Publications section of the Prelude Therapeutics website.

Discovery Programs

- **Advancement of Earlier-Stage Candidates Expected in 2021.** The Company remains on track to submit an IND application in 2021 for PRT2527, which is designed to be a potent and selective CDK9 inhibitor. Prelude 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 Featured at the 2021 AACR Annual Meeting**. A poster presentation on the Company's SMARCA2 protein degradation program was featured at the AACR Annual Meeting in April 2021. A copy of the poster is available in the Publications section of the Prelude Therapeutics website.

First Quarter 2021 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of March 31, 2021 were $363.0 million.

- **Research and Development (R&D) Expenses**: For the first quarter of 2021, R&D expense increased by $7.9 million to $16.5 million. The increase was mainly 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 oral PRT1419, as well as preparation for the anticipated initiation of the Phase 1 trial for IV PRT1419 in the first half of 2021. We also incurred an increase in chemistry, manufacturing, and other costs for those trials.

- **General and Administrative (G&A) Expenses**: For the first quarter of 2021, G&A expense increased by $4.3 million to $5.5 million. The increase was primarily due to an increase in personnel related expense due to increases in employee headcount and an increase in the Company's professional fees as it expanded operations to support R&D efforts and incurred additional costs to operate as a public company.

- **Net Loss:** For the first quarter of 2021, net loss was $21.3 million, or $0.47 per share, compared with a net loss of $9.5 million, or $5.12 per share, for the same period in 2020.

- **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.

STATEMENTS OF OPERATIONS
(UNAUDITED)

(in thousands, except share and per share data)	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Operating expenses:		
Research and development	$ 16,470	$ 8,536
General and administrative	5,497	1,201
Total operating expenses	21,967	9,737
Loss from operations	(21,967)	(9,737)
Other income, net	667	226
Net loss	$ (21,300)	$ (9,511)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.47)	$ (5.12)
Weighted average common shares outstanding, basic and diluted	45,121,955	1,857,023

BALANCE SHEETS
(UNAUDITED)

(in thousands, except share data)	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 362,990	$ 218,309
Prepaid expenses and other current assets	2,028	2,500
Total current assets	365,018	220,809
Property and equipment, net	2,627	2,480
Right-of-use asset	2,186	—
Deferred offering costs	—	301
Total assets	$ 369,831	$ 223,590
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,842	$ 3,920
Accrued expenses and other current liabilities	6,179	7,455
Operating lease liability	1,403	—
Total current liabilities	12,424	11,375
Other liabilities	—	32
Operating lease liability	840	—
Total liabilities	13,264	11,407
Stockholders' equity:		
Voting common stock, $ par value: shares authorized; and shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	4	3
Non-voting common stock, $ par value; shares authorized; and shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	1	1
Additional paid-in capital	485,288	319,605
Accumulated deficit	(128,726)	(107,426)
Total stockholders' equity	356,567	212,183
Total liabilities and stockholders' equity	$ 369,831	$ 223,590

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