Phathom Pharmaceuticals Announces New Data at ACG 2021 Annual Scientific Meeting

October 24, 2021

- Data from Phase 3 PHALCON-HP trial highlighted in oral presentation and recognized with the ACG Governors Award for Excellence in Clinical Research
- Phase 1 population PK data abstract concludes the large body of pre-existing clinical data related to vonoprazan in Asian populations can be reliably applied to non-Asian populations
- Real-world physician and patient-based Study of Acid-Related Disorders (SOARD) provides perceptions of disease burden and highlights unmet needs in the treatment of *H. pylori* and erosive esophagitis

FLORHAM PARK, N.J., Oct. 24, 2021 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, announced today data from the PHALCON-HP Phase 3 study, the largest U.S. registrational trial ever conducted for *H. pylori,* will be presented during an oral session at the ACG 2021 Annual Scientific Meeting organized by the American College of Gastroenterology, in Las Vegas, Nevada, Oct. 22-27. In advance of the oral presentation, the abstract was selected as the recipient of the ACG Governors Award for Excellence in Clinical Research.

PHALCON-HP showed that both vonoprazan in combination with amoxicillin and clarithromycin (vonoprazan triple therapy) and vonoprazan in combination with amoxicillin (vonoprazan dual therapy) demonstrated superior eradication rates in all patients compared to a current standard of care therapy consisting of the proton pump inhibitor (PPI), lansoprazole, in combination with amoxicillin and clarithromycin.

“Eradication rates with PPI-based triple therapy for *H. pylori* infection has been declining over the last two decades, mainly due to increased resistance to antibiotics,” said Professor William D. Chey, M.D., AGAF, FACG, FACP, Professor of Medicine and Director of the GI Physiology Laboratory at Michigan Medicine. “This study demonstrated meaningfully enhanced eradication rates for these vonoprazan regimens versus a standard of care PPI-based triple therapy and highlighted the potential for a new antibiotic-sparing dual therapy treatment option.”

In the primary endpoint analyses of the PHALCON-HP study comparing the non-inferiority of vonoprazan-based therapies to lansoprazole triple therapy in patients with *H. pylori* without strains resistant to antibiotics, eradication rates with vonoprazan triple therapy and vonoprazan dual therapy were 84.7% ($p<0.0001$) and 78.5% ($p=0.0037$), respectively, compared to 78.8% for lansoprazole triple therapy. In the secondary endpoint analyses comparing the superiority of vonoprazan-based therapies to lansoprazole triple therapy in all patients, eradication rates with vonoprazan triple therapy and dual therapy were 80.8% ($p=0.0001$) and 77.2% ($p=0.0063$), respectively, compared to 68.5% for lansoprazole triple therapy. Both vonoprazan-based regimens were generally well tolerated with a safety profile comparable to lansoprazole-based triple therapy in the trial.

“These data support the potential of both vonoprazan triple and dual therapies, if approved, as new treatment options for *H. pylori* and reinforce Phathom’s commitment to changing the landscape for acid-related diseases,” said Azmi Nabulsi, M.D., Chief Operating Officer at Phathom. “We’ve recently submitted our NDAs for vonoprazan in *H. pylori*, and we continue to advance our research into the clinical profile of vonoprazan and its impact on acid suppression.”

During the meeting, Dr. Colin Howden, MD, AGAF, FACG, Professor Emeritus, University of Tennessee College of Medicine will also present a poster on a study evaluating the population pharmacokinetic (PK) model of vonoprazan. The study analyzed data from 1,156 patients to determine the effects of race and disease status on the PK impacts of vonoprazan exposure. The study concluded that patient race (Asian vs. non-Asian) and disease state (healthy volunteers vs. GERD patients) did not affect vonoprazan exposure in a clinically meaningful way.

Phathom is also presenting results from the Study of Acid-Related Disorders (SOARD) which explored perceptions of disease burden for *H. pylori* and erosive esophagitis among physicians and patients. Physicians completed an online survey recording treatment goals, preferences, satisfaction, and perceived disease burden. A subset completed chart review data of patients with *H. pylori* and dyspepsia or erosive esophagitis who had received a PPI as part of their treatment. The same patients completed a survey capturing data on treatment goals, satisfaction, and adherence. In this study, only 29% of physicians strongly agreed that they were satisfied with current *H. pylori* treatment options and 57% of patients stated they were not completely satisfied. When it came to erosive esophagitis, 84% of patients wanted long-lasting treatment options while only 44% considered their current therapy a long-lasting solution for their disease. The study uncovered many unmet

needs from the perspective of both physicians and patients in the treatment of *H. pylori* and erosive esophagitis suggesting that new treatment options are needed.

A full list of Phathom-sponsored abstracts at ACG 2021 include:

- **A Population Pharmacokinetic Model of Vonoprazan: Evaluating the Effects of Race and Disease Status on Exposure** (Poster Session, P0981)
- **Patient Burden and Treatment Goals in the Management of Erosive Esophagitis in the United States: Results From the Study of Acid-Related Disorders (SOARD)** (Poster Session, P0304)
- **Treatment Patterns, Goals, Satisfaction, and Adherence in the Management of H. pylori Infection in the United States: Results from the Study of Acid-Related Disorders (SOARD)** (Poster Session, P2030)
- **Vonoprazan Dual and Triple Therapy for Helicobacter pylori Eradication** (Oral Session)
- **Helicobacter pylori Resistance Rates in the US and Europe: Data From the PHALCON-HP Study** (Poster Session, P3081)

Following the conclusion of ACG 2021, the abstracts will be posted to Phathom's publications and scientific section of the company website.

About Helicobacter pylori (*H. pylori*) infection
H. pylori is a bacterial pathogen that is estimated to infect over 200 million individuals in the United States and Europe. Approximately 50% of the world and 36% of the US population are infected with the bacterium.[1] In many cases, *H. pylori* is acquired in childhood and through intrafamilial transmission.[2] As a result of the chronic inflammation induced by *H. pylori* infection, infected patients develop a range of pathologies including dyspepsia, peptic ulcer disease, gastric cancer, and mucosa-associated lymphoid tissue (MALT) lymphoma.[3] Studies have found that roughly 1 in 5 patients treated for *H. pylori* will fail first line therapy when using standard clarithromycin triple therapy.[1,4]

About PHALCON-HP
PHALCON-HP was a randomized, multicenter, Phase 3 trial that enrolled 1046 patients of which 992 patients with a confirmed *H. pylori* infection were randomized to one of three arms: vonoprazan 20 mg administered twice a day (BID) and amoxicillin 1g administered three times a day (TID) (n=324); vonoprazan 20 mg BID, amoxicillin 1g BID and clarithromycin 500 mg BID (n=338); and lansoprazole 30 mg BID, amoxicillin 1g BID and clarithromycin 500 mg BID (n=330). Each treatment regimen was administered for 14 days. Diagnoses of infection and test of cure were confirmed by 13C-urea breath test. Additional efficacy analyses were conducted using the pre-specified per protocol population (n=822), a subset of the mITT population comprised of patients who were protocol compliant.

About the Study of Acid Related Disorders (SOARD)
SOARD was a physician and patient-based study conducted by Phathom in 2020-2021 that explored the perceptions of disease burden and the unmet needs in the management of *H. pylori* and erosive esophagitis. The study was US-based and used a survey overseen by an academic steering committee of thought leaders in gastroenterology and primary care. Data from both health care provider surveys and patient surveys were matched to medical records to further evaluate clinical characteristics, testing and procedures, and treatment. Participation included GIs (n=102), primary care physicians (n=149), and patients with *H. pylori* (n=77) and erosive esophagitis (n=73).

About Vonoprazan
Vonoprazan is an investigational, 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 FDA has awarded qualified infection disease product (QIDP) status and granted Fast Track designation to vonoprazan in combination with both amoxicillin and clarithromycin and with amoxicillin alone for the treatment of *H. pylori* infection. Phathom submitted new drug applications in September 2021 to the U.S. FDA for vonoprazan-based regimens for the treatment of H. pylori infection. 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 and follow the Company on LinkedIn and Twitter.

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 potential for vonoprazan-based therapies for treatment of *H. pylori* infection to serve as new treatment options, and the potential for vonoprazan dual therapy to be a new antibiotic-sparing treatment option. 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: reported top-line data is based on preliminary analysis of key efficacy and safety data is subject to more audit and verification procedures that could result in material changes in the final data; we may experience delays submitting the NDA including in the event that the FDA does not agree with the Company's interpretation of the data or feedback from the FDA that may be inconsistent with feedback received at prior meetings with the FDA; Phathom's ability to access additional capital under the term loan facility is subject to certain conditions including verification by the lender that the clinical milestone has been met; 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; Phathom's QIDP and Fast Track designations may be withdrawn or 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.

CONTACTS
Media Contact:
Nick Benedetto
1-877-742-8466
media@phathompharma.com

Investor Contact:
Joe Hand
1-877-742-8466
ir@phathompharma.com

[1] Hooi et al. Gastroenterology. 2017;153:420
[2] Chey et al. Am J Gastroenterol.2017;112:212
[3] Malfertheiner et al. Gut. 2017;66:6
[4] Alsamman et al. Dig Dis Sci. 2019;64:2893