Phathom Pharmaceuticals Announces Initiation of Pivotal Phase 3 Clinical Trial for Vonoprazan in Helicobacter Pylori (H. pylori) Infection

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BUFFALO GROVE, Ill.--(BUSINESS WIRE)--Dec. 23, 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-HP. In this pivotal Phase 3 clinical trial, clinicians will evaluate vonoprazan in combination with amoxicillin (vonoprazan dual therapy) and vonoprazan in combination with amoxicillin and clarithromycin (vonoprazan triple therapy) for the successful eradication of *H. pylori* infection. With the initiation of PHALCON-HP, vonoprazan is now being evaluated in two pivotal trials to support regulatory submissions in two different disease areas in the United States and Europe. Earlier this month, the company initiated PHALCON-EE, a pivotal trial evaluating vonoprazan for both the healing and maintenance of healing of erosive esophagitis as well as the relief of heartburn. Topline data from both PHALCON-HP and PHALCON-EE are expected in 2021.

PHALCON-HP is a randomized, multicenter, Phase 3 trial that is planned to enroll approximately 975 patients with *H. pylori* infection. Participants will be randomized 1:1:1 to one of three arms: vonoprazan 20 mg administered twice a day (BID) and amoxicillin 1g administered three times a day (TID); vonoprazan 20 mg BID, amoxicillin 1 g BID and clarithromycin 500 mg BID; and lansoprazole 30 mg BID, amoxicillin 1 g BID and clarithromycin 500 mg BID. Each treatment regimen will be administered for 14 days. The primary endpoint of PHALCON-HP is the percentage of patients with successful eradication of *H. pylori* infection.

“The initiation of the PHALCON-HP study is another significant step in the development of vonoprazan for underserved patients living with gastrointestinal diseases,” said Azmi Nabulsi, MD, Chief Operating Officer of Phathom. “There are millions of people living with *H. pylori* infection in the United States and Europe and due to increased antibiotic resistance, eradication rates for patients treated with currently available therapies are declining. In addition to the troubling symptoms of *H. pylori* infection, *H. pylori* patients have an increased risk of developing other serious diseases including gastric cancer and mucosa-associated lymphoid tissue (MALT) lymphoma. Vonoprazan, if approved, represents a first-in-class treatment that we believe will be a much needed new therapeutic option for *H. pylori* patients.”

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. As a result of the chronic inflammation induced by *H. pylori* infection, approximately 20% of infected patients develop a range of pathologies including dyspepsia, peptic ulcer disease, gastric cancer, and mucosa-associated lymphoid tissue (MALT) lymphoma. Gastric cancer is the third most common cause of cancer-related death worldwide, and over 80% of gastric cancers are attributed to *H. pylori* infection.

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. The FDA has designated vonoprazan as a qualified infectious disease product (QIDP) and awarded Fast Track status for the treatment of *H. pylori* infection in combination with both amoxicillin and clarithromycin and with amoxicillin alone. Phathom in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda, which completed 17 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 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 timing of topline data from the ongoing vonoprazan trials, and 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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