Press Releases

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

-- PTG-300 demonstrates pharmacodynamic-based proof of concept in normal healthy volunteers --

NEWARK, Calif., Sept. 20, 2017 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq: PTGX) today announced preliminary results from the Phase 1 study of PTG-300 in normal healthy volunteers. PTG-300 is an injectable hepcidin mimetic peptide, discovered using the company's proprietary technology platform. Protagonist is developing PTG-300 as a potential treatment for patients with ineffective erythropoiesis in rare diseases such as beta-thalassemia and myelodysplastic syndromes (MDS).

The Phase 1 randomized, placebo-controlled single ascending- and repeat-dose study is being conducted to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of PTG-300 in 62 normal healthy male volunteers. The study includes five cohorts of subjects in single ascending doses ranging from 1 mg to 40 mg, administered by subcutaneous injection.

Preliminary data following completion of these five single-dose cohorts indicates PTG-300's ability to achieve a dose-related reduction in serum iron, which persists beyond 72 hours at higher dose levels. This effect provides pharmacodynamic-based proof-of-concept for PTG-300 in healthy male volunteers. PTG-300 showed a dose-dependent increase in blood exposure, and was well tolerated, with no serious adverse events or dose-limiting toxicities. The most common adverse event was a transient and self-limited erythema (redness) at the injection site in some subjects at 10 mg or higher doses.

"Based on this encouraging data, we have amended the study to include two additional cohorts of an 80 mg single dose and a 40 mg dose for two weekly doses. These cohorts will further enhance the evaluation of the PK-PD effects and tolerability of PTG-300. We expect to report final top line results of the amended study in the fourth quarter of 2017," said Richard Shames, M.D., Chief Medical Officer at Protagonist.

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. 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. Such damage to the bone marrow, liver, and heart leads to the increased risks of ineffective erythropoiesis-induced anemia, liver disease, heart attack, heart failure, diabetes, and premature death. 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 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 a Phase 1 clinical study before the end of 2017. The company recently announced it has entered into a worldwide collaboration with Janssen Biotech 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 treatment of rare diseases such as beta-thalassemia and myelodysplastic syndromes (MDS). 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 initiation and availability of results of our clinical trials, enrollment in our clinical trials, 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 "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 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. 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 June 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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