

Phathom[®]

PHARMACEUTICALS

Phathom Pharmaceuticals to Present VOQUEZNA[®] (vonoprazan) Data at DDW 2024 Annual Meeting

May 15, 2024

- *First oral presentation of Phase 3 data evaluating the investigational use of VOQUEZNA[®] in Non-Erosive Reflux Disease (NERD)¹*
- *New research on Erosive gastroesophageal reflux disease (GERD) demonstrating high health care resource utilization, real world treatment patterns in newly diagnosed patients and diagnostic accuracy of grading disease severity, to be presented^{2,3,4}*

FLORHAM PARK, N.J., May 15, 2024 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal (GI) diseases, today announced that the company will present data from multiple studies for its first-in-class treatment VOQUEZNA[®] (vonoprazan) including an oral presentation at Digestive Disease Week[®] (DDW) 2024, being held May 18-21 in Washington, D.C.

Phathom's Phase 3 results evaluating the investigational use of VOQUEZNA in Non-Erosive Reflux Disease (NERD) will be featured in an oral presentation during the congress.¹ In addition, poster presentations showcasing real-world evidence on suboptimal treatment patterns of newly diagnosed Erosive GERD patients treated with proton pump inhibitors (PPIs), and an analysis highlighting high healthcare resource utilization (HCRU) costs associated with Erosive GERD, among other important clinical data updates and broader clinical sessions, will be showcased.^{2,3,4}

"This year's abstracts showcase the breadth of the data we will be presenting at DDW, reaffirming Phathom's continued commitment to helping improve the lives of people affected by acid-related gastrointestinal disorders," said Eckhard Leifke, M.D., Chief Medical Officer at Phathom. "Notably, we are excited to unveil novel findings highlighted in three posters and an oral presentation during the conference, including the first time data from our Phase 3 study of the investigational use of VOQUEZNA in Non-Erosive GERD will be presented during a medical congress. Our team eagerly anticipates meaningful interactions with physicians that treat the conditions we are working to transform."

Phathom announced in December 2023 that the U.S. Food and Drug Administration (FDA) accepted for review the company's New Drug Application (NDA) for VOQUEZNA as a daily treatment of heartburn associated with Non-Erosive GERD and assigned a Prescription Drug User Fee Act (PDUFA) target action date of July 19, 2024.

In addition to these three poster sessions and one oral presentation, Phathom will sponsor a product theater highlighting VOQUEZNA as an approved treatment for Erosive Esophagitis, also referred to as Erosive GERD, and will also have a presence on the exhibit floor at booth #911 throughout the conference.

A high-level schedule of Phathom activities at DDW 2024 can be found below:

Sunday, May 19, 2024

- **Certified DDW 2024 Symposium: What's New in the Treatment of Erosive Esophagitis and Gastroesophageal Reflux Disease**
 - Time: 6:00-8:00 pm ET
 - Presenters: Prakash Gyawali, M.D.; Rena Yadlapati, M.D.; Leila Kia, M.D.
 - Independent CME sponsored by Phathom Pharmaceuticals

Monday, May 20, 2024

- **Comparison of Local Investigator-Reported vs Centrally Adjudicated Los Angeles Grades of Erosive Esophagitis in Patients Screened for Participation in a Randomized Trial³**
 - Time: 12:30 pm ET
 - Presentation #: 4034836
 - Poster Session

- **Real-world Treatment Patterns Among Newly Diagnosed Patients with Erosive Esophagitis in the U.S.**⁴
 - Time: 12:30 pm ET
 - Presentation #: 4036034
 - Poster Session
- **VOQUEZNA® (vonoprazan) Product Theater – The Power to Help Heal and Maintain Healing of Erosive GERD in Adults: A Novel Treatment with First-in-Class Acid Suppression**
 - Time: 12:50 pm ET
 - Product theater #2
 - Oral Presentation by Dr. Brooks D. Cash, M.D., Chief of the Division of Gastroenterology, Hepatology, and Nutrition at the University of Texas Health Science Center at Houston
- **Vonoprazan for the Treatment of Heartburn in Non-Erosive Reflux Disease: A Randomized Trial**¹
 - Time: 4:45 pm ET
 - Presentation #: 4025446
 - Oral Presentation

Tuesday, May 21, 2024

- **Erosive Esophagitis is Associated with High Health Care Resource Utilization and Frequent Changes in Medications**²
 - Time: 2:30 pm ET
 - Presentation #: 4036411
 - Poster Session

Following the meeting, abstracts will be available on the [Phathom's publications and scientific section](#) of the company website.

VOQUEZNA is marketed exclusively by Phathom Pharmaceuticals, Inc. Please visit [VoqueznaPro.com](#) to learn more about VOQUEZNA.

About DDW

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 18-21, 2024 in Washington, D.C. The meeting showcases more than 3,500 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at [www.ddw.org](#).

INDICATION AND IMPORTANT SAFETY INFORMATION

What is VOQUEZNA?

- VOQUEZNA® (vonoprazan) is a prescription medicine used in adults:
 - for the healing of all grades of Erosive Esophagitis (Erosive Gastroesophageal Reflux Disease or Erosive GERD) and relief of heartburn associated with Erosive GERD in adults.
 - for the maintenance of healing of all grades of Erosive GERD and relief of heartburn associated with Erosive GERD in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VOQUEZNA is contraindicated in patients with a known hypersensitivity to vonoprazan or any component of VOQUEZNA, or in patients receiving rilpivirine-containing products.

WARNINGS AND PRECAUTIONS

Presence of Gastric Malignancy: In adults, symptomatic response to therapy with VOQUEZNA does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing in patients who have a suboptimal response or an early symptomatic relapse after completing treatment with VOQUEZNA. In older patients, also consider endoscopy.

Acute Tubulointerstitial Nephritis: Acute tubulointerstitial nephritis (TIN) has been reported with VOQUEZNA. If suspected, discontinue VOQUEZNA and evaluate patients with suspected acute TIN.

Clostridioides difficile-Associated Diarrhea: Published observational studies suggest that proton pump inhibitors (PPIs) may be associated with an increased risk of *Clostridioides difficile*-associated diarrhea (CDAD), especially in hospitalized patients. VOQUEZNA may also increase the risk of CDAD. Consider CDAD in patients with diarrhea that does not improve. Use the shortest duration of VOQUEZNA appropriate to the condition being treated.

Bone Fracture: Several published observational studies suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine, especially in patients receiving high dose (multiple daily doses) and long-term therapy (a year or longer). Bone fracture, including osteoporosis-related fracture, has also been reported with vonoprazan. Use the shortest duration of VOQUEZNA appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to the established treatment guidelines.

Severe Cutaneous Adverse Reactions (SCAR): Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with VOQUEZNA. Discontinue VOQUEZNA at the first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation.

Vitamin B12 (Cobalamin) Deficiency: Long-term use of acid-suppressing drugs can lead to malabsorption of Vitamin B12 caused by hypo- or achlorhydria. Vitamin B12 deficiency has been reported postmarketing with vonoprazan. If clinical symptoms consistent with vitamin B12 deficiency are observed in patients treated with VOQUEZNA, consider further workup.

Hypomagnesemia and Mineral Metabolism: Hypomagnesemia has been reported postmarketing with vonoprazan. Hypomagnesemia may lead to hypocalcemia and/or hypokalemia and may exacerbate underlying hypocalcemia in at-risk patients.

Consider monitoring magnesium levels prior to initiation of VOQUEZNA and periodically in patients expected to be on prolonged treatment, in patients taking drugs that may have increased toxicity in the presence of hypomagnesemia or drugs that may cause hypomagnesemia. Treatment of hypomagnesemia may require magnesium replacement and discontinuation of VOQUEZNA.

Consider monitoring magnesium and calcium levels prior to initiation of VOQUEZNA and periodically while on treatment in patients with a preexisting risk of hypocalcemia. Supplement with magnesium and/or calcium, as necessary. If hypocalcemia is refractory to treatment, consider discontinuing VOQUEZNA.

Interactions with Diagnostic Investigations for Neuroendocrine Tumors: Serum chromogranin A (CgA) levels increase secondary to drug-induced decreases in gastric acidity. The increased CgA level may cause false positive results in diagnostic investigations for neuroendocrine tumors. Temporarily discontinue VOQUEZNA treatment at least 14 days before assessing CgA levels and consider repeating the test if initial CgA levels are high.

Fundic Gland Polyps: Use of VOQUEZNA is associated with a risk of fundic gland polyps that increases with long-term use, especially beyond one year. Fundic gland polyps have been reported with vonoprazan in clinical trials and during postmarketing use with PPIs. Most patients who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of VOQUEZNA appropriate to the condition being treated.

ADVERSE REACTIONS:

Healing of Erosive GERD: The most common adverse reactions ($\geq 2\%$ of patients in the VOQUEZNA arm) include gastritis (3%), diarrhea (2%), abdominal distention (2%), abdominal pain (2%), and nausea (2%).

Maintenance of Healed Erosive GERD: The most common adverse reactions ($\geq 3\%$ of patients in the VOQUEZNA arm) include gastritis (6%), abdominal pain (4%), dyspepsia (4%), hypertension (3%), and urinary tract infection (3%).

DRUG INTERACTIONS

VOQUEZNA has the potential for clinically important drug interactions, including interactions with drugs dependent on gastric pH for absorption, drugs that are substrates for certain CYP enzymes, and some diagnostic tests. Avoid concomitant use of VOQUEZNA with atazanavir or nelfinavir. See full Prescribing Information for more details about important drug interactions. Consult the labeling of concomitantly used drugs to obtain further information about interactions with vonoprazan.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding is not recommended during treatment. Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, advise patients not to breastfeed during treatment with VOQUEZNA.

Renal Impairment: For the healing of Erosive GERD, dosage reduction is recommended in patients with severe renal impairment (eGFR < 30 mL/min).

Hepatic Impairment: For the healing of Erosive GERD, dosage reduction is recommended in patients with moderate to severe hepatic impairment (Child-Pugh Class B and C).

You are encouraged to report suspected adverse reactions by contacting Phathom Pharmaceuticals at 1-888-775-PHAT (7428) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see [full Prescribing Information](#) for VOQUEZNA.

About Erosive GERD (gastroesophageal reflux disease)

Erosive GERD, also referred to as Erosive Esophagitis (EE), is a subtype of gastroesophageal reflux disease (GERD) characterized by erosions in the gastric mucosa caused by acidic reflux of stomach contents into the esophagus.⁵ There are estimated to be over 65 million individuals with GERD in the U.S., of which approximately 30% have Erosive GERD.^{6,7,8} 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.⁶

About VOQUEZNA®

VOQUEZNA® (vonoprazan) tablets contain vonoprazan, an oral small molecule potassium-competitive acid blocker (PCAB). PCABs are a novel class of medicines that block acid secretion in the stomach. Phathom in-licensed the U.S. rights to vonoprazan from Takeda, which markets the product in Japan and numerous other countries in Asia and Latin America.

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 to vonoprazan, a first-in-class potassium-competitive acid blocker (PCAB) that is currently marketed in the United States as VOQUEZNA® (vonoprazan) tablets for the treatment of Erosive GERD and relief of related heartburn in adults, in addition to VOQUEZNA® TRIPLE PAK® (vonoprazan tablets, amoxicillin capsules, clarithromycin tablets) and VOQUEZNA® DUAL PAK® (vonoprazan tablets, amoxicillin capsules) for the treatment of *H. pylori* infection in adults. For more information about Phathom, visit the company's website at www.phathompharma.com and follow on [LinkedIn](#) and [X](#).

Forward Looking Statement

This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about the PDUFA action date for and FDA approval of the Company's NDA for NERD and vonoprazan's ability to treat patients affected by acid-related gastrointestinal disorders. 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: we may not be able to successfully commercialize VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, which will depend on a number of factors including coverage and reimbursement levels from governmental authorities and health insurers as well as market acceptance by healthcare providers; risks inherent in the 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 obtain and maintain intellectual property protection and non-patent regulatory exclusivity for vonoprazan; 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 most recent 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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