Phathom Pharmaceuticals Announces Regulatory Update and Plans for 2023 Erosive Esophagitis and H. pylori Commercial Launch

April 4, 2023

- Favorable feedback following meeting with the U.S. Food and Drug Administration (FDA) allows for planned resubmission of erosive esophagitis new drug application (NDA) this quarter
- Combined commercial launch of vonoprazan for erosive esophagitis and *H. pylori* indications expected Q4 2023, if approved

FLORHAM PARK, N.J., April 04, 2023 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today provided a regulatory update following its recent meeting with the FDA regarding the complete response letters (CRLs) for Phathom's erosive esophagitis NDA and *H. pylori* post approval supplement (PAS) to VOQUEZNA® TRIPLE PAK® and VOQUEZNA® DUAL PAK® NDAs. Both CRLs were solely related to specifications and controls for a nitrosamine drug substance related impurity, N-nitroso-vonoprazan (NVP).

Since first detecting trace levels of NVP, Phathom conducted extensive root cause investigations and implemented mitigation measures, including a minor tablet reformulation, to inhibit the growth of NVP. Phathom has shared available stability data with the FDA on this reformulation and received feedback on the resubmission requirements, including the expected stability data requirements. Based on this input, Phathom anticipates resubmitting the NDA for erosive esophagitis in the second quarter of 2023 which, if approved, could lead to a combined commercial launch of the erosive esophagitis and *H. pylori* indications in the fourth quarter of 2023. Phathom also anticipates submitting a PAS for VOQUEZNA® TRIPLE PAK® and VOQUEZNA® DUAL PAK® with FDA action expected in the fourth quarter of 2023.

"We are very pleased with the outcome of our FDA meeting and the clear feedback we received from the Agency regarding requirements to obtain potential regulatory approvals for both erosive esophagitis and *H. pylori* before year end," said Terrie Curran, President and Chief Executive Officer of Phathom. "We believe the data package, including stability data that we have shared with the Agency, and which we continue to generate, demonstrate that the mitigation measures we have implemented are successfully achieving their intended effects of limiting and controlling NVP, the sole deficiency noted in the prior CRLs. We appreciate the regulatory clarity provided by the FDA, allowing us to plan to resubmit the erosive esophagitis NDA this quarter and providing a well-defined path for us to potentially deliver vonoprazan to patients suffering from erosive GERD and *H. pylori* infection before the end of the year."

About Phathom Pharmaceuticals, Inc.

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

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 Phathom's expectations on timing of resubmitting the NDA for erosive esophagitis and the post approval supplement for its *H. pylori* NDAs, the anticipated product launches in *H. pylori* and erosive esophagitis and our belief that the stability data generated will demonstrate that we have limited and controlled NVP to meet the FDA's requirements. 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: Phathom may be unable to generate the required data to meet the acceptable intake (AI) of its nitrosamine impurity, or may be unable to reduce the impurity to an acceptable level throughout the shelf life of the product, to obtain approval for its erosive esophagitis NDA or to bring vonoprazan to market for patients with erosive esophagitis, if approved, or for patients with *H. pylori*, if our PAS is 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 esophagitis 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; Phathom's ability to maintain undisrupted business operations due to the ongoing spread 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 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.

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