Phathom Pharmaceuticals Resubmits Erosive GERD New Drug Application to FDA

May 23, 2023

- Anticipated FDA action date in Q4 2023; if approved, combined launch for Erosive GERD and *H. pylori* indications planned before year end

- If approved, vonoprazan would be the first innovative acid suppressant from a new drug class approved for the treatment of Erosive GERD in the U.S. in over 30 years

FLORHAM PARK, N.J., May 23, 2023 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today announced that it has resubmitted its New Drug Application (NDA) 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, to the U.S. Food and Drug Administration (FDA).

This resubmission responds to the Complete Response Letter (CRL) issued by the FDA in February 2023 relating to specifications and controls for a nitrosamine drug substance related impurity, N-nitroso-vonoprazan (NVP). As previously communicated, Phathom implemented mitigation measures, including a minor drug product tablet reformulation, to inhibit the growth of NVP, and has been conducting a stability program to demonstrate these measures are effective and support the commercial shelf life.

“We are very pleased to announce the resubmission of our NDA seeking approval for vonoprazan as the first innovative acid suppressant for the treatment of Erosive GERD in the U.S. in over 30 years,” said Terrie Curran, President and Chief Executive Officer of Phathom. “Our resubmission includes three-months of stability data required by the FDA to reinitiate their review and demonstrates the reformulation is proving effective in limiting the presence of NVP and controlling its growth well below the FDA’s acceptable daily intake limit. As agreed with the Agency, we plan to provide the final six-month stability data during their review as it becomes available. The data we have collected so far, and our statistical modeling, reinforce our confidence that the reformulated vonoprazan tablets comfortably support the 24-month shelf life we originally requested. We are excited with the progress we have made and look forward to the potential approval of our NDA later this year.”

The NDA resubmission contains three months of stability data for six batches of the reformulated vonoprazan tablets. The three-month data demonstrate that Phathom’s mitigation measures are controlling NVP growth through three months and keeping levels well below the acceptable daily intake limit of 96 ng/day or 2.4 ppm (parts per million) based on the maximum approved daily dose of 40 mg/day. All of the manufactured reformulated batches have demonstrated control of NVP through three months of long-term stability conditions that are more than tenfold below the acceptable intake limit and which Phathom believes support the requested shelf life of 24 months based on its statistical modeling. In addition, the NDA is supported by extensive clinical data including efficacy and safety data from Phathom’s pivotal Phase 3 PHALCON-EE trial, a randomized, double-blind, multicenter trial that enrolled 1,024 patients with Erosive GERD in the U.S. and Europe and compared vonoprazan to lansoprazole, a proton pump inhibitor (PPI), in the healing and maintenance of healing of Erosive GERD, and relief of associated heartburn symptoms.

Phathom expects the NDA to be classified as a Class 2 resubmission with a six-month review period and plans to provide the FDA with six-month stability data from its ongoing stability program during the regulatory review process. If the NDA is approved, a combined U.S. commercial launch for the Erosive GERD and *H. pylori* indications is planned for the fourth quarter of 2023.

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, 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

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 comfortably 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 refuse to accept our NDA resubmission prior to full review; 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.

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