Protagonist Therapeutics Completes Enrollment for Phase 2 Study of Rusfertide in Polycythemia Vera and Announces Plans for Data Update at an Upcoming Medical Meeting

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-- Rapid completion of Phase 2 enrollment signals further momentum for the development of rusfertide in polycythemia vera --

NEWARK, Calif., April 27, 2021 /PRNewswire/ -- Protagonist Therapeutics, Inc. ("Protagonist" or the "Company") (Nasdaq: PTGX), today announced the completion of enrollment for the Company's Phase 2 study of rusfertide (PTG-300) in polycythemia vera ("PV"). Enrollment easily exceeded the targeted 50 evaluable patients for the study. Those patients eligible for enrollment, but unable to participate in the Phase 2 study, will have the opportunity to enroll in the planned upcoming Phase 3 study, which was announced in March 2021.

The Company will provide an interim update on the Phase 2 study at a major medical meeting in the second quarter of 2021. The Phase 2 study of rusfertide in PV consists of an open-label dose finding phase, followed by a blinded withdrawal phase and an open-label extension. Preliminary data from the Phase 2 study indicated rusfertide's potential to maintain hematocrit to target levels per guidelines set by the National Comprehensive Cancer Network ("NCCN"). PV patients face a higher risk of thrombotic events, including heart attack and stroke, when hematocrit levels are not maintained at target levels.

"The completion of enrollment for this Phase 2 study marks a significant milestone on the path to the full development of rusfertide in polycythemia vera, and we look forward to sharing the latest developments at a major medical conference in the coming months," said Sam Saks, M.D., Chief Medical Officer at Protagonist. "We are encouraged by the promising data generated thus far, and by the positive engagement of global regulatory agencies with respect to the pivotal Phase 3 study, which we plan to initiate in early 2022."

"We extend our sincerest thanks to the patients, investigators, and partners who have made the rapid achievement of this milestone possible," said Dinesh Patel, PhD, Protagonist's President and Chief Executive Officer. "The high level of interest and momentum that have characterized our enrollment process to date are reflective of the severity of the unmet need in polycythemia vera and the potential benefit of rusfertide as a novel, natural hormone mimetic-based non-cytoreductive therapy for this indication. We are well positioned to rapidly advance our Phase 2 and 3 studies of rusfertide in polycythemia vera, mindful of its potential to address and fulfill unmet needs in this challenging rare disease."

About Protagonist Therapeutics

Protagonist Therapeutics is a clinical stage biopharmaceutical company with multiple peptide-based investigational new chemical entities in different stages of development. Rusfertide (PTG-300) is 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 of a once weekly, subcutaneously self-administered dose of rusfertide.

PN-943 is an investigational orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in a 150 patient Phase 2 study for the potential treatment of inflammatory bowel disease, with ulcerative colitis as the initial targeted indication. PTG-200 is an orally delivered, gut-restricted, interleukin-23 receptor specific antagonist peptide in a Phase 2 clinical trial for Crohn's disease. Two additional second-generation oral interleukin-23 receptor antagonist candidates, PN-235 and PN-232, are in early stages of clinical development. The Company has developed a proprietary technology platform to discover and develop novel peptide-based therapeutics to address significant unmet medical needs and transform existing treatment paradigms. Protagonist is headquartered in Newark, California. For further information, please visit www.protagonist-inc.com.

About Polycythemia Vera

Polycythemia vera is a myeloproliferative neoplasm characterized primarily by the increased production of red blood cells. Well-established treatment guidelines focus on maintaining hematocrit levels continuously below 45 percent to reduce the risk of thrombotic events. Unfortunately, current treatment options are unable to maintain hematocrit to below the 45 percent target for many patients and may be associated with serious side effects. The prevalence of polycythemia vera is approximately 44 to 57 patients per 100,000 people in the U.S. The prevalence rate in Europe is similar.

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 plans to conduct a Phase 3 trial evaluating rusfertide for PV. 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, 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 Annual Report on Form 10-K for the year ended December 31, 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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