

## PRESS RELEASE

[<< Back](#)

[View printer-friendly version](#)

### Protagonist Therapeutics Announces First Patient Dosed in a Phase 2 Study of Oral IL-23 Receptor Antagonist PTG-200 (JNJ-67864238) in the Treatment of Crohn's Disease

**-- Clinical efficacy results for the Janssen Collaboration Asset are expected in 2021 --**  
NEWARK, Calif., Nov. 6, 2019 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced that the first patient has been dosed in a Phase 2 study of PTG-200 (also referenced as JNJ-67864238) in patients with moderate to severe Crohn's disease. PTG-200 is an oral, gut-restricted, interleukin-23 receptor (IL-23R) antagonist for the potential treatment of inflammatory bowel diseases. Protagonist Therapeutics and Janssen Research & Development are jointly conducting the development of PTG-200 through completion of Phase 2 clinical proof of concept in the treatment of Crohn's disease.



"We are pleased to be progressing PTG-200 in collaboration with Janssen in a Phase 2 study in patients with Crohn's disease," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "We believe this gut-restricted oral therapy may offer meaningful advantages over injectable therapeutics currently available for Crohn's disease and other inflammatory bowel diseases. We look forward to results from this study in 2021."

The global, randomized, double blind, placebo-controlled, Phase 2 study is evaluating the efficacy of oral administration of PTG-200 in 90 patients with moderate to severe Crohn's disease. The study will assess the effect of twice-daily dosing of PTG-200 on change from baseline in Crohn's Disease Activity Index (CDAI) score at week 12 as the primary endpoint. The study will also assess change from baseline in simple endoscopic score for Crohn's disease (SES-CD), rates of clinical response and remission, endoscopic response and remission, and patient-reported outcome (PRO)-2 remission. Additional information on the PTG-200 Crohn's disease study is available at <https://clinicaltrials.gov/ct2/show/NCT04102111>.

According to the terms of the development agreement between Protagonist and Janssen Research & Development, Janssen will be responsible for further development and commercialization activities beyond Phase 2 development. Protagonist is eligible to receive over \$1 billion in research, development, regulatory and sales milestone payments related to PTG-200 and related compounds and has an option to co-detail PTG-200 and related compounds in the U.S. market.

#### **About PTG-200 (JNJ-67864238)**

PTG-200 is an oral peptide interleukin-23 receptor (IL-23R) antagonist being co-developed with Janssen, for the treatment of inflammatory bowel disease and is initially in development for the treatment of patients with Crohn's disease. PTG-200 is designed to offer choices to patients in addition to injectable antibody

therapeutics that target the IL-23 pathway, including the potential for improved safety and tolerability and better compliance compared to therapeutics administered by injection.

Results from a Phase 1 randomized, double blind, placebo-controlled, single- and multiple-dose escalation trial in healthy volunteers demonstrated that PTG-200 was well tolerated, with pharmacokinetic measures consistent with the gut-restricted design of PTG-200.

### **About Protagonist Therapeutics, Inc.**

Protagonist Therapeutics is a clinical stage biopharmaceutical company that utilizes its proprietary peptide technology platform to discover and develop novel peptide-based drugs to transform existing treatment paradigms for patients with significant unmet medical needs. PTG-300 is an injectable hepcidin mimetic in development for the treatment of iron overload anemia and related rare blood diseases. PTG-200 is an oral, gut-restricted interleukin-23 receptor specific antagonist peptide in clinical development for the potential treatment of inflammatory bowel disease. The Company has a worldwide license and collaboration agreement with Janssen Research & Development for the clinical development of PTG-200. PN-943 is an oral, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in clinical development for the potential treatment of inflammatory bowel disease, with ulcerative colitis as the initial intended indication expected to commence in the first half of 2020.

Protagonist is headquartered in Newark, California. 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 new debt facility, intentions or current expectations concerning, among other things, future financing activities, achievement of clinical development milestones and the availability of results of our clinical trials. In some cases, you can identify these statements by forward-looking words such as "expect," "will," "intend," "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 ability to achieve certain clinical development milestones and other specified conditions and our ability to develop and commercialize our product candidates. Additional information concerning these and other risk factors affecting our business can be found in our periodic filings with the Securities and Exchange Commission, including under the heading "Risk Factors" contained in our Quarterly Report on Form 10-Q for the three and six months ended June 30, 2019, 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.

 View original content to download multimedia:<http://www.prnewswire.com/news-releases/protagonist-therapeutics-announces-first-patient-dosed-in-a-phase-2-study-of-oral-il-23-receptor-antagonist-ptg-200-jnj-67864238-in-the-treatment-of-crohns-disease-300953227.html>

SOURCE Protagonist Therapeutics, Inc.

Solebury Trout, Rich Allan (media), Tel: +1 646-378-2958, Email:  
rallan@soleburytrout.com; Brian Korb (investors), Tel: +1 646-378-2923, Email:  
bkorb@soleburytrout.com