Protagonist Therapeutics Announces First Subject Dosed in Phase 1 Study of Oral IL-23 Receptor Antagonist PN-235 (JNJ-77242113)

December 16, 2020

-- Safety, tolerability and pharmacokinetics results expected in 2021 --

NEWARK, Calif., Dec. 16, 2020 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced that the first subject has been dosed in a Phase 1 study of PN-235 (also referenced as JNJ-77242113), an oral interleukin-23 receptor (IL-23R) antagonist peptide. The study is designed to determine the safety, tolerability and pharmacokinetics of PN-235 in approximately 100 healthy volunteers. PN-235 is being developed as part of a portfolio strategy of discovering and developing oral IL-23 receptor antagonists as part of an ongoing collaboration with Janssen Biotech, Inc.

"PN-235 is the first second-generation, oral, IL-23 receptor antagonist candidate as part of our research collaboration with Janssen to enter clinical development and was discovered through the application of the Protagonist peptide technology platform," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "We are extremely pleased with the success of our collaborative efforts, and see significant potential for multiple indications with orally delivered therapeutics that act by targeting the well-validated IL-23 pathway. We expect Phase 1 results in 2021."

The PN-235 Phase 1 study will be conducted in three parts: a single ascending dose, a multiple ascending dose, and a randomized, crossover solid dose comparison part. The primary endpoint is safety as measured by number and severity of adverse events. Secondary outcomes include pharmacokinetics measurements of peak concentration (Cmax) of and area under the curve (AUC). Information on the study is available at https://clinicaltrials.gov/ct2/show/NCT04621630.

Protagonist and Janssen have established a co-development and commercialization agreement for IL-23 receptor targeted therapeutics with applications in various disease areas. According to the terms of the agreement, Janssen will be responsible for further development and commercialization activities of candidates beyond Phase 2 development. 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, Inc.

Protagonist Therapeutics is a clinical stage biopharmaceutical company that utilizes a proprietary technology platform to discover and develop novel peptide-based therapeutics to address significant unmet medical needs and transform existing treatment paradigms for patients. PTG-300 is an injectable hepcidin mimetic in development for the treatment of polycythemia vera and other blood disorders. PTG-200 is an orally delivered, gut-restricted, interleukin-23 receptor specific antagonist peptide in development for the treatment of inflammatory bowel disease, with Crohn's disease as the initial indication. In addition to PTG-200, two oral peptide interleukin-23 receptor antagonist candidates are in development and have been selected for advancement into clinical studies. PN-943 is an orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in development for the treatment of inflammatory bowel disease, with ulcerative colitis as the initial targeted indication.

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, the potential of our product candidates to improve standards of care, our ability to fund operations into future periods, and our expectations regarding the timing of the initiation of clinical trials. 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, 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 quarter ended September 30, 2020, 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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