PRESS RELEASE

<< Back

View printer-friendly version

Protagonist Therapeutics Announces New Development Candidate PN-10943 for the Treatment of Inflammatory Bowel Disease

-- Oral, gut-restricted alpha-4-beta-7 integrin antagonist peptide PN-10943 has demonstrated greater potency and target engagement in preclinical studies as compared to PTG-100 --

-- Phase 1 study of PN-10943 to begin in December 2018; pharmacodynamic readouts of blood receptor occupancy expected in the first half of 2019 --

-- PN-10943 to replace PTG-100 in clinical development for inflammatory bowel disease; Company's cash runway extended by additional six months to end of 2020 --

NEWARK, Calif., Nov. 27, 2018 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced that the Company plans to begin clinical development of PN-10943, an oral, gut-restricted alpha-4-beta-7 integrin antagonist peptide for the treatment of inflammatory bowel disease (IBD). In preclinical studies, PN-10943 has demonstrated superior properties to PTG-100 as measured by *in vitro* potency, target engagement based on *in vivo* pharmacodynamic (PD) readouts of blood receptor occupancy (%RO) and effects on T cell trafficking, and efficacy in disease models of colitis. The Company is replacing PTG-100 with PN-10943 as a development candidate for the treatment of IBD based on an assessment of preclinical data from PN-10943 and recent feedback from global regulatory authorities on further development of PTG-100.

"Because of the strength of our peptide technology platform, we have had the flexibility to discover and evaluate PN-10943 as a backup peptide with improved drug characteristics over PTG-100," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "Based on the superiority of PN-10943 in preclinical studies and recent feedback from the FDA requesting an additional Phase 2 dose range finding study with PTG-100, advancing PN-10943 into clinical development as a replacement for PTG-100 is the most efficient allocation of resources for the Company with minimal impact on overall development timelines. We expect to begin a Phase 1 study of PN-10943 in healthy volunteers by the end of 2018, with results of the study expected in the first half of 2019. The safety, pharmacokinetic (PK) and PD data from this study will be used to design a Phase 2a study for PN-10943 in patients with ulcerative colitis."

"Development of PN-10943 will enable us to incorporate knowledge and experience acquired from our prior studies with PTG-100, which has provided early evidence of safety and preliminary efficacy with an oral, gut-restricted alpha-4-beta-7 integrin antagonist peptide approach in patients with ulcerative colitis. Having achieved this clinical proof-of-concept with PTG-100, we are now able to execute on this validated approach with the more potent peptide PN-10943. In addition, replacing PTG-100 in our pipeline provides greater financial flexibility by now extending our cash runway to fund operations by an additional six months to the end of 2020. This projection assumes the receipt of a potential $25M milestone payment from Janssen and does not include other potential

milestone payments. From an overall portfolio perspective, with our other assets besides PN-10943, we expect to advance PTG-200 in a Phase 2 Crohn's study with Janssen, and to obtain POC data in patients with PTG-300 before the end of 2020."

The planned PN-10943 Phase 1 study will be a randomized, double-blind, placebo-controlled, dose escalation (100, 300, 1000 and 1400 mg) trial in normal healthy volunteers. The first part of the study consists of single ascending doses of PN-10943. The second part of the study will involve the administration of PN-10943 over 14 consecutive days in escalating dose cohorts. Primary endpoints for the study are safety and tolerability of PN-10943. Secondary endpoints include evaluation of PK and PD parameters of %RO.

A corporate update including a brief summary of preclinical data of PN-10943 in comparison to PTG-100 and key milestones for all development assets in the pipeline (PN-10943, PTG-200 and PTG-300) will be provided on a conference call hosted by Protagonist. Additional details from preclinical studies of PN-10943 will be presented at a future medical conference.

Conference Call and Webcast Information

Protagonist executives will host a conference call and webcast with slides available at 4:30 p.m. ET/1:30 p.m. PT today. To access the live call, dial 1-844-515-9178 (U.S./Canada) or 1-614-999-9313 (international) and refer to conference ID number 1173975. The call will also be webcast and will be accessible from "Events & Presentations" in the Investors section of the company's website at www.protagonist-inc.com. A replay will be available on the company's website approximately two hours after the call and will remain available for 60 days.

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-200 is an oral peptide interleukin-23 receptor antagonist in development for the treatment of Crohn's disease, and it has completed Phase 1 studies in healthy volunteers. The company has entered into a worldwide license and collaboration agreement with Janssen Biotech for the clinical development of PTG-200. PN-10943 is an oral, gut-restricted alpha-4-beta-7 integrin antagonist peptide that is under development for treatment of ulcerative colitis. Protagonist is also 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. A global Phase 2 trial in beta-thalassemia patients will be initiated by the end of 2018.

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 including PN-10943, the timing of the initiation and availability of results of our clinical trials and our potential milestone payment receipt and cash runway. 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 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 three months ended September 30, 2018, 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.

View original content to download multimedia:http://www.prnewswire.com/news-releases/protagonist-therapeutics-announces-new-development-candidate-pn-10943-for-the-treatment-of-inflammatory-bowel-disease-300756297.html

SOURCE Protagonist Therapeutics, Inc.

Solebury Trout, Rich Allan (media), Tel: +1 646-378-2958, Email: rallan@troutgroup.com or Marcy Nanus (investors), Tel: +1 646-378-2927, Email: mnanus@soleburytrout.com