Phathom Pharmaceuticals Announces Plans to Initiate Vonoprazan Development Program in Non-Erosive Reflux Disease (NERD)

December 14, 2020

Management and Key Opinion Leaders to discuss NERD and the vonoprazan NERD development program during virtual Investor Day webcast today at 1:00 PM (ET)

FLORHAM PARK, N.J., Dec. 14, 2020 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today announced plans to expand its vonoprazan development program into non-erosive reflux disease (NERD). NERD is a major subcategory of gastroesophageal reflux disease (GERD) and is characterized by reflux-related symptoms in the absence of esophageal mucosal erosions. There are over 65 million U.S. patients living with GERD, and it is estimated that approximately two-thirds of this population have NERD.

The vonoprazan NERD development program is expected to evaluate vonoprazan in clinical trials that have the potential to offer patients increased dosing regimen flexibility in the management of their NERD symptoms as compared to many current U.S. treatments. The NERD development program plan is expected to include the evaluation of both vonoprazan continuous and on-demand dosing regimens. As a next step in its NERD development program, Phathom anticipates initiating a Phase 2 clinical trial in mid-2021 to evaluate various doses of vonoprazan as an on-demand therapy for patients with NERD.

“The planned expansion of our clinical program to evaluate vonoprazan as a potential therapy for NERD further highlights our commitment to addressing the unmet needs of patients suffering from acid-related disorders,” said Azmi Nabulsi, MD, Chief Operating Officer of Phathom. “The treatment options currently available to the millions of patients suffering with NERD in the U.S. are known to have limitations such as slow onset and limited efficacy. Based on vonoprazan’s pharmacological profile, we believe it has the potential to overcome these limitations and provide NERD patients with powerful symptom relief as well as greater dosing flexibility for managing their disease. We have recently received feedback from FDA regarding our proposed program and are now moving forward with plans to initiate our Phase 2 dose-ranging trial with an on-demand regimen in mid-2021.”

The NERD development program would mark Phathom’s third clinical program evaluating vonoprazan. Phathom is also conducting two pivotal Phase 3 trials to support regulatory submissions in other disease areas. Last month, the Company completed patient enrollment in PHALCON-EE, a pivotal trial evaluating vonoprazan for both the healing and maintenance of healing of erosive esophagitis as well as the relief of heartburn. Enrollment is currently ongoing for PHALCON-HP, another pivotal trial evaluating vonoprazan in combination with antibiotics for the eradication of *H. pylori* infection. Phathom expects to complete enrollment in PHALCON-HP in January 2021 with topline results expected in the second quarter of 2021. PHALCON-EE topline results are expected in the second half of 2021.

About Non-Erosive Reflux Disease (NERD)
Non-erosive reflux disease (NERD) is a major subcategory of gastroesophageal reflux disease (GERD). It is characterized by reflux-related symptoms in the absence of esophageal mucosal erosions/breaks at conventional endoscopy. There are estimated to be over 65 million individuals with GERD in the U.S. Symptoms of NERD can include episodic heartburn, especially at night, regurgitation, problems swallowing, and chest pain.

Management Update During Virtual Investor Day Webcast
Phathom is hosting a virtual Investor Day today, December 14, 2020 beginning at 1 pm Eastern Time. Members of Phathom’s management team and gastroenterology key opinion leaders will provide updates on the company’s pipeline and commercial strategy.

To view the live webcast, visit http://bit.ly/PHAT-investor-day-2020. Please log in approximately 10 minutes prior to the scheduled start time.

A replay of the webcast and the slide presentation will be available after the meeting on the News & Events section of the Phathom website at https://investors.phathompharma.com/news-events/events-and-presentations.

About Vonoprazan
Vonoprazan is an oral small molecule potassium-competitive acid blocker (P-CAB). P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown the potential to have rapid, potent, and durable anti-secretory effects as a single agent in the treatment of gastroesophageal reflux disease (GERD) and in combination with antibiotics for the treatment of Helicobacter pylori (*H. pylori)* infection. The U.S. Food and Drug Administration (FDA) has designated as a qualified infectious disease product (QIDP) and awarded Fast Track status to vonoprazan for the treatment of *H. pylori* infection in combination with both amoxicillin and clarithromycin and with amoxicillin alone. Phathom in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda, which completed 19 Phase 3 trials for vonoprazan and received marketing approval in Japan and numerous other countries in Asia and Latin America.

About Phathom
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 novel potassium competitive acid blocker (P-CAB) in late-stage development for the treatment of acid-related disorders. For more information about Phathom, visit the Company’s website at www.phathompharma.com or follow the Company on social media: LinkedIn at www.linkedin.com/company/phathompharma and Twitter @PhathomPharma.

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 when the Company expects to commence its Phase 2 clinical trial of vonoprazan in NERD, when the Company expects to complete enrollment of patients in its PHALCON-HP Phase 3 clinical trial; the expected availability of topline results from the PHALCON-EE and PHALCON-HP Phase 3 clinical trials; and the potential to receive regulatory and exclusivity benefits as a result of QIDP and Fast Track designations. 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 has discretion whether to pursuant the NERD development program and may choose to delay or cancel its planned development program in NERD based on, among other things, further discussions with the FDA; the rate of patient enrollment and drop-outs in PHALCON-EE and PHALCON-HP due to the COVID-19 pandemic is highly uncertain due to factors outside Phathom's control; potential additional delays in the commencement, enrollment and completion of clinical trials; patients already enrolled in PHALCON-EE and PHALCON-HP may not complete the clinical trials or public health conditions and governmental restrictions may lead Phathom to stopping such trials all together, which may adversely impact Phathom's trial results and development plans; 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; QIDP and Fast Track designations may not actually lead to a faster development or regulatory review or extended exclusivity, and would not assure FDA approval of vonoprazan; Phathom's ability to obtain and maintain intellectual property protection for vonoprazan; Phathom's ability to comply with its license agreement with Takeda; our 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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