Protagonist Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Corporate Update

March 10, 2021

-- Regulatory guidance anticipated in the first half of 2021 for registrational clinical development plan of investigational drug, rusfertide (PTG-300), for polycythemia vera --

-- Company expects to share findings from ongoing hereditary hemochromatosis study for rusfertide (PTG-300) in the second half of 2021 --

-- Strong cash position to fund planned operations through the first half of 2024 --

-- Management to host conference call today at 4:30 p.m. EST --

NEWARK, Calif., March 10, 2021 /PRNewswire/ -- Protagonist Therapeutics, Inc. ("Protagonist" or the "Company") (Nasdaq: PTGX) today reported financial results and provided a corporate update for the fourth quarter and full year ended December 31, 2020.

"The year 2020 marked a significant period of growth for Protagonist as we focused on expanding the scope of our pipeline and advancing different development molecules in multiple clinical programs and indications," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "In December, we released compelling interim data from our ongoing Phase 2 trial with our most advanced candidate, rusfertide, which has received orphan drug designation and Fast Track designation for the treatment of polycythemia vera, a rare disease that affects about 100,000 treated patients in the U.S. alone. In the first half of 2021, we expect to complete our planned regulatory interactions and finalize the registrational clinical development plan, which represents an important turning point for the Company as rusfertide has the potential to become a new therapeutic treatment option for polycythemia vera patients. Continuing with the momentum of building our rusfertide portfolio, we expect to announce initial results of the hereditary hemochromatosis proof-of-concept trial in the second half of 2021 and select an additional indication for this candidate in 2021."

Dr. Patel added, "This past year, we continued to make progress with our ongoing 150-patient, Phase 2 IDEAL trial in ulcerative colitis with the gut-restricted alpha-4-beta-7 integrin blocker PN-943 and expect to complete this study in 2022. During the year, we also added two new clinical development stage assets to the ongoing oral IL-23 receptor antagonist program with our partner, Janssen. With a strong cash position through mid-2024, we look forward to focusing our capital to continue building value across our portfolio."

PRODUCT DEVELOPMENT AND CORPORATE UPDATE

Disorders of Red Blood Cells and Iron Regulation

Rusfertide (PTG-300)
Investigational, injectable, hepcidin mimetic discovered through our peptide technology platform. Hepcidin regulates iron homeostasis and controls the absorption, storage, and distribution of iron in the body. Rusfertide is currently being evaluated for disorders associated with iron overload and excessive erythrocytosis (red blood cell production).

- At the American Society of Hematology conference this past December, Protagonist presented updated data for 18 patients with polycythemia vera ("PV") treated with rusfertide in the ongoing Phase 2 study, which demonstrated dramatic decreases in the need for therapeutic phlebotomy by maintaining control over blood hematocrit levels.
- By mid-2021, Protagonist expects to complete enrollment of 50 patients for the ongoing Phase 2 study of rusfertide in low-risk and high-risk PV patients requiring frequent phlebotomy treatment.
- The Company is consulting with regulatory authorities on the registrational clinical development plan for rusfertide in PV in the first half of 2021.
- In December 2020, Protagonist released findings from a large-scale independent analysis of real-world data, which demonstrated that hematocrit levels are not adequately managed for a majority of PV patients on currently available treatment options, across broad categories, including both high-risk and low-risk patient groups.
- In December 2020, the U.S. Food and Drug Administration ("FDA") granted Fast Track designation to rusfertide for PV. In October 2020, the European Medicines Agency ("EMA") granted orphan drug designation to this candidate in the same indication. The FDA previously awarded rusfertide orphan drug designation in the U.S.
- Protagonist is expecting to announce preliminary results in the second half of 2021 from the ongoing Phase 2 open-label

proof-of-concept study of rusfertide in patients with hereditary hemochromatosis ("HH"); a disease affecting over a million people in the U.S. and with no approved therapies.
- Beyond PV and HH, the Company expects to select a third indication for rusfertide in 2021.
- During the first quarter of 2021, Protagonist initiated a new open-label Phase 2 study for rusfertide in PV patients with routinely elevated hematocrit levels (>48%).

Inflammatory Bowel Diseases

PN-943
Investigational, orally delivered, gut-restricted alpha-4-beta-7 specific integrin antagonist for inflammatory bowel diseases.

- The 150-patient Phase 2 study (the "IDEAL" study) evaluating the safety, tolerability and efficacy of PN-943 in patients with moderate to severe ulcerative colitis is underway and completion is expected in 2022.

Oral IL-23 Receptor Antagonists

PTG-200; PN-235; PN-232
Investigational, orally delivered, IL-23 receptor antagonists.

- In October 2020, Protagonist and Janssen announced two new, second-generation oral candidates, PN-235 and PN-232, to be developed as part of our joint oral IL-23 pathway blocker portfolio strategy. A Phase 1 study of PN-235 and a Phase 1 study of PN-232 are expected to be completed in the second half of 2021.
- The Phase 2A proof-of-concept study (the "PRISM" study) with the first-generation candidate PTG-200 for patients with moderate to severe Crohn's disease is continuing to enroll in 2021.

Financial Update

- During the fourth quarter of 2020, the Company raised approximately $115.0 million through an underwritten public offering of common stock where 5,476,189 shares were sold at a price to the public of $21.00 per share.
- The Company sold an additional 918,000 shares through its At-the-Market ("ATM") program during October 2020, raising $18.9 million at an average net price of $20.56 per share.
- Throughout 2020, Protagonist raised $255 million in capital, net expenses, through two public offerings and its ATM program.

Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities as of December 31, 2020 were $307.8 million. The Company expects current cash, cash equivalents and marketable securities and access to its debt facility to be sufficient to fund its planned operating and capital expenditures through first half of 2024.
- **License and Collaboration Revenue:** License and collaboration revenue was $5.7 million for the fourth quarter of 2020 compared to $2.7 million for the same period of 2019. The increase was primarily due to the additional services provided to Janssen under the collaboration agreement during 2020 related to PN-232 and PN-235. License and collaboration revenue for the full year 2020 was $28.6 million compared to $0.2 million for 2019. The increase that occurred in Protagonist's year over year revenue under the Janssen collaboration included: completion of additional services during 2020, primarily related to PN-232 and PN-235; an update to the forecast for remaining services to be completed under the collaboration, accelerating our overall percentage completion under the accounting performance obligation; and the previously reported 2019 one-time cumulative adjustment related to the application of revenue recognition principles following the May 2019 amendment of the Janssen collaboration agreement, which previously reduced revenue by $9.4 million during 2019.
- **Research and Development ("R&D") Expenses:** R&D expenses for the fourth quarter and full year 2020 were $19.5 million and $74.5 million respectively, as compared to $15.9 million and $65.0 million, respectively, for the same periods of 2019. The increases were primarily due to advancing our clinical trials with our pipeline assets rusfertide and PN-943, as well as all three of our IL-23 receptor antagonist assets under the Janssen collaboration (PTG-200, PN-235 and PN-232).
- **General and Administrative ("G&A") Expenses:** G&A expenses for the fourth quarter and full year 2020 were $5.0 million and $18.6 million, respectively, as compared to $4.1 million and $15.7 million for the same periods of 2019. The increases were primarily related to professional fees, insurance costs and employee compensation related expenses supporting the growth in our operations.
- **Net Loss:** The fourth quarter net loss was $18.9 million, or a net loss of $0.48 per share, and the full year 2020 net loss was $66.2 million, or a net loss of $1.92 per share, compared to the fourth quarter of 2019 net loss of $17.5 million, or a net loss of $0.63 per share, and the full year 2019 net loss was $77.2 million, or a net loss of $2.98 per share.

Conference Call and Webcast Information

To access the live call, dial 1-844-515-9178 (U.S./Canada) or 1-614-999-9313 (International) and refer to conference ID #: 7756175. A live webcast of the call will also be accessible on the Investors section of the Company's website at www.protagonist-inc.com. The replay will be available on the company's website approximately two hours after the call and will remain available for 60 days.

About Protagonist Therapeutics

Protagonist Therapeutics is a clinical stage biopharmaceutical company with multiple peptide-based new chemical entities in different stages of development. Rusfertide (PTG-300) is an injectable hepcidin mimetic in a Phase 2 proof-of-concept clinical trial for polycythemia vera, and a separate Phase 2 clinical study for hereditary hemochromatosis. PN-943 is an orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in a 150 patient Phase 2 study for the potential treatment of inflammatory bowel disease, with ulcerative colitis as the initial targeted indication. PTG-200 is an orally delivered, gut-restricted, interleukin-23 receptor specific antagonist peptide in a Phase 2 clinical trial for Crohn's disease. Two additional second-generation oral interleukin-23 receptor antagonist candidates PN-235 and PN-232, are in early stages of clinical development. The Company has developed a proprietary technology platform to discover and develop novel peptide-based therapeutics to address significant unmet medical needs and transform existing treatment paradigms.

Protagonist is headquartered in Newark, California. For further information, please visit www.protagonist-inc.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our intentions or current expectations concerning, among other things, the timing of our discussions with regulatory authorities, our expectations regarding enrollment in, and announcement of data from, our ongoing clinical trials and our plans to evaluate rusfertide for an additional indication. In some cases, you can identify these statements by forward-looking words such as "anticipate," "believe," "may," "will," "expect," or the negative or plural of these words or similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, our ability to develop and commercialize our product candidates, our ability to earn milestone payments under our collaboration agreement with Janssen, the impact of the current COVID-19 pandemic on our discovery and development efforts, our ability to use and expand our programs to build a pipeline of product candidates, our ability to obtain and maintain regulatory approval of our product candidates, our ability to operate in a competitive industry and compete successfully against competitors that have greater resources than we do, and our ability to obtain and adequately protect intellectual property rights for our product candidates. Additional information concerning these and other risk factors affecting our business can be found in our periodic filings with the Securities and Exchange Commission, including under the heading "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this press release.

PROTAGONIST THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(Amounts in thousands except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
License and collaboration revenue - related party	$ 5,650	$ 2,719	$ 28,628	$ 231
Operating expenses:				
Research and development [1]	19,486	15,911	74,506	65,003
General and administrative [1]	4,994	4,107	18,638	15,749
Total operating expenses	24,480	20,018	93,144	80,752
Loss from operations	(18,830)	(17,299)	(64,516)	(80,521)
Interest income	80	679	900	2,813
Interest expense	(127)	(167)	(598)	(169)
Loss on early repayment of debt	—	—	(585)	—
Other (expense) income, net	(9)	142	(46)	(1)

Loss before income tax (expense) benefit	(18,886)	(16,645)	(64,845)	(77,878)
Income tax (expense) benefit	—	(856)	(1,305)	691
Net loss	$ (18,886)	$ (17,501)	$ (66,150)	$ (77,187)
Net loss per share, basic and diluted	$ (0.48)	$ (0.63)	$ (1.92)	$ (2.98)
Weighted-average shares used to compute net loss per share, basic and diluted	39,605,193	27,610,696	34,396,446	25,894,024

(1) Amounts include non-cash stock-based compensation expense.

Stock-based Compensation
(In thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Research and development	$ 1,023	$ 1,113	$ 4,121	$ 4,350
General and administrative	944	1,047	3,778	4,003
Total stock-based compensation expense	$ 1,967	$ 2,160	$ 7,899	$ 8,353

PROTAGONIST THERAPEUTICS, INC.
Selected Consolidated Balance Sheet Data
(In thousands)

	December 31, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 307,809	$ 133,017
Working capital	275,365	109,905
Total assets	324,468	154,917
Long-term debt, net	—	9,794
Deferred revenue-related party	14,477	41,530
Accumulated deficit	(283,811)	(217,661)
Total stockholders' equity	279,606	79,964

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