Press Releases

Protagonist Therapeutics Initiates Phase 1 Study with Novel Hepcidin Mimetic, PTG-300

-- PTG-300 for Potential Treatment of Iron Overload in Rare Diseases --

NEWARK, Calif., May 25, 2017 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq: PTGX) today announced that the company has initiated a Phase 1 clinical study of PTG-300 in normal healthy volunteers. PTG-300 is an injectable hepcidin mimetic peptide discovered using the company's proprietary technology platform, and it is being developed as a potential treatment for patients with chronic iron overload in rare diseases such as beta-thalassemia.

Hepcidin is a principal regulator of iron homeostasis in humans, and low levels of hepcidin may be associated with iron overload-related diseases such as thalassemia, myelodysplastic syndrome, and hereditary hemochromatosis. Iron overload can damage target organs and tissues including the bone marrow, liver, and heart leading to increased risks of anemia, liver disease, heart attack, heart failure, diabetes, and premature death. Beta-thalassemia is a rare, inherited blood disorder characterized by an underproduction of hemoglobin that affects nearly 15,000 people in the United States with greater prevalence in the rest of the world.

"We are pleased with the pre-clinical data for PTG-300, which has showed efficacy in a beta-thalassemia mouse model and demonstrated a dose-dependent reduction in serum iron levels across three different healthy animal species," stated Dinesh V. Patel, Ph.D., President and Chief Executive Officer, Protagonist Therapeutics. "The initiation of this study marks the progression of Protagonist's second drug candidate into clinical development, and we remain on track to have three different assets in our clinical pipeline by the end of 2017."

The Phase 1 single ascending dose study will evaluate the safety, tolerability, and pharmacokinetics of PTG-300 in normal healthy volunteers. In addition, the effect of PTG-300 on baseline serum iron levels will be analyzed to evaluate pharmacodynamics-based clinical proof-of-concept. The company expects to report results from this trial in the fourth quarter of 2017.

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), chronic gastrointestinal diseases 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 moderate-to-severe ulcerative colitis. PTG-200, a potential first-in-class oral Interleukin-23 receptor antagonist for potential treatment of IBD, initially Crohn's disease, is currently in pre-clinical development and is expected to enter Phase 1 clinical studies in the second half of 2017.

In addition to PTG-100 and PTG-200, the company is developing an injectable hepcidin mimetic PTG-300 as a potential orphan drug for the treatment of rare diseases such as beta-thalassemia. PTG-300 is currently being studied in 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, the timing of initiation and availability of results of our clinical trials, enrollment in our clinical trials, our capital resources, the possibility of obtaining orphan drug designation, and the potential for eventual regulatory approval of our product candidates. In some cases, you can identify these statements by forward-looking words such as "anticipate," "believe," "may," "will," "continue," "expects," "potential," 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 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 March 31, 2017, filed with

the Securities and Exchange Commission on May 10, 2017. 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/protagonist-therapeutics-initiates-phase-1-study-with-novel-hepcidin-mimetic-ptg-300-300463683.html

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