

# Phathom<sup>®</sup>

## PHARMACEUTICALS

### Phathom Pharmaceuticals Announces VOQUEZNA<sup>®</sup> (vonoprazan) Tablets for Erosive GERD and Associated Heartburn Added to Express Scripts National Formularies for Commercial Patients

February 13, 2024

- *One of the largest pharmacy benefit management (PBM) companies in the United States has added VOQUEZNA (vonoprazan) tablets to its national formularies for commercial plans, effective immediately*

FLORHAM PARK, N.J., Feb. 13, 2024 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today announced the placement of VOQUEZNA<sup>®</sup> (vonoprazan) tablets for the treatment of adults with Erosive Esophagitis, commonly referred to as Erosive GERD (gastroesophageal reflux disease), and relief of heartburn associated with Erosive Esophagitis on the Express Scripts national formularies, effective immediately. VOQUEZNA is the first and only FDA-approved potassium-competitive acid blocker (PCAB) and the first new class of Erosive GERD treatment to become available in the United States in over 30 years. Commercial access for VOQUEZNA tablets is now estimated at 60 million covered lives in the United States.

"We are thrilled to announce VOQUEZNA has been added to Express Scripts' national formularies, highlighting one of the largest pharmacy benefit management companies in the U.S. is now providing millions of patients the potential for immediate access to our novel treatment for Erosive GERD," said Martin Gilligan, Chief Commercial Officer of Phathom. "This formulary placement aligns with our expectations of offering broad access with a single step through a generic proton pump inhibitor (PPI). Given that most Erosive GERD patients have already undergone treatment with a PPI, and many continue to express dissatisfaction with their current regimens, we are pleased with this outcome. Additionally, we are actively engaging with the other major PBMs and health plans to further increase coverage and ensure that patients suffering from Erosive GERD have widespread access to VOQUEZNA."

Erosive GERD, also referred to as Erosive Esophagitis, is a subtype of GERD that affects approximately 20 million people in the U.S. Research shows high dissatisfaction among patients and prescribers with current therapies<sup>1</sup> and according to medical claims analysis, approximately 35% of Erosive GERD patients treated with a prescription PPI switch to a different PPI within three months of initial treatment.<sup>2</sup>

Phathom is also offering programs for eligible patients who face coverage or affordability issues, including co-pay assistance for patients with commercial insurance. For more information, please visit [www.voquezna.com/savings](http://www.voquezna.com/savings).

VOQUEZNA is available by prescription only and marketed exclusively by Phathom Pharmaceuticals. For more information about VOQUEZNA visit [voquezna.com](http://voquezna.com)

<sup>1</sup> Vaezi MF, Brunton S, Mark Fendrick A, et al. Patient journey in erosive oesophagitis: real- world perspectives from US physicians and patients. *BMJ Open Gastro* 2022;9:e000941. doi:10.1136/ bmjgast-2022-000941

<sup>2</sup> AESARA claims

#### INDICATIONS AND USAGE

VOQUEZNA<sup>®</sup> (vonoprazan) is a potassium-competitive acid blocker (PCAB) indicated:

- 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](http://www.fda.gov/medwatch).

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

## About VOQUEZNA®

VOQUEZNA® (vonoprazan) tablets contain vonoprazan, an oral small molecule potassium-competitive acid blocker (PCAB), approved in the U.S. for the treatment of adults with Erosive Esophagitis, also known as Erosive GERD, and the relief of heartburn associated with Erosive GERD. PCABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan is the first gastric anti-secretory agent from a novel class approved in the United States in over 30 years, and has shown rapid, potent, and durable anti-secretory effects. 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 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](http://www.phathompharma.com) and follow the Company on [LinkedIn](#) and [X](#).

## 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 patient access and continued expansion in commercial coverage with other payers. 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 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; 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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