Phathom Pharmaceuticals Presents New Data at Digestive Disease Week® (DDW) 2023

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- Higher *H. pylori* eradication rates demonstrated with vonoprazan-based regimens vs. lansoprazole triple therapy, regardless of different baseline demographics and clinical characteristics
- Meta-analysis shows potassium-competitor acid blockers (PCABs), including vonoprazan, provide a longer duration of pH >4, higher predicted Erosive GERD healing rates, and lower probabilities of failure to achieve healing

FLORHAM PARK, N.J., May 09, 2023 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today announced new data from two post-hoc analyses presented in poster presentations at Digestive Disease Week® (DDW) 2023, held May 6-9 in person in Chicago, IL and virtually.

Sub-group analysis from PHALCON-HP Trial: *H. pylori* eradication rates with vonoprazan
Data from a post-hoc subgroup analysis of the pivotal Phase 3 PHALCON-HP study demonstrated higher *H. pylori* eradication rates with vonoprazan-based regimens, as compared to proton pump inhibitor (PPI) lansoprazole-based triple therapy, regardless of different baseline demographics and clinical characteristics and provide further insights into the PHALCON-HP study.

“These results provide meaningful insight and increased confidence in the ability for vonoprazan-based regimens to deliver higher *H. pylori* infection eradication rates, as compared to PPI-based clarithromycin and amoxicillin triple therapy, regardless of a patient’s varying demographics, including age, weight, ethnicity, and other clinically important characteristics,” said Professor William D. Chey, M.D., AGAF, FACG, FACP, Pollard Professor of Medicine and Chief of the Division of GI & Hepatology at the University of Michigan. “Acid suppression remains a critical factor in helping to address unmet needs associated with *H. pylori* treatments, and these data further demonstrate the potential to meaningfully enhance eradication rates across different baseline demographics by replacing PPI-based treatment with vonoprazan.”

PHALCON-HP was the largest Phase 3 registration trial ever conducted in *H. pylori* infection and randomized 992 patients with confirmed *H. pylori* infection at sites across the United States and Europe. The pivotal trial demonstrated superiority of vonoprazan, a first-in-class potassium-competitive acid blocker (PCAB), in combination with amoxicillin (vonoprazan dual therapy), and vonoprazan in combination with clarithromycin and amoxicillin (vonoprazan triple therapy), over the commonly used PPI-based triple regimen of lansoprazole, amoxicillin and clarithromycin.

In the PHALCON-HP sub-group analyses, the magnitude of treatment effect for vonoprazan dual therapy and vonoprazan triple therapy versus lansoprazole triple therapy were generally similar across subgroups based on baseline demographics and clinical characteristics, including age, sex, race, ethnicity, region, and body mass index (BMI).

Model-based meta-analysis of the relationship between pH control and Erosive GERD healing rates
Additionally, in a separate poster presented at DDW, a model-based meta-analysis evaluated the relationship between pH control and healing rates of Erosive Gastroesophageal Reflux Disease (GERD), also known as erosive esophagitis, across different classes of acid-suppressant drugs. Published pharmacodynamic (PD) and clinical studies of anti-secretory drugs, including histamine$_2$–receptor antagonists (H_2RAs), PPIs, and PCABs, including vonoprazan, were used to evaluate the mean percent of time with pH >4.0 per 24 hours (after 5-8 days of dosing), and mucosal healing in patients with Erosive GERD, respectively.

Acid suppression has been shown to be an important factor in the treatment of acid-related gastrointestinal disorders, especially Erosive GERD. Previous research has concluded that reduction of GERD symptoms and mucosal healing correlates with the number of hours that intragastric acid is suppressed to a pH > 4.0.

In the model, PCABs were shown to provide the longest duration of pH >4.0, higher predicted healing rates, and lower probabilities of failure to achieve 80-90% healing rates, as compared to H_2RAs and PPIs. By week 4, PCABs attained median healing rates nearly 200% higher than H_2RAs and 25% higher than PPIs (~90% for PCABs, ~30% for H_2RAs, 70% for PPIs). By week 8, median healing rates for PCABs increased to nearly 100%, whereas H_2RAs and PPIs reached ~50% and ~78%, respectively.

“This provides additional confirmation about the important potential of the PCAB treatment class for gastroenterologists and their patients and suggests the novel mechanism of action of PCABs achieve more effective and prolonged acid suppression which may have a meaningful clinical impact in creating an environment more conducive to healing of Erosive GERD,” said Eckhard Leifke, M.D., Chief Medical Officer of Phathom. “Phathom understands the clinical importance of bringing the first PCAB to the U.S. market as an exciting development in the treatment of Erosive GERD.”

Phathom also has a physical presence on the exhibit floor at booth #1815 throughout the medical meeting. Following the conclusion of DDW 2023, the abstracts will be posted to Phathom’s publications and scientific section of the company website.

About Phathom Pharmaceuticals, Inc.
Phathom Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases. Phathom has in-licensed the exclusive rights in the United States, Europe, and Canada to vonoprazan, a first-in-class potassium-competitive acid blocker (PCAB). For more information about Phathom, visit the Company’s website at www.phathompharma.com and follow the Company on LinkedIn and Twitter.

About DDW

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 6-9, 2023. The meeting showcases more than 3,100 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

Forward Looking Statements

This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about the potential of vonoprazan-based therapies to meaningfully enhance *H. pylori* eradication rates by replacing PPI-based treatment; and the potential of vonoprazan as a treatment for Erosive GERD. 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: Phathom may be unable to generate the required data to meet the acceptable intake (AI) of its nitrosamine impurity, or may be unable to reduce the impurity to an acceptable level throughout the shelf life of the product, to obtain approval for its Erosive GERD NDA or to bring vonoprazan to market for patients with Erosive GERD, if approved, or for patients with *H. pylori*, if our prior approval supplement is approved; risks associated with product manufacturing or formulation changes required to be made in connection with achieving the AI; the FDA may disagree that the existing safety and efficacy data, together with additional data, is sufficient to approve the Erosive esophagitis NDA or supplements to the *H. pylori* NDAs; the inherent risks of clinical development of vonoprazan; 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 ability to access additional capital under its term loan facility and royalty interest finance agreements is subject to certain conditions; Phathom's ability to obtain and maintain intellectual property protection for vonoprazan; Phathom's ability to comply with its license agreement with Takeda; 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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