

PRESS RELEASE

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Protagonist Therapeutics Announces Completion of Phase 1 Clinical Trial of Oral IL-23 Receptor Antagonist PTG-200

-- Results in normal healthy volunteers provide safety, pharmacokinetic and pharmacodynamic data --

NEWARK, Calif., Nov. 6, 2018 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today announced top-line results from the Phase 1 study of PTG-200, an oral peptide interleukin-23 receptor antagonist, in 80 normal healthy volunteers. Results of the randomized, double-blind, placebo-controlled, single- and multiple-dose escalation study demonstrated that administration of PTG-200 was well-tolerated. No serious adverse events or dose-limiting toxicities were observed. The pharmacokinetic and pharmacodynamic parameters were consistent with the gastrointestinal-restricted design of PTG-200.



"Results from this study provide the first clinical data in support of PTG-200 and creates a path forward for its evaluation as a potential first-in-class oral IL-23 pathway based therapeutic for treatment of IBD," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "An oral drug targeting the IL-23 pathway would be a novel addition to the oral targeted therapy treatment landscape while building upon proven injectable therapeutic agents that work through similar validated mechanisms for IBD. We look forward to working towards a U.S. IND filing with our collaboration partner Janssen Biotech in the coming months."

About PTG-200

PTG-200 is an oral peptide interleukin-23 receptor (IL-23R) antagonist being co-developed with Janssen Biotech, Inc., initially for the treatment of patients with Crohn's disease. PTG-200 is designed to offer advantages over 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.

A Phase 1 randomized, double-blind, placebo-controlled, single- and multiple-dose escalation trial in eighty healthy volunteers has been completed at a single site in Australia. The study was conducted in two parts: single-ascending doses and multiple ascending doses of PTG-200.

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-100 is an oral alpha-4-beta-7 integrin antagonist peptide that is under development for potential treatment of inflammatory bowel diseases. PTG-200 is an oral peptide interleukin-23 receptor antagonist in development for the treatment of Crohn's disease. The company has entered into a worldwide license and collaboration agreement with Janssen

Biotech for the clinical development of PTG-200. 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. The company has completed a Phase 1 clinical trial of PTG-300, which established safety/tolerability and pharmacodynamic-based clinical proof-of-concept in normal healthy volunteers. The U.S. Food and Drug Administration and EMA have granted Orphan Drug Designation to PTG-300 for beta-thalassemia for which a global Phase 2 trial is to be initiated in the fourth quarter of 2018. Treatment of patients with myelodysplastic syndromes, hereditary hemochromatosis and polycythemia vera represent additional opportunities for future development of PTG-300.

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, our research and development plans, the utility of our intellectual property, and the adequacy of our capital resources. In some cases, you can identify these statements by forward-looking words such as "anticipate," "believe," "may," "will," "would," or "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 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 June 30, 2018 as 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.

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