Phathom Pharmaceuticals Provides Update on New Drug Application Review of Vonoprazan for Erosive Esophagitis

January 3, 2023

FLORHAM PARK, N.J., Jan. 03, 2023 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases and disorders, today announced that the U.S. Food and Drug Administration (FDA) has notified the Company that no action will be taken on the Company's new drug application (NDA) for vonoprazan, a novel potassium-competitive acid blocker (PCAB), under review as a treatment for erosive esophagitis, on or prior to the current Prescription Drug User Fee Act (PDUFA) target action date of January 11, 2023.

On August 2, 2022, the Company announced that it had detected trace levels of a nitrosamine impurity, N-nitroso-vonoprazan (NVP) in commercial batches and was working closely with the FDA to obtain approval of a proposed acceptable daily intake limit, test method, and controls to address this impurity prior to releasing vonoprazan-based products to the market. While an acceptable daily intake limit for NVP has now been established by the FDA at 96 ng/day, the FDA has requested additional stability data demonstrating that levels of NVP remain below that limit throughout the proposed shelf life of the product. The Company is actively in the process of both generating additional stability data and discussing with the FDA the nature and extent of such requested data. As a result, Phathom no longer expects product launches for *H. pylori* or erosive esophagitis in the first quarter of 2023.

"While we are disappointed not to launch vonoprazan later this quarter, we are otherwise very pleased with the NDA review progress, including ongoing label negotiations which we are optimistic will conclude shortly," said Terrie Curran, President and Chief Executive Officer of Phathom. "We are confident in our ability to meet the nitrosamine limit and expect to update anticipated launch timing after gaining further clarity on the stability requirements from the FDA. Meanwhile, we are maintaining our launch-readiness position and remain excited about vonoprazan's commercial potential as the first major innovation in the U.S. erosive GERD market in over 30 years."

About Phathom Pharmaceuticals, Inc.
Phathom Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases and disorders. Phathom 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 to generate additional data to support the launch and proposed shelf life of vonoprazan and the potential approval of our EE NDA and anticipated product launches in *H. pylori* and erosive esophagitis and the timing thereof. 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 limit of NVP, or may be unable to reduce the NVP intake levels to an acceptable level throughout the shelf life of the product, to obtain approval of its EE NDA or to bring the product to market for its EE NDA, if approved, or its approved *H. pylori* NDAs; risks associated with product manufacturing or formulation changes required to be made in connection with the required intake limit; the FDA may disagree that the existing safety and efficacy data, together with additional data, is sufficient to approve the EE NDA; the potential for the FDA to delay taking action related to the EE NDA following the FDA's decision not to do so on or prior to the PDUFA target action date; 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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