Phathom Pharmaceuticals Submits Two NDAs to U.S. FDA for Vonoprazan-based Treatment Regimens for the Treatment of H. pylori Infection

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FLORHAM PARK, N.J., Sept. 08, 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 that it has submitted two new drug applications (NDAs) to the U.S. Food and Drug Administration (FDA) for the use of vonoprazan in combination with amoxicillin and clarithromycin (vonoprazan triple therapy) and vonoprazan in combination with amoxicillin (vonoprazan dual therapy) as a treatment for Helicobacter pylori (*H. pylori*) infection in adults. With current standard of care therapies, *H. pylori* eradication rates have declined in the U.S. If approved, vonoprazan-based treatments offer two new therapeutic options that have demonstrated superior eradication rates as compared to standard of care lansoprazole-based triple therapy.

“The submission of these NDAs is the first step towards addressing the declining *H. pylori* eradication rates in the U.S. and providing new potential treatment options for the millions of *H. pylori* sufferers in need of more efficacious treatments,” said Azmi Nabulsi, M.D., Chief Operating Officer at Phathom. “Today’s announcement underscores Phathom’s commitment to changing the treatment landscape for acid-related diseases. If approved, patients and healthcare providers would have two novel options to combat this highly prevalent bacterial infection. We look forward to working with the FDA to advance these vonoprazan-based treatment regimens toward approval. If approved, we anticipate launch in the U.S. in the second half of 2022.”

These NDAs are based on the positive data previously announced from Phathom’s pivotal Phase 3 PHALCON-HP trial, the largest U.S. registrational trial ever conducted for *H. pylori*. The study evaluated eradication rates of *H. pylori* infection using vonoprazan triple therapy and vonoprazan dual therapy compared to lansoprazole-based triple therapy. Vonoprazan triple therapy and vonoprazan dual therapy successfully met the study’s primary non-inferiority endpoints and all secondary endpoints, demonstrating superior eradication rates versus lansoprazole-based triple therapy among all patients including in patients with clarithromycin resistant strains of *H. pylori.*

The FDA has previously designated vonoprazan triple therapy and vonoprazan dual therapy as qualified infectious disease products (QIDP) and awarded them Fast Track designation, in each case, for the treatment of *H. pylori* infection. In connection with the NDA submissions, Phathom requested Priority Review, which, if granted, will shorten the review period from 10 months to 6 months following FDA acceptance of the submissions for filing.

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.[2,4]

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 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 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 potential acceptance and approval by the FDA of our NDAs for vonoprazan; the ability of vonoprazan-based treatments to address declining *H. pylori* eradication rates; and our plans to commercially launch vonoprazan in the second half of 2022. 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] 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.

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