Phathom Pharmaceuticals Provides Clinical Trial Status Update

June 15, 2020

First New Patients Randomized in PHALCON-EE and PHALCON-HP Trials Since Temporary Pause Announced in March

FLORHAM PARK, N.J., June 15, 2020 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today announced that it has randomized the first new patients in each of its two Phase 3 clinical trials since temporarily pausing new patient randomization in response to the COVID-19 pandemic.

"We are pleased to have resumed enrollment and randomization of new patients in our PHALCON-EE and PHALCON-HP Phase 3 studies of vonoprazan that we temporarily paused in March due to the COVID-19 pandemic," said Azmi Nabulsi, MD, Chief Operating Officer of Phathom. "Utilizing relevant practice guidelines, our teams have been working closely with our investigators to determine the timing of individual trial sites to safely resume screening and randomization of new patients in our PHALCON studies. We are encouraged by the eagerness and readiness of these sites to enroll new patients into our programs and are excited to continue to advance the clinical development of vonoprazan."

In March, Phathom temporarily paused new patient randomization in its PHALCON-EE and PHALCON-HP clinical trials. The decision was not based on any study-related COVID-19 infections or other safety events but rather was in support of global efforts to combat the spread of the SARS-CoV-2 coronavirus. During the temporary pause, Phathom worked closely with sites to ensure patients who were already enrolled and randomized in the PHALCON-EE and PHALCON-HP studies could remain safely in the trial with as little disruption as possible. Phathom has not experienced any interruptions to clinical trial supply, including manufacturing and the overall supply chain.

Phathom continues to closely monitor the COVID-19 situation and, at this time, continues to expect to provide top-line data from the PHALCON-EE and PHALCON-HP trials in 2021.

About Vonoprazan
Vonoprazan is an oral small molecule potassium-competitive acid blocker (P-CAB). P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown the potential to have rapid, potent, and durable anti-secretory effects as a single agent in the treatment of gastroesophageal reflux disease (GERD) and in combination with antibiotics for the treatment of Helicobacter pylori (*H. pylori)* infection. The U.S. Food and Drug Administration (FDA) has designated vonoprazan as a qualified infectious disease product (QIDP) and awarded Fast Track status for the treatment of *H. pylori* infection in combination with both amoxicillin and clarithromycin and with amoxicillin alone. Phathom in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda, which completed 18 Phase 3 trials for vonoprazan and received marketing approval in 13 countries in Asia and Latin America.

About PHALCON-EE
PHALCON-EE is a randomized, double-blind, two-phase, multicenter Phase 3 trial that is planned to enroll approximately 1,000 patients with erosive esophagitis (EE) in the U.S. and Europe. The first phase of the trial is evaluating the efficacy and safety of vonoprazan 20 mg administered once-daily (QD) compared to lansoprazole 30 mg QD for the healing of EE for up to eight weeks. The second phase of the trial is evaluating the efficacy and safety of vonoprazan 10 mg QD and 20 mg QD compared to lansoprazole 15 mg QD for the maintenance of healing of EE for 24 weeks. Both phases are also evaluating heartburn symptoms.

About PHALCON-HP
PHALCON-HP is a randomized, multicenter, Phase 3 trial that is planned to enroll approximately 975 patients with *H. pylori* infection in the U.S. and Europe. Participants are being randomized 1:1:1 to one of three arms: vonoprazan 20 mg administered twice a day (BID) and amoxicillin 1g administered three times a day (TID); vonoprazan 20 mg BID, amoxicillin 1 g BID and clarithromycin 500 mg BID; and lansoprazole 30 mg BID, amoxicillin 1 g BID and clarithromycin 500 mg BID. Each treatment regimen is being administered for 14 days. PHALCON-HP is evaluating the percentage of patients with successful eradication of *H. pylori* infection.

About Phathom
Phathom Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases and disorders. Phathom has in-licensed the exclusive rights in the United States, Europe, and Canada to vonoprazan, a novel potassium competitive acid blocker (P-CAB) in late-stage development for the treatment of acid-related disorders. For more information about Phathom, visit the company's website at www.phathompharma.com or follow the Company on LinkedIn at www.linkedin.com/company/phathompharma.

Forward Looking Statements
Phathom cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the expected availability of vonoprazan to be delivered to clinical trial sites; the potential to receive regulatory and exclusivity benefits as a result of QIDP and Fast Track designations; and when we expect to provide topline data for the Phase 3 clinical trials of vonoprazan. The inclusion of forward-looking statements should not be regarded as a representation by Phathom that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Phathom's business, including, without limitation: the rate of patient enrollment in PHALCON-EE and PHALCON-HP which, due to the COVID-19 pandemic, is highly uncertain due to factors outside our control; potential additional delays in the commencement, enrollment and completion of clinical trials; patients already enrolled in PHALCON-EE and PHALCON-HP may not complete the clinical trials or public health conditions and governmental restrictions may lead us to stopping such trials all

together, which may adversely impact our trial results and development plans; our dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of vonoprazan that may limit its development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; QIDP and Fast Track designations may not actually lead to a faster development or regulatory review or extended exclusivity, and would not assure FDA approval of vonoprazan; our ability to obtain and maintain intellectual property protection for vonoprazan; our ability to comply with our license agreement with Takeda; our ability to maintain undisrupted business operations due to the recent spread of the COVID-19 coronavirus, including delaying or otherwise disrupting our clinical trials, manufacturing and supply chain, and other risks described in the company's prior press releases and the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's Annual Report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Phathom undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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