Phathom Pharmaceuticals Provides Regulatory Updates

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FLORHAM PARK, N.J., Feb. 09, 2023 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today announced regulatory updates for its approved products, VOQUEZNA™ TRIPLE PAK™ and VOQUEZNA DUAL PAK™, approved in the U.S. for the treatment of *H. pylori* infection, and its pending New Drug Application (NDA) for vonoprazan for the treatment of erosive esophagitis. Phathom has received complete response letters from the U.S. Food and Drug Administration (FDA) relating to its erosive esophagitis NDA and *H. pylori* post approval supplement, both of which address specifications and controls for a nitrosamine drug substance related impurity, *N*-nitroso-vonoprazan (NVP), that was detected in the initial commercial launch materials of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. These letters formalize FDA's request, announced by the Company last month, that Phathom provide additional stability data to demonstrate that levels of the impurity previously found in vonoprazan drug product will remain at or below the daily acceptable intake throughout the proposed shelf life of the product. No additional deficiencies were cited by the FDA in either letter.

Phathom has conducted extensive root cause investigations regarding the trace levels of the impurity since it was detected and has implemented mitigation measures to control the levels of NVP below the acceptable intake. Phathom expects to meet with the FDA in the first quarter of this year to discuss the resubmission plan and timeline that the Company believes will lead to approval and launch of products containing vonoprazan.

"We remain encouraged with the progress we have made in generating additional stability data to meet FDA's request and are eagerly awaiting our meeting with the FDA anticipated later this quarter to discuss our ongoing efforts, share our data, and gain alignment on resubmission and potential approval timelines," said Terrie Curran, President and Chief Executive Officer of Phathom. "We are pleased that no other review issues were cited related to our erosive esophagitis NDA and that our labeling discussions continued to progress since our announcement last month, resulting in a near final label. We are confident that our ongoing stability program will generate the required data and will clear the pathway to potential approval and launch of these important products for patients in need of new treatment options for erosive esophagitis and *H. pylori* infection."

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 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 of generating stability data necessary to support the proposed shelf life of vonoprazan and the potential approval of its erosive esophagitis NDA and post approval supplement for its *H. pylori* NDAs, and anticipated product launches in *H. pylori* and erosive esophagitis. 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*; 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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