PRESS RELEASE

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Protagonist Therapeutics Initiates Phase 2 Trial of Novel Hepcidin Mimetic PTG-300 for the Treatment of Patients with Beta Thalassemia

-- Initial Phase 2 results expected in the second half of 2019 --

NEWARK, Calif., Jan. 9, 2019 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced that the first patient has been dosed in the Phase 2 study of PTG-300, an injectable hepcidin mimetic peptide in development for the treatment of patients with beta thalassemia, a rare disease characterized by chronic anemia and iron overload. The study is designed to evaluate the safety and preliminary efficacy of PTG-300 in patients with transfusion-dependent or non-transfusion-dependent beta thalassemia. In a completed Phase 1 study in healthy volunteers, administration of PTG-300 was well tolerated and demonstrated a dose-related and sustained reduction in serum iron levels.

"We are encouraged to move forward with clinical development of PTG-300 in patients with beta thalassemia," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "In addition to beta thalassemia, PTG-300 has broad potential in the treatment of other disorders, including hereditary hemochromatosis and the myeloproliferative neoplasms polycythemia vera and myelodysplastic syndrome. The Phase 2 trial incorporates an open label trial design and we expect to report initial results in the second half of 2019. We are actively evaluating additional disease indications for development of PTG-300 and plan to commence on a second indication in the second half of 2019."

The global Phase 2 study is a single-arm, open label, multiple-ascending dose design which will evaluate safety, proof-of-concept and dose finding in approximately 84 adolescent and adult patients with anemia associated with non-transfusion-dependent or transfusion-dependent beta thalassemia. Non-transfusion-dependent patients will receive 12 weeks treatment with PTG-300 in escalating dose cohorts. The primary efficacy endpoint in non-transfusion-dependent patients will be change in hemoglobin from baseline. Transfusion-dependent patients will receive 16 weeks treatment with PTG-300 in escalating dose cohorts. The primary efficacy endpoint in transfusion-dependent patients will be a change in transfusion burden from baseline.

About PTG-300

PTG-300 is an injectable hepcidin mimetic in clinical development for the potential treatment of beta thalassemia, a rare disease characterized by chronic anemia and iron overload. Hepcidin is a natural peptide hormone that is a critical regulatory hormone governing iron absorption, recycling and utilization by the body. Iron plays an essential role in various body functions, especially blood formation. Excess iron in the body is toxic, resulting in tissue and organ damage over time. Abnormally low hepcidin levels caused by genetic mutations or secondary pathology can be replaced by a hepcidin mimetic to restore iron homeostasis. PTG-300 has been granted Orphan Drug designation in the U.S. and EU and has received Fast Track designation by the FDA for development in the treatment of beta thalassemia. Treatment of patients with polycythemia vera, myelodysplastic syndromes and hereditary hemochromatosis represent additional opportunities for future development of PTG-300.

About Protagonist Therapeutics

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-300 is an injectable hepcidin mimetic for the potential treatment of anemia and iron overload related to rare blood diseases with an initial focus on beta thalassemia. 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. PN-943 is an oral, gut-restricted alpha-4-beta-7 integrin antagonist peptide in development for the treatment of inflammatory bowel disease.

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-300, and the timing of 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 enroll and complete our planned clinical trials, 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, 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.

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SOURCE Protagonist Therapeutics, Inc.

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