Phathom Pharmaceuticals Announces Submission of Six-Month Stability Data in Support of Erosive GERD New Drug Application

August 21, 2023

- Six-month stability data remain more than 10x below the acceptable intake limit set by the U.S. Food and Drug Administration (FDA) and continue to support the requested product shelf life

- Submission of six-month stability data satisfies Phathom's stability data submission requirements for Erosive GERD New Drug Application (NDA) for vonoprazan with a Prescription Drug User Fee Act (PDUFA) goal date of November 17, 2023

FLORHAM PARK, N.J., Aug. 21, 2023 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today announced it has submitted to the FDA six-month stability data from its long-term and accelerated stability program for its reformulated vonoprazan tablets. The additional stability was required for the FDA to complete its NDA review for vonoprazan, a novel first-in-class potassium-competitive acid blocker (PCAB), for the treatment of Erosive GERD (gastroesophageal reflux disease), also referred to as erosive esophagitis.

With the submission of these data, Phathom has satisfied the FDA's request for additional data in response to the Complete Response Letter (CRL) issued in February 2023 relating to specifications and controls for a nitrosamine drug substance related impurity, N-nitroso-vonoprazan (NVP). Phathom resubmitted the NDA for vonoprazan for Erosive GERD in May 2023 on the basis of three months of stability data and was assigned a PDUFA goal date of November 17, 2023.

"We are happy to share that the six-month stability data continue to demonstrate effective control of NVP, which is another big step forward as we prepare for a planned launch in the fourth quarter of this year," said Terrie Curran, President and Chief Executive Officer of Phathom. "The latest stability data confirm that our minor product reformulation has limited the presence of NVP, and we believe these data comfortably support the proposed shelf life for vonoprazan tablets. We look forward to working with the FDA as it completes its review."

The long-term and accelerated six-month data from Phathom's stability program have demonstrated that the minor drug product tablet reformulation is controlling NVP growth through six months and keeping levels greater than tenfold below the acceptable daily intake limit of 96 ng/day or 2.4 ppm based on the maximum approved daily dose of 40 mg/day.

The NDA seeks regulatory approval for vonoprazan as a treatment for the healing and maintenance of healing of Erosive GERD, and relief of associated heartburn symptoms, and was previously classified as a Class 2 resubmission with a six-month review period. If approved, a combined U.S. commercial launch for Erosive GERD and *H. pylori* is planned for the fourth quarter of 2023.

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 Erosive GERD 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 the pending prior approval supplements to the convenience pack NDAs are approved; 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