Phathom Pharmaceuticals Announces Completion of Patient Enrollment in Pivotal Phase 3 Helicobacter pylori (H. pylori) Trial

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- **Topline results expected in second quarter of 2021**
- **NDA submission for *H. pylori* expected in second half of 2021**

FLORHAM PARK, N.J., Jan. 19, 2021 (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 completed patient enrollment in PHALCON-HP, a pivotal Phase 3 clinical trial of vonoprazan in combination with amoxicillin (vonoprazan dual therapy) and vonoprazan in combination with amoxicillin and clarithromycin (vonoprazan triple therapy) for the eradication of *H. pylori* infection. Phathom continues to expect topline results from the study in the second quarter of 2021.

PHALCON-HP is a randomized, multicenter, Phase 3 trial that has enrolled over 1,000 patients with *H. pylori* infection. Participants are evenly randomized 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 1g BID and clarithromycin 500 mg BID; and lansoprazole 30 mg BID, amoxicillin 1g BID and clarithromycin 500 mg BID. Each treatment regimen is administered for 14 days. The primary endpoint is the percentage of patients with successful eradication of *H. pylori* infection.

“The completion of patient enrollment in the PHALCON-HP trial marks another significant milestone for Phathom and for the millions of people with *H. pylori* infection. In the U.S. and Europe, one-in-three adults are believed to carry *H. pylori*, which, if left untreated, can lead to dyspeptic symptoms, ulcers, and gastric cancer. These regions are experiencing declining *H. pylori* eradication rates due to increasing antibiotic resistance which we believe can be addressed with more potent inhibition of gastric acid. Our ability to enroll patients in the PHALCON-HP trial during a pandemic highlights the demand for new therapeutic regimens to combat this chronic bacterial infection,” said Azmi Nabulsi, M.D., Phathom’s Chief Operating Officer. “Phathom greatly appreciates the commitment and execution of our investigators and clinicians involved in PHALCON-HP and thanks all our patient volunteers for their participation.”

PHALCON-HP is one of two Phase 3 trials evaluating vonoprazan in gastrointestinal diseases. The second trial, PHALCON-EE, is a randomized, double-blind, two-phase, multicenter trial evaluating vonoprazan in the treatment of erosive esophagitis (EE). Patient enrollment in PHALCON-EE was completed in November 2020 with topline results expected in the second half of 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 as a qualified infectious disease product (QIDP) and awarded Fast Track status to vonoprazan 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 19 Phase 3 trials for vonoprazan and received marketing approval in Japan and numerous other countries in Asia and Latin America.

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 social media: LinkedIn at www.linkedin.com/company/phathompharma and Twitter @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 topline results from the PHALCON-EE and PHALCON-HP Phase 3 clinical trials; the expected submission of a New Drug Application for the eradication of *H. pylori* infection, and the potential to receive regulatory and exclusivity benefits as a result of QIDP and Fast Track designations. 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: potential additional delays in the commencement, enrollment and completion of clinical trials due to the COVID-19 pandemic and other factors outside of Phathom’s control; patients already enrolled in PHALCON-EE and PHALCON-HP may not complete the clinical trials or public health conditions and governmental restrictions may lead Phathom to stop such trials all together, which may adversely impact its trial results and development plans; Phathom’s 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; Phathom’s ability to obtain and maintain intellectual property protection for vonoprazan; Phathom’s ability to comply with its license agreement with Takeda; Phathom’s ability to maintain undisrupted business operations due to the ongoing spread of the COVID-19

coronavirus, including delaying or otherwise disrupting its 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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