Phathom Pharmaceuticals Announces Initiation of Pivotal Phase 3 Clinical Trial for Vonoprazan in Erosive Esophagitis

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BUFFALO GROVE, Ill.--(BUSINESS WIRE)--Dec. 2, 2019-- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, announced today the initiation of PHALCON-EE, the Company's pivotal Phase 3 clinical trial of vonoprazan for both the healing and maintenance of healing of erosive esophagitis (EE) as well as the relief of heartburn.

PHALCON-EE is a randomized, double-blind, two-phase, multicenter Phase 3 trial that is planned to enroll approximately 1,000 patients with EE in the U.S. and Europe. The first phase of the trial will evaluate 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 will evaluate 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 will also evaluate heartburn symptoms.

"We're pleased to have dosed the first patient in the PHALCON-EE study, a critical milestone in our mission to improve the lives of patients with acid-related disorders," said Azmi Nabulsi, MD, Chief Operating Officer of Phathom. "Vonoprazan, if successfully developed and approved for the healing and maintenance of healing of erosive esophagitis, as well as heartburn relief in those patients, would be the first new class of medicine available to patients in the U.S. and Europe in this category in over 30 years. We believe vonoprazan has the potential to become an important treatment alternative for the millions of patients not well-treated with the current standard of care."

About Erosive Esophagitis

Erosive Esophagitis (EE) is a major type of gastroesophageal reflux disease (GERD) characterized by erosions in the gastric mucosa caused by acidic reflux of stomach contents into the esophagus. There are estimated to be over 65 million individuals with GERD in the U.S., of which approximately 30% have EE. In addition to experiencing troubling heartburn symptoms, patients with inadequately treated EE may progress to more severe diseases including Barrett's esophagus and esophageal cancer.

About Vonoprazan

Vonoprazan, is an 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 rapid, potent, and durable anti-secretory effects and has demonstrated clinical benefits over standard of care treatments 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. Phathom in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda, which completed 17 Phase 3 trials for vonorpazan and received marketing approval in Japan and eight 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 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**.

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 to become the first new class of medicine and an important treatment alternative for patients not well-treated with the current standard of care. 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: potential delays in the commencement, enrollment and completion of clinical trials; the success of our clinical trials of vonoprazan, and the results of prior clinical trials and other investigator-initiated clinical trials of vonoprazan are not necessarily predictive of our future results and the FDA and comparable foreign regulatory authorities may not accept the data from such prior trials to support approval; regulatory developments in the United States and foreign countries, including FDA and EMA developments that may be inconsistent with feedback received to date; 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; 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 Registration Statement on Form S-1 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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