# Protagonist's Hepcidin Mimetic Candidate PTG-300 Receives Fast Track Designation from the U.S. Food and Drug Administration for Development in the Treatment of Polycythemia Vera

December 2, 2020

NEWARK, Calif., Dec. 2, 2020 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to PTG-300 in the treatment of polycythemia vera, a rare disease characterized by the excessive production of red blood cells. PTG-300 is an injectable synthetic peptide mimetic of the natural hormone hepcidin that has demonstrated the ability to dramatically decrease the requirement for phlebotomy in an ongoing Phase 2 study in polycythemia vera patients. PTG-300 has previously received orphan drug designation for the treatment of polycythemia vera from the U.S. FDA.

"Fast Track designation reflects the potential for PTG-300 to improve upon the treatments that are currently available for patients with polycythemia vera, and provides opportunities to substantially accelerate clinical development," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "We continue to enroll and treat patients in our ongoing Phase 2 study, with complete enrollment expected in mid-2021. We look forward to working closely with the FDA to discuss and finalize a pivotal program in the first half of 2021."

The FDA Fast Track Program is designed to facilitate the development and expedite the review of new therapeutics that are intended to treat serious conditions and that demonstrate the potential to address unmet medical needs. Drugs that receive this designation benefit from more frequent interactions and meetings with the FDA and potential pathways for expedited approval.

A Phase 2 study of PTG-300 in patients with polycythemia vera is currently enrolling subjects. Additional information is available at http://ptg300pvstudy.com/.

**About Polycythemia Vera**

Polycythemia vera is a myeloproliferative neoplasm characterized primarily by the increased production of red blood cells. Well-established treatment guidelines focus on maintaining hematocrit levels continuously below 45 percent to reduce the risk of thrombotic events. Unfortunately, current treatment options are unable to maintain hematocrit to below the 45 percent target for many patients and may be associated with serious side effects. There are an estimated 100,000 patients with polycythemia vera in the U.S. and approximately 100,000 patients in major EU countries.

**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 therapeutics to address significant unmet medical needs and transform existing treatment paradigms for patients. PTG-300 is an injectable hepcidin mimetic in development for the treatment of polycythemia vera and other blood disorders. PTG-200 is an orally delivered, gut-restricted, interleukin-23 receptor specific antagonist peptide in development for the treatment of inflammatory bowel disease, with Crohn's disease as the initial indication. In addition to PTG-200, two oral peptide interleukin-23 receptor antagonist candidates from a collaboration with Janssen Biotech, Inc., are in development and have been selected for advancement into clinical studies. PN-943 is an orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in development for the treatment of inflammatory bowel disease, with ulcerative colitis as the initial targeted indication.

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 potential of our product candidates to improve upon available therapies and our expectations regarding our interactions with regulatory authorities and the timing of the enrollment in our clinical trial. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

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SOURCE Protagonist Therapeutics, Inc.

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