Protagonist Therapeutics Announces Fast Track Designation Granted by U.S. FDA to Hepcidin Mimetic PTG-300

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- Designation applies to development for the treatment of chronic anemia in patients with beta-thalassemia -

NEWARK, Calif., Sept. 27, 2018 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to therapeutic candidate PTG-300 for the treatment of chronic anemia due to ineffective erythropoiesis in patients with beta-thalassemia. PTG-300 is an injectable hepcidin mimetic that has been granted Orphan Drug Designation by the FDA for beta-thalassemia, a rare disease characterized by iron overload.

"We are pleased to have received Fast Track designation for PTG-300 as recognition of its potential in beta-thalassemia, our initial area of focus and a rare disease with unmet medical need," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "We remain on track to initiate a Phase 2 clinical trial in beta-thalassemia patients by the end of the year. The Phase 2 trial incorporates an open label trial design with objective endpoints that will enable us to assess the performance of PTG-300 in an accurate and timely manner. In addition, the therapeutic mechanism of PTG-300 suggests potential for future development in the treatment of a broad range of blood disorders, including hereditary hemochromatosis and rare diseases such as polycythemia vera and myelodysplastic syndrome."

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.

About PTG-300 and Hepcidin

PTG-300, an injectable hepcidin mimetic, is currently 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 the main regulatory hormone governing iron absorption, recycling and utilization by the body. Iron plays an essential role in various body functions, especially blood formation, but too much iron 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 by the FDA for development in the treatment of beta-thalassemia. Treatment of patients with myelodysplastic syndromes, hereditary hemochromatosis and polycythemia vera represent additional opportunities for future development of PTG-300.

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 antagonist peptide that is under development for potential treatment of inflammatory bowel diseases. The company's interleukin-23 receptor antagonist peptide, PTG-200, is currently in a Phase 1 clinical trial in healthy volunteers to support a Phase 2 study in Crohn's disease. The IL-12/23 pathway blockade is an approach that has been validated through an FDA-approved injectable antibody drug. The company has entered into a worldwide license and collaboration agreement with Janssen Biotech for the clinical development of PTG-200. Protagonist has also applied its innovative peptide platform outside of gastrointestinal disease areas and is 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.

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, our research and development plans, the utility of our intellectual property, and the adequacy of our capital resources. In some cases, you can identify these statements by forward-looking words such as "anticipate," "believe," "may," "will," "would," or "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 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 June 30, 2018 as 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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