Phathom Pharmaceuticals Submits Vonoprazan NDA to FDA for the Treatment of Erosive Esophagitis

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FLORHAM PARK, N.J., March 14, 2022 (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 a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for the use of vonoprazan as a treatment for adults for the healing of all grades of erosive esophagitis (EE) and relief of heartburn, and maintenance of healing of all grades of EE and relief of heartburn.

Erosive esophagitis, a major type of gastroesophageal reflux disease (GERD), affects approximately 20 million people in the U.S. In addition to experiencing troubling heartburn symptoms, patients with inadequately treated EE may progress to more severe diseases including Barrett's esophagus, a condition in which esophageal tissue changes can progress to cancer.

"The submission of this NDA is another exciting step towards bringing the first major innovation to the U.S. GERD market in over 30 years," said Azmi Nabulsi, M.D., Chief Operating Officer at Phathom. "Proton pump inhibitors (PPIs) are currently the standard of care for EE yet approximately half of all U.S. patients progress their lines of therapy annually. We believe there is great interest among patients and healthcare providers for new treatment options to address the shortcomings of current treatment. If approved, vonoprazan has the potential to satisfy the large unmet needs of millions of patients and set a new treatment paradigm in EE."

This NDA is based on the positive data previously announced from Phathom's pivotal Phase 3 PHALCON-EE trial, a randomized, double-blind, multicenter trial that enrolled 1,024 patients with EE in the U.S. and Europe and compared vonoprazan to lansoprazole, a standard of care PPI, in the healing and maintenance of healing of EE, and heartburn symptom relief. PHALCON-EE successfully met its primary endpoints and key secondary superiority endpoints.

About Erosive Esophagitis
Erosive esophagitis is a condition characterized by the presence of breaks, or erosions, in the esophageal tissue caused by constant irritation of the mucosal surface and subsequent loss of defense mechanisms against acid and digestive enzymes. Chronic erosive esophagitis can lead to complications including peptic stricture, a narrowing of the esophagus that causes difficulty swallowing, and Barrett's esophagus, a condition in which esophageal tissue changes can progress to cancer. Uncontrolled reflux disease can also result in extra-esophageal diseases such as respiratory problems, chest pain, angina, and increased mortality.

About PHALCON-EE
PHALCON-EE was a randomized, double-blind, two-phase, multicenter, Phase 3 trial that enrolled 1,024 patients with EE in the U.S. and Europe. The first phase of the trial evaluated the efficacy and safety of vonoprazan 20 mg administered once-daily (QD) compared to lansoprazole 30 mg QD for the healing of EE for up to eight weeks. The second phase of the trial evaluated the efficacy and safety of vonoprazan 10 mg QD and 20 mg QD compared to lansoprazole 15 mg QD for the maintenance of healing of EE for 24 weeks. Both phases also evaluated heartburn symptoms.

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 and follow the Company on LinkedIn and Twitter.

Forward Looking Statements
The Company 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. The inclusion of forward-looking statements should not be regarded as a representation by the Company 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 the Company's business, including, without limitation: we may not obtain regulatory approval of our NDAs for the treatment of *H. pylori*, erosive esophagitis, or the other indications in which we are developing vonoprazan; even if we receive regulatory approval, the Company may experience delays in its plans to commercially launch vonoprazan in particular as we currently have a limited marketing and no sales organization and have no experience as a company in commercializing products; the Company may experience delays in designing and initiating a Phase 3 on-demand study in NERD, including in the event that the FDA does not agree with the Company's study design or its interpretation of the data; the Company will require substantial additional financing to achieve its goals and may not be able to obtain such financing on acceptable terms, or at all; the Company'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; previously granted 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; the Company's ability to obtain and maintain intellectual property protection for vonoprazan; the Company's ability to comply with its license agreement with Takeda; the Company's ability to maintain undisrupted business operations due to the ongoing presence 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 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 the Company 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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