Protagonist Therapeutics Discontinues Phase 2b PROPEL Trial of PTG-100 for the Treatment of Ulcerative Colitis following Interim Analysis

March 26, 2018

Protagonist to host conference call today at 5:00 am PT/8:00 am ET

NEWARK, Calif., March 26, 2018 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq: PTGX) today announced that the Company is discontinuing the Phase 2b PROPEL study of PTG-100, its investigational oral GI-restricted alpha-4-beta-7 integrin antagonist peptide, in patients with moderate to severe ulcerative colitis (UC). This decision followed a planned interim analysis by an independent Data Monitoring Committee (DMC) of unblinded efficacy and safety data from the first 65 patients from the ongoing 240 patient trial who had completed the 12 week treatment with PTG-100. Using pre-specified criteria, the DMC deemed the trial to be futile based on an analysis of the primary endpoint of clinical remission. No safety concerns were noted in the analysis.

Based on the DMC's recommendation received after the market close on Friday, and while further review of the data is being conducted, Protagonist is notifying PROPEL trial investigators that randomization of potential participants and further treatment of patients currently in the study will be discontinued. Additionally, the Company will postpone its decision about the initiation of a Phase 2/3 clinical trial of PTG-100 in chronic pouchitis until after its full review of the interim data from the UC PROPEL study.

"We are very disappointed with this futility-based outcome which was also accompanied by an unexpectedly high placebo rate. We will conduct an extensive review of the complete dataset on the totality of patients enrolled in the trial before making any further decisions about the future development of PTG-100," said Dinesh V. Patel, Ph.D., President and Chief Executive Officer of Protagonist Therapeutics. "We are very grateful to the patients and investigators who participated in the PROPEL trial. Protagonist remains committed to progressing its other peptide-based assets currently in clinical development, PTG-200 and PTG-300, and to discovering new peptide-based therapeutic entities to address significant unmet medical needs."

About the Phase 2b PROPEL Trial

The Phase 2b *PROPEL* trial is a global, randomized, double-blind, placebo-controlled, two-stage adaptive clinical trial to assess the safety, efficacy, and dose-optimization of three doses (150mg, 300mg, or 900mg) of PTG-100 compared to placebo for 12 weeks in patients with moderate to severe ulcerative colitis. The primary efficacy endpoint of the study is the proportion of patients who achieve clinical remission as defined by rectal bleeding, stool frequency, and endoscopic subscores of the Mayo score.

Conference Call and Webcast Information

Protagonist executives will host a conference call at 5:00 a.m. PT/8:00 a.m. ET today. To access the live call, dial 1-844-515-9178 (U.S./Canada) or 1-614-999-9313 (international) and refer to conference ID number 4883118. The call will also be webcast and will be accessible from "Events & Presentations" in the Investors section of the company's website at www.protagoinst-inc.com. A replay will be available on the company's website approximately two hours after the call and will remain available for 90 days.

About Protagonist Therapeutics

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 was being developed for inflammatory bowel diseases (IBD). The company's interleukin-23 receptor antagonist peptide, PTG-200, is currently being studied in a Phase 1 clinical trial in healthy volunteers to support further development in Crohn's disease. The IL-12/23 pathway blockade is an approach that has been validated through an FDA-approved injectable antibody drug. The company has entered into a worldwide license and collaboration agreement with Janssen Biotech for the clinical development of PTG-200. Protagonist has also applied its versatile platform outside of the GI disease areas and is developing an injectable hepcidin mimetic, PTG-300, for the treatment of anemia related to rare blood diseases with an initial focus on beta-thalassemia. PTG-300 recently completed a Phase 1 clinical trial, which established pharmacodynamic-based clinical proof-of-concept in normal healthy volunteers. The U.S. Food and Drug Administration has granted Orphan Drug Designation to PTG-300 for beta-thalassemia.

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.

View original content with multimedia:http://www.prnewswire.com/news-releases/protagonist-therapeutics-discontinues-phase-2b-propel-trial-of-ptg-100-for-the-treatment-of-ulcerative-colitis-following-interim-analysis-300619191.html

SOURCE Protagonist Therapeutics, Inc.

Bioscribe, Inc., Michelle Linn, Tel: +1 774-696-3803, Email: Michelle@Bioscribe.com, For Investors: The Trout Group, Marcy Nanus, Tel: +1 646-378-2927, Email: mnanus@troutgroup.com