Press Releases

Protagonist Therapeutics Announces Final Phase 1 Study Results with Novel Hepcidin Mimetic, PTG-300

- Results demonstrate pharmacodynamic-based clinical proof of concept
- Studies in beta-thalassemia and myelodysplastic syndrome patients planned for 2018

NEWARK, Calif., Dec. 14, 2017 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq: PTGX) today announced final top-line results from the randomized, placebo-controlled, single ascending- and repeat-dose Phase 1 study of PTG-300, the company's injectable hepcidin mimetic peptide, in normal healthy volunteers.

The results, which included the successful completion of the study extension to include two additional dose cohorts, confirm the previously announced preliminary data showing the ability of PTG-300 to achieve a dose-related and sustained effect on iron distribution based on reduction in serum iron and transferrin saturation. PTG-300 treatment was well-tolerated, with no serious adverse events or dose-limiting toxicities reported. The most common adverse events were localized and transient injection site reactions in some subjects.

"We are very pleased with the positive results from this initial safety, pharmacokinetic and pharmacodynamic (PD) study of PTG-300 in normal healthy volunteers," said Richard S. Shames, M.D., Protagonist Therapeutics Chief Medical Officer. "These results clearly demonstrate PD-based clinical proof-of-concept (POC) for PTG-300. They also set the stage for further discussions with the Health Authorities in early 2018, regarding our Investigational New Drug (IND) application and ex-U.S. clinical trial applications to initiate global trials of PTG-300 in patients with beta-thalassemia and myelodysplastic syndrome (MDS)."

About Hepcidin and Anemia/Iron Overload Diseases

PTG-300, an injectable hepcidin mimetic, is currently in clinical development for the potential treatment of beta-thalassemia and MDS, rare diseases characterized by chronic anemia and iron overload. PTG-300 therapy may also be beneficial in other diseases such as hereditary hemochromatosis, polycythemia vera, siderophilic infections, and liver fibrosis which provide

opportunities for further development. Hepcidin is a 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 and causes organ damage over time. Abnormally low hepcidin levels, caused by genetic mutations or secondary pathology, can result in the body absorbing and storing more iron than is needed, leading to iron overload.

About Protagonist Therapeutics

Protagonist Therapeutics is a clinical-stage biopharmaceutical company with a proprietary technology platform which is utilized to discover and develop novel peptide-based drugs to address significant unmet medical needs. Its primary focus is on developing potential first-in-class, oral targeted therapy-based peptide drugs that work by blocking biological pathways that are currently targeted by marketed injectable antibody drugs. Protagonist's initial lead peptide product candidates, PTG-100 and PTG-200, are based on this approach, and the company believes these candidates have the potential to transform the existing treatment paradigm for inflammatory bowel disease (IBD), consisting primarily of ulcerative colitis and Crohn's disease.

PTG-100, a potential first-in-class oral peptide alpha-4-beta-7 integrin antagonist, is currently in a global Phase 2B clinical trial for the treatment of moderate-to-severe ulcerative colitis. PTG-200, a potential first-in-class oral Interleukin-23 receptor antagonist in development for the treatment of IBD, initially Crohn's disease, has entered a Phase 1 clinical trial. Protagonist has entered into a worldwide agreement with Janssen Biotech, Inc. to co-develop and commercialize PTG-200 for all indications, including IBD.

In addition to PTG-100 and PTG-200, the company is developing an injectable hepcidin mimetic PTG-300 for the potential treatment of anemia and iron overload disorders, including rare diseases such as beta-thalassemia and MDS. PTG-300 has now completed a Phase 1 clinical trial.

Protagonist is headquartered in Newark, California with its pre-clinical and clinical staff in California, and discovery operations both in California and in 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 collaborations, the initiation and availability of results of our clinical trials, research and development and capital resources. 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 history of net operating losses, our reliance on third parties and uncertainty regarding our ability to achieve profitability, 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 quarter ended September 30, 2017 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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Joan Kureczka, Kureczka/Martin Associates, Tel: +1 415-821-2413, Email: Joan@Kureczka-martin.com, OR For Investors: The Trout Group, Marcy Nanus, Tel: +1 646-378-2927, Email: mnanus@troutgroup.com