Protagonist Therapeutics Reports Third Quarter 2018 Financial Results and Provides Corporate Update

November 6, 2018

-- Clinical, endoscopic, histologic and biomarker data are consistent with a dose-related clinical efficacy response of PTG-100 in the PROPEL Phase 2 ulcerative colitis study, providing support for PTG-100 as a well-tolerated, oral, gut-restricted alpha-4-beta-7-integrin-targeted therapy --

-- Safety, pharmacokinetic and pharmacodynamic Phase 1 data for oral IL-23 receptor antagonist PTG-200 (partnered with Janssen Biotech) support Phase 2 development in Crohn's disease --

-- Orphan Designation from European Medicines Agency granted to hepcidin mimetic PTG-300 for the treatment of beta-thalassemia, adding to Fast Track Designation and Orphan Drug Designation from U.S. FDA --

NEWARK, Calif., Nov. 6, 2018 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported its financial results for the third quarter ended September 30, 2018, and provided a corporate update on its clinical development programs.

"We are pleased to report continued progress from each of the three clinical programs evaluating differentiated and novel therapeutics enabled by our proprietary peptide engineering platform," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "We recently presented safety and efficacy data from the Phase 2 PROPEL study. Notably, these data show dose-dependent histologic remission in ulcerative colitis patients. The cumulative data for PTG-100, which now includes clinical, endoscopic, histologic and biomarker data, is supportive of the GI-restricted, oral targeted therapy approach for potential treatment of inflammatory bowel diseases."

"In addition, we recently announced successful completion of the Phase 1 clinical trial of the oral interleukin-23 receptor antagonist PTG-200. We are working closely with our partner Janssen Biotech to support the U.S. IND filing for a Phase 2 Crohn's trial in the coming months."

"Our hepcidin mimetic PTG-300 is on track for initiation of an open label, global, phase 2 trial in beta-thalassemia patients by year end. We are encouraged to note that PTG-300 now has Orphan Drug Designation both from the U.S. FDA and European Medicines agency, as well as Fast Track designation from the U.S. FDA for beta-thalassemia."

Product Development Update:

PTG-100

- Clinical data from the PROPEL Study presented at the recent United European Gastroenterology Week demonstrated that treatment with PTG-100, an oral, gut-restricted alpha-4-beta-7 integrin antagonist peptide, was well tolerated and associated with higher rates of clinical remission relative to placebo.
- The dose-dependent increase in rates of histologic remission, the blood biomarker data and topline safety data presented at the meeting expand upon the clinical remission and endoscopic response results announced previously in August 2018 that involved an independent, blinded re-read of endoscopies and had demonstrated signals of clinical efficacy.
- The totality of the data from the Phase 2 PROPEL study in UC patients provides first evidence of safety and clinical efficacy with an oral alpha-4-beta-7 integrin specific antagonist agent and supports further development of PTG-100.

PTG-200

- The Phase 1 study of PTG-200, an oral peptide IL-23 receptor antagonist partnered with Janssen Biotech, was successfully completed. Top-line results from this randomized, double-blind, placebo-controlled, single- and multiple-dose escalation study in 80 normal healthy volunteers demonstrated that PTG-200 treatment was well tolerated, with no serious adverse events or dose-limiting toxicities observed. Pharmacokinetic and pharmacodynamic parameters were consistent with the gastrointestinal-restricted design of PTG-200.
- Results from this study provide the first clinical data in support of PTG-200 and creates a path forward for its evaluation as a potential first-in-class oral IL-23 pathway based therapeutic for treatment of IBD.
- Protagonist and Janssen Biotech are working towards filing a U.S. IND in the coming months to support a Phase 2 clinical study in Crohn's disease patients.

PTG-300

- The Company remains on track to initiate a global Phase 2 clinical trial in beta-thalassemia patients in the fourth quarter of 2018.
- The U.S. FDA granted Fast Track Designation to PTG-300 for the treatment of chronic anemia due to ineffective erythropoiesis in patients with beta-thalassemia. This designation will facilitate the future development and expedite the review process of PTG-300.
- The European Medicines Agency granted Orphan Drug Designation to PTG-300 in the treatment of beta-thalassemia.

Orphan drug designation from the U.S. FDA had been previously granted for PTG-300 for potential treatment of beta-thalassemia. An orphan designation provides regulatory and financial incentives for development as well as certain benefits upon regulatory approval, if received.

Corporate Update – Financing:

- Protagonist announced the completion of a financing with investors including BVF Partners L.P. and their affiliates for gross proceeds of $22 million in August 2018. This enables the company to fund the development of its multiple clinical assets in diverse disease indications addressing unmet medical needs.

Financial Results

Protagonist reported a net loss of $8.7 million and $25.1 million, respectively, for the third quarter and first nine months of 2018, as compared to a net loss of $4.8 million and $33.9 million, respectively, for the same periods of 2017. The increase in net loss for the third quarter of 2018 as compared to the prior year period was driven primarily by a decrease in revenue under the Janssen Collaboration Agreement related to proportional performance as measured by actual costs incurred as a percentage of budgeted costs, and increases in research and development (R&D) and general and administrative (G&A) expenses. The decrease in net loss for the first nine months of 2018 as compared to the prior year period was driven primarily by an increase in revenue under the Janssen Collaboration Agreement, which became effective in the third quarter of 2017, partially offset by increases in R&D and G&A expenses. The net loss for the third quarter and first nine months of 2018 includes non-cash stock-based compensation of $2.0 million and $4.8 million, respectively, as compared to $1.2 million and $3.1 million, respectively, for the same periods of 2017.

R&D expenses for the third quarter and first nine months of 2018 were $12.1 million and $45.2 million, respectively, as compared to $11.2 million and $34.5 million, respectively, for the same periods of 2017. The increases in R&D expenses were primarily due to costs related to contract manufacturing and the preparation for and conduct of clinical trials for our product candidates. R&D expenses for the third quarter and first nine months of 2018 included increases in salaries and employee-related expenses due to an increase in R&D personnel.

G&A expenses for the third quarter and first nine months of 2018 were $3.4 million and $10.2 million, respectively, as compared to $2.6 million and $8.7 million, respectively, for the same periods of 2017. The increases in G&A expenses were primarily due to increases in salaries and employee-related expenses to support the growth of our operations.

Protagonist ended the third quarter with $138.5 million in cash, cash equivalents and investments. The company expects to have sufficient financial resources to fund operations to mid-2020.

About Protagonist Therapeutics, Inc.

Protagonist Therapeutics is a clinical stage biopharmaceutical company that utilizes a proprietary technology platform to discover and develop novel peptide-based drugs to transform existing treatment paradigms for patients with significant unmet medical needs. PTG-100 is an oral alpha-4-beta-7 integrin specific antagonist peptide that is under development for potential treatment of inflammatory bowel diseases. PTG-200 is an oral peptide interleukin-23 receptor antagonist in development for the treatment of Crohn's disease. The company has entered into a worldwide license and collaboration agreement with Janssen Biotech for the clinical development of PTG-200. Protagonist is also developing an injectable hepcidin mimetic, PTG-300, for the potential treatment of anemia and iron overload related to rare blood diseases with an initial focus on beta-thalassemia. The company has completed a Phase 1 clinical trial of PTG-300, which established safety/tolerability and pharmacodynamic-based clinical proof-of-concept in normal healthy volunteers. The U.S. Food and Drug Administration has granted Orphan Drug designation and Fast Track designation to PTG-300 for beta-thalassemia for which a global Phase 2 trial is to be initiated in the fourth quarter of 2018.

Protagonist is headquartered in Newark, California, with pre-clinical and clinical staff in California and discovery operations in both California and Brisbane, Queensland, Australia. For further information, please visit http://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 potential for our programs including PTG-100 and the initiation and availability of results of our clinical trials. 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, 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. We discuss many of these risks in greater detail under the heading "Risk Factors" contained in our quarterly report on Form 10-Q for the three months ended September 30, 2018, to be filed with the Securities and Exchange Commission. 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.
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**

License and collaboration revenue - related party	$ 6,117	$ 8,781	$ 28,572	$ 8,781
Operating expenses:				
Research and development	12,145	11,168	45,249	34,457
General and administrative	3,361	2,593	10,180	8,708
Total operating expenses	15,506	13,761	55,429	43,165
Loss from operations	(9,389)	(4,980)	(26,857)	(34,384)
Interest income	654	155	1,798	479
Net loss	$ (8,735)	$ (4,825)	$ (25,059)	$ (33,905)
Net loss per share, basic and diluted	$ (0.38)	$ (0.29)	$ (1.15)	$ (2.01)
Weighted-average shares used to compute net loss per share, basic and diluted	22,912,279	16,911,575	21,750,562	16,851,672

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

	September 30, 2018	December 31, 2017
Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities	$ 138,517	$ 155,459
Working capital	$ 123,401	$ 108,392
Total assets	$ 148,856	$ 163,734
Deferred revenue – related party	$ 7,970	$ 31,752
Accumulated deficit	$ (126,609)	$ (101,550)
Total stockholders' equity	$ 123,958	$ 120,632

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