Phathom Pharmaceuticals Announces FDA Acceptance of NDA Resubmission for Erosive GERD

June 12, 2023

- Prescription Drug User Fee Act (PDUFA) goal date of November 17, 2023
- Combined launch of vonoprazan for Erosive GERD and *H. pylori* indications planned for Q4 2023, if approved

FLORHAM PARK, N.J., June 12, 2023 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today announced that the U.S. Food and Drug Administration (FDA) has acknowledged that its New Drug Application (NDA) resubmission for vonoprazan, a novel first-in-class potassium-competitive acid blocker (PCAB), for the treatment of Erosive GERD (gastroesophageal reflux disease) constitutes a complete response to the February 2023 complete response letter (CRL). The FDA has classified this as a Class 2 resubmission and assigned a Prescription Drug User Fee Act (PDUFA) goal date of November 17, 2023.

"We are thrilled to announce the FDA has set a PDUFA goal date of November 17, 2023, for our Erosive GERD NDA and has acknowledged that our resubmission responds to the nitrosamine related issues cited in the complete response letter we received earlier this year and allows the Agency to continue its review of our NDA," said Terrie Curran, President and Chief Executive Officer of Phathom. "This significant milestone brings us one step closer to the approval of a new class of treatment for Erosive GERD representing the first major innovation to the U.S. GERD market in over 30 years. We eagerly await the potential approval of vonoprazan and the combined launch of both Erosive GERD and *H. pylori* indications in the fourth quarter."

The NDA resubmission, which was submitted in response to the CRL issued by the FDA in February 2023, contained three months of stability data of reformulated vonoprazan tablets to support the commercial shelf life of vonoprazan. Phathom will continue to provide additional stability data during the regulatory review as previously agreed with FDA as part of this resubmission.

About Erosive GERD

Erosive GERD (gastroesophageal reflux disease), also known as Erosive Esophagitis, is a major type of 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 Erosive GERD. In addition to experiencing troubling heartburn symptoms, patients with inadequately treated Erosive GERD may progress to more severe diseases including Barrett's esophagus and esophageal cancer.

About Phathom Pharmaceuticals

Phathom Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases. Phathom has in-licensed the exclusive rights in the United States, Europe, and Canada to vonoprazan, a first-in-class potassium-competitive acid blocker (PCAB). 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

This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about the potential of vonoprazan as a treatment for Erosive GERD and *H. pylori*; Phathom's expectations that the stability data will support the requested shelf life of 24 months; the timing of potential approval of the NDA; and the timing of a U.S. commercial launch for Erosive GERD and *H. pylori* indications. 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 determine that the NDA resubmission does not adequately address the deficiencies raised in the CRL; future data generated from our stability program may be different from the data generated to date and may not demonstrate that our mitigation efforts will meet the acceptable intake (AI) of the nitrosamine impurity, or reduce the impurity to an acceptable level throughout the six-month period required by FDA or the shelf life of the product, to obtain approval for its Erosive GERD NDA or to bring vonoprazan to market for patients with Erosive GERD, if approved, or for patients with *H. pylori*, if our anticipated supplements to NDAs are approved; prior to commercial launch of the *H. pylori* convenience packs, Phathom must submit post approval supplements to the relevant NDAs and Phathom may not submit such supplements on the timeframe it expects and the FDA may not approve such supplements to the *H. pylori* convenience pack NDAs; risks associated with product manufacturing or formulation changes required to be made in connection with achieving the AI; the FDA may disagree that the existing safety and efficacy data, together with additional data, is sufficient to approve the Erosive GERD NDA or supplements to the *H. pylori* 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 access additional capital under its term loan facility and royalty interest finance agreements is subject to certain conditions; Phathom's ability to obtain and maintain intellectual property protection for vonoprazan; Phathom's ability to comply with its license agreement with Takeda; 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.

MEDIA CONTACT

Nick Benedetto
1-877-742-8466
media@phathompharma.com

INVESTOR CONTACT
Eric Sciorilli
1-877-742-8466
ir@phathompharma.com