PRESS RELEASE

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Protagonist Therapeutics Initiates Phase 2 Study of Novel Hepcidin Mimetic PTG-300 in the Treatment of Patients with Hereditary Hemochromatosis

NEWARK, Calif., Jan. 6, 2020 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced that a Phase 2 study of its novel hepcidin mimetic PTG-300 in patients with hereditary hemochromatosis has been initiated. Hereditary hemochromatosis is a blood disorder that causes the body to absorb too much iron from the diet, resulting in the accumulation of iron in the body's tissues and organs, particularly in skin, heart, liver, pancreas and joint tissues.

"We are pleased to begin this clinical proof-of-concept study in hereditary hemochromatosis, expanding upon our ongoing studies of PTG-300 in beta-thalassemia and polycythemia vera," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "PTG-300 was discovered through the application of our technology platform and is designed to have better drug-like properties for use as a therapeutic in comparison to the natural hormone hepcidin. Hereditary hemochromatosis is a genetic disorder predominantly due to a mutation in the HFE gene leading to a deficiency of hepcidin in the body. Therefore, treatment of this disorder with the hepcidin mimetic PTG-300 could potentially serve as a hormone replacement therapy for these patients."

"Current treatments for hereditary hemochromatosis, including periodic phlebotomy, can be a significant burden to patients," commented Samuel Saks, M.D., Protagonist Chief Medical Officer. "PTG-300 could potentially reduce the need for phlebotomy and offer a safer and better long-term solution to management of the disease. Guidelines for hereditary hemochromatosis focus on controlling serum transferrin saturation (TSAT) and ferritin to prevent long-term complications. Given the TSAT reductions from PTG-300 observed to date in both healthy volunteers and beta-thalassemia patients, as well as regulation of organ iron content in a mouse model of hereditary hemochromatosis, we believe that a significant reduction in phlebotomy may be possible with PTG-300 treatment in patients with hereditary hemochromatosis."

This Phase 2 study of PTG-300 in hereditary hemochromatosis is an open label, multicenter study designed to evaluate the effects of PTG-300 over 24 weeks of treatment. The endpoints of this proof-of-concept study include change in TSAT and serum iron levels, reductions in phlebotomy requirements, and an assessment of participant-reported outcomes (SF-36 survey). Additional information on the PTG-300 hereditary hemochromatosis study is available at https://clinicaltrials.gov/ct2/show/NCT04202965.

About Hereditary Hemochromatosis

Hereditary hemochromatosis is a blood disorder caused by a deficiency of hepcidin hormone and is characterized by excessive iron accumulation in body tissues. There are approximately 1.3 million individuals diagnosed in the U.S. Current treatment involves phlebotomy, or removal of blood, at regular intervals. Accumulation of excess iron can cause restrictive cardiomyopathy, diastolic dysfunction, heart failure, cirrhosis, and other effects, including an increased risk for hepatocellular carcinoma.

About PTG-300

PTG-300 is an injectable hepcidin mimetic in clinical development for the potential treatment of beta-thalassemia, polycythemia vera (PV) and hereditary hemochromatosis (HH). 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 HH, and the need for transfusions and chelation therapies in thalassemia and myelodysplastic syndrome. 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 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 in development for the potential treatment of iron overload anemia and related rare blood diseases including beta-thalassemia, polycythemia vera and hereditary hemochromatosis. PTG-200 is an oral, gut-restricted interleukin-23 receptor specific antagonist peptide in Phase 2 clinical development for the potential treatment of inflammatory bowel disease, with Crohn's disease as the initial indication. The Company has 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 specific antagonist peptide in clinical development for the potential treatment of inflammatory bowel disease, with a Phase 2 ulcerative colitis study expected to commence in the second quarter 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 hereditary hemochromatosis, the Company's success at finding appropriate doses of PTG-300 for the treatment of hereditary hemochromatosis, the results of future studies for the treatment of hereditary hemochromatosis, the potential utility of PTG-300 in blood disorders including hereditary hemochromatosis, beta-thalassemia, and polycythemia vera, the possibility of treatment of hereditary hemochromatosis with PTG-300 as a hormone replacement therapy, the Company's ability to fund its clinical trials, the potential of PTG-300 to significantly reduce the need for phlebotomy for patients with hereditary hemochromatosis, the potential for PTG-300 to be a safer and better long-term solution to management of hereditary hemochromatosis, the initiation of and enrollment of patients in the Company's clinical trials, the results

of clinical trials and the outlook for our other programs. In some cases, you can identify these statements by forward-looking words such as "believe," "expect," "potential," "could," "possible," 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, and 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 quarterly period ended September 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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SOURCE Protagonist Therapeutics, Inc.

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