Press Releases

Protagonist Therapeutics Initiates Phase 1 Trial of Oral Peptide IL-23 Receptor Antagonist, PTG-200

-- Novel Drug Candidate, Licensed to Janssen Biotech, Enters Development as Potential 'Oral Targeted Therapy' for Inflammatory Bowel Disease --

NEWARK, Calif., Nov. 9, 2017 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq: PTGX) today announced the initiation of dosing in a Phase I healthy volunteer study of PTG-200, a potential first-in-class, gastrointestinal-restricted, oral peptide interleukin (IL)-23 receptor antagonist. PTG-200 works by blocking the IL-23 pathway, a mechanism that has been targeted by currently marketed injectable antibody treatments for inflammatory bowel disease (IBD) and other autoimmune conditions.

"We are very pleased to initiate this first-in-human trial of PTG-200," said Richard S. Shames, M.D., Protagonist Therapeutics Chief Medical Officer. "There remains a significant need for novel improved therapies in inflammatory bowel disease. An oral treatment could offer significant advantages, including improved patient convenience and compliance, and the potential for improved safety and tolerability."

"The initiation of the first human study of PTG-200 is an important step forward in our collaboration with Janssen around this asset," said Dinesh Patel, Ph.D., Protagonist President and Chief Executive Officer. "Protagonist started the year with one drug candidate in clinical development, and we are now ending 2017 with three assets in clinical development, all of which emerged from our innovative peptide technology platform."

The Phase 1 study, which is being conducted in Australia, is a randomized, double-blind, placebo-controlled, single and multiple dose-escalation trial in approximately eighty healthy volunteers. The study will be conducted in three parts: single-ascending doses of PTG-200; multiple ascending doses; and a single dose cross-over, comparing tablet to capsule formulations of PTG-200. Primary endpoints for the study are safety and tolerability of PTG-200. Secondary endpoints include the identification of the maximally tolerated dose and evaluation of pharmacokinetic and pharmacodynamic parameters.

Protagonist is developing PTG-200 in collaboration with Janssen Biotech, Inc. (Janssen), which has licensed the worldwide rights to PTG-200 for all indications including IBD.

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, is currently being studied in 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 in iron overload disorders, including rare diseases such as beta-thalassemia and 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, 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 "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 reliance on third parties, 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, and our ability to effectively conduct clinical trials 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, For Investors: The Trout Group, Marcy Nanus, Tel: +1 646-378-2927, Email: mnanus@troutgroup.com