Phathom Pharmaceuticals Announces Results from VONO-103, a Phase 1 Study Evaluating Gastric Acid Inhibition of Vonoprazan and Lansoprazole (PREVACID®)

September 27, 2021

Vonoprazan 20 mg demonstrated significantly greater acid suppressive effects over the 7-day study period compared to lansoprazole (PREVACID®) 30 mg, a proton pump inhibitor (PPI)

FLORHAM PARK, N.J., Sept. 27, 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 reported results from VONO-103, a Phase 1 trial evaluating the effects of vonoprazan 20 mg once daily ("QD") and lansoprazole 30 mg QD in healthy U.S. subjects. In the study, vonoprazan demonstrated significantly greater acid inhibition as compared to lansoprazole. The study treatments were generally well tolerated with no serious adverse events reported.

The primary pharmacodynamic endpoints of VONO-103 were mean gastric pH over twenty-four hours ("mean 24-hour pH value") and the percentage of time with gastric pH above 4 (pH>4 holding time ratio or "pH>4 HTR") on Days 1 and 7. Gastric pH levels are measured on a logarithmic scale from 0.0 to 14.0, in which each point represents a 10-fold change in acidity and higher pH values represent lower acidity.

Following the first dose, the mean 24-hour gastric pH value on Day 1 for vonoprazan was 4.6 as compared to 2.8 for lansoprazole ($p<0.0001$). The least squares mean pH>4 HTR on Day 1 for vonoprazan was 62.2% as compared to 23.2% for lansoprazole.[1]

The greater gastric acid inhibition was maintained after seven days of once daily dosing. The mean 24-hour pH value on Day 7 for vonoprazan was 5.9 as compared to 3.8 for lansoprazole ($p<0.0001$). The least squares mean pH>4 HTR on Day 7 was 86.8% for vonoprazan as compared to 42.1% for lansoprazole.[1]

"Acid suppression has been shown to be an important factor in the treatment of acid-related gastrointestinal disorders," said Eckhard Leifke, M.D., Chief Medical Officer of Phathom. "We are very pleased with today's results, as they demonstrate that vonoprazan provides more powerful gastric acid suppression after both one day and seven days of once daily administration as compared to the PPI, lansoprazole."

VONO-103 is the first pharmacokinetic and pharmacodynamic (PK/PD) and safety study comparing vonoprazan 20 mg QD and lansoprazole 30 mg QD. Phathom is also currently conducting PHALCON-EE, a Phase 3 study in patients with erosive esophagitis, comparing vonoprazan and lansoprazole in both healing and maintenance of healing of erosions, as well as the relief of heartburn. Topline results of PHALCON-EE are expected in October 2021.

About VONO-103

VONO-103 is a Phase 1, open-label, randomized, 2-period crossover study evaluating the PK/PD profile and safety and tolerability of vonoprazan 20 mg QD in comparison to lansoprazole 30 mg QD, in healthy subjects. Lansoprazole 30 mg QD is the approved dose for "short term treatment of erosive esophagitis (EE)" – an 8-week course of treatment for healing of EE. In each period of the VONO-103 study, doses of either vonoprazan 20 mg or lansoprazole 30 mg were administered once daily (QD) for 7 consecutive days. Gastric pH was measured continuously over a 24-hour period at baseline and on Days 1 and 7 of Periods 1 and 2. Between periods there was a seven-day wash out. The study was conducted in a study center in the U.S. The primary pharmacodynamic endpoints were mean gastric pH over 24 hours and the percentage of time with gastric pH >4 (pH>4 holding time ratio or "pH>4 HTR") on Days 1 and 7.

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 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 Phase 3 clinical trial. 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 FDA may disagree that the existing safety and efficacy data is sufficient to accept or approve the 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 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 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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[1] The least squares mean difference in pH>4 HTR on Days 1 and 7 for vonoprazan vs. lansoprazole was 39.0% [95% confidence interval (CI): 31.9-46.0; p<0.0001] and 44.6% [95% CI: 37.6-51.7; p<0.0001], respectively.