

## PRESS RELEASE

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### Protagonist Therapeutics Initiates Phase 2 Study of Novel Hepcidin Mimetic PTG-300 in the Treatment of Patients with Polycythemia Vera

NEWARK, Calif., Oct. 30, 2019 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced that the first patient has been dosed in a Phase 2 study of PTG-300 in patients with polycythemia vera (PV), a myeloproliferative disorder characterized by overproduction of red blood cells.

"In addition to our ongoing study of PTG-300 in patients with beta-thalassemia, we are excited to expand its clinical development with the initiation of this proof-of-concept study in polycythemia vera," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "An important aspect of the mechanism of action of the hepcidin mimetic PTG-300 is to reduce iron availability, which is required to support the excessive erythropoiesis which occurs in PV, thereby potentially enabling PTG-300 to manage this excessive erythropoiesis and ultimately reduce the phlebotomy burden in these patients."

The Phase 2 study of PTG-300 in PV is designed to monitor the safety profile and to obtain preliminary evidence of efficacy in patients requiring phlebotomy. The study is expected to enroll approximately 30 patients and consists of a 16-week open-label dose escalation stage every 4 weeks from 10 mg to 80 mg and a 12-week maintenance period at doses which generate desired hematocrit levels followed by a 12-week randomized and blinded withdrawal stage. The study has an open-label extension for up to one year to monitor long term safety and benefits of the drug. The endpoints of this clinical proof-of-concept study include measurement of blood parameters (hematocrit and hemoglobin levels), reductions or delay in phlebotomy requirements, and improvements in quality-of-life symptoms. Additional information on the Phase 2 PTG-300 PV study is available at <https://clinicaltrials.gov/ct2/show/NCT04057040>.

#### **About PTG-300**

PTG -300 is an injectable hepcidin mimetic in clinical development for the potential treatment of beta-thalassemia and polycythemia vera. Hepcidin is a natural peptide hormone that regulates iron absorption and utilization in the body through sequestration and release from tissue macrophages and intestinal enterocytes. Iron plays an essential role in various body functions, especially blood formation. Excess iron in the body is toxic, resulting in bone marrow, tissue and organ damage over time. In settings of tissue iron overload and dysregulated erythropoiesis, treatment with PTG-300 can potentially reduce the need for phlebotomies, such as in the treatment of PV and hereditary hemochromatosis, and the need for transfusions and chelation therapies in thalassemia and MDS. PTG-300 has been granted Orphan Drug designation in the U.S. and EU and has received Fast Track designation from the U.S. Food and Drug Administration for development in the potential treatment of beta-thalassemia.

#### **About Protagonist Therapeutics, Inc.**


Protagonist Therapeutics is a clinical stage biopharmaceutical company that utilizes its proprietary peptide technology platform to discover and develop novel peptide-based drugs to transform existing treatment paradigms for patients with significant unmet medical needs. PTG-300 is an injectable hepcidin mimetic in

development for the treatment of iron overload anemia and related rare blood diseases. PTG-200 is an oral, gut-restricted interleukin-23 receptor specific antagonist peptide in clinical development for the potential treatment of inflammatory bowel disease. The Company has a worldwide license and collaboration agreement with Janssen Biotech for the clinical development of PTG-200 and a Phase 2 study in Crohn's disease is expected to begin in the fourth quarter of 2019. PN-943 is an oral, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in clinical development for the potential treatment of inflammatory bowel disease, with ulcerative colitis as the initial intended indication expected to commence in the first half of 2020.

Protagonist is headquartered in Newark, California. 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 of PTG-300 as a possible treatment for polycythemia vera and beta-thalassemia, the enrollment of patients in our clinical trials and the outlook for our other programs. In some cases, you can identify these statements by forward-looking words such as "will," "expect," "potential," 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. 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 Quarterly Report on Form 10-Q for the three and six months ended June 30, 2019, 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.

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