Protagonist Therapeutics Announces First Subject Dosed in Phase 1 Study of Oral IL-23 Receptor Antagonist PN-232

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NEWARK, Calif., May 24, 2021 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced that the first human subject has been dosed in a Phase 1 study of PN-232, a novel oral interleukin-23 receptor (IL-23R) antagonist peptide. This study is designed to determine the safety, tolerability, and pharmacokinetics of PN-232 in healthy volunteers. Recruitment for the study is ongoing.

"PN-232 is a second-generation, oral, IL-23 receptor antagonist candidate currently being developed in collaboration with Janssen Research & Development, LLC," said Dinesh V. Patel, Ph.D., President and Chief Executive Officer at Protagonist. "Today's announcement marks another step forward in our joint efforts to discover and develop novel oral treatment regimens for diseases that are moderated by intervention on the IL-23 pathway. Our joint efforts have now led to three different oral IL-23 antagonists: PTG-200, PN-235, and PN-232."

This Phase 1 study is designed to determine the safety, tolerability, and pharmacokinetics of PN-232 in healthy volunteers. It is a first-in-human study for PN-232 that will be conducted in three parts. Part 1 is a single ascending dose study, Part 2 is multiple ascending dose study, and Part 3 is crossover solid dose comparison and effect-of-food study. More complete information on the study is available at https://clinicaltrials.gov/ct2/show/NCT04819620.

Protagonist and Janssen Biotech, Inc., have a research, co-development and commercialization agreement for IL-23 receptor targeted therapeutics with applications in various disease areas. According to the agreement, Janssen will be responsible for development and commercialization activities of compound candidates beyond Phase 2. Protagonist is eligible to receive research, development, regulatory and sales milestone payments and has an option to co-detail products in the U.S. market.

About Protagonist Therapeutics
Protagonist Therapeutics is a biopharmaceutical company with multiple peptide-based investigational new chemical entities in different stages of development, all derived from the Company's proprietary technology platform.

Protagonist-developed compounds currently include rusfertide (PTG-300), an investigational, injectable hepcidin mimetic in a Phase 2 proof-of-concept clinical trial for polycythemia vera, and a separate Phase 2 clinical study for hereditary hemochromatosis. Based on the feedback provided by the FDA and EU regulatory authorities, the Company plans to initiate a single, global Phase 3 randomized, placebo-controlled trial evaluating the efficacy and safety of a once weekly, subcutaneously self-administered dose of rusfertide. Additionally, PN-943 is an investigational orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide currently in a Phase 2 study for the potential treatment of inflammatory bowel disease, with ulcerative colitis as the initial targeted indication.

The Company has a worldwide license and collaboration agreement with Janssen Biotech, Inc., for the development of oral peptide IL-23 receptor antagonists. Compounds included in this agreement are PTG-200, PN-235 and PN-232. PTG-200 is an orally delivered, gut-restricted, interleukin-23 receptor specific antagonist peptide in a Phase 2 clinical trial for Crohn's disease. PN-235 and PN-232, both second-generation oral interleukin-23 receptor antagonist candidates, are in Phase 1 studies.

Protagonist is headquartered in Newark, California. For further information, please visit 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, our expectations regarding the timing of clinical trial collaborations with Janssen, for example. 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 agreements, the impact of the current COVID-19 pandemic on our discovery and development efforts, 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. 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 year ended March 31, 2021, 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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