Phathom Pharmaceuticals Announces Publication of Data from Phase 3 pHalcon-NERD-301 Study Showing VOQUEZNA® (vonoprazan) Improved Nocturnal GERD Symptoms in Patients with Non-Erosive Reflux Disease

October 25, 2025

- *Data published in the American Journal of Gastroenterology showed rapid and sustained relief of nighttime gastroesophageal reflux disease (GERD) symptoms in patients treated with VOQUEZNA, including clinically meaningful increases in heartburn-free nights observed after the first dose and maintained through 24 weeks of treatment*

- *Analysis of exploratory endpoints showed durable improvements in measures of nocturnal symptom severity and sleep-related impacts throughout the full treatment period*

FLORHAM PARK, N.J., Oct. 25, 2025 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal (GI) diseases, today announced that results of additional analyses from its pivotal Phase 3 pHalcon-NERD-301 trial evaluating VOQUEZNA® (vonoprazan) tablets in patients with Non-Erosive Reflux Disease (NERD) have been published in the *American Journal of Gastroenterology*. The article, titled *"Vonoprazan Improves Nocturnal Gastroesophageal Reflux Symptoms in Non-Erosive Reflux Disease"*, underscores the significant burden of nighttime GERD symptoms and the potential role of VOQUEZNA in addressing this aspect of the disease.

Nighttime GERD symptoms are highly prevalent, affecting up to an estimated 80% of patients with GERD, and can be associated with impaired sleep, reduced work productivity, and increased risk of esophageal and respiratory complications. Despite lifestyle interventions and the widespread use of proton pump inhibitors (PPIs) and H2-receptor antagonists (H2RAs), many patients experience inadequate relief of nocturnal symptoms, which remain underrepresented in clinical research.

"Nocturnal symptoms can be among the most disruptive and difficult-to-manage aspects of GERD," said Philip Katz, MD, MACG, Professor of Medicine, Weill Cornell Medicine and study author who serves as a consultant for Phathom Pharmaceuticals. "This large, randomized trial provides important support for VOQUEZNA's potential role in improving sleep and daily functioning for patients with Non-Erosive Reflux Disease."

In the Phase 3 pHalcon-NERD-301 trial, 772 patients were randomized to VOQUEZNA 10 mg, 20 mg, or placebo for an initial 4-week period. Patients on VOQUEZNA continued blinded active treatment for a 20-week extension, while those on placebo were re-randomized to VOQUEZNA 10 mg or 20 mg for the extension phase.

Key findings include:

- **Percentage of Heartburn-Free Nights:** At week 4, patients receiving VOQUEZNA 10 mg and 20 mg achieved mean percentages of heartburn-free nights of 59.9% and 56.4%, respectively, compared to 43.3% for placebo (nominal $p<0.0001$, exploratory analysis not adjusted for multiple comparisons). Median percentages of heartburn-free nights during the 4-week placebo-controlled treatment period were 70.4% for VOQUEZNA 10 mg, 71.0% for VOQUEZNA 20 mg, and 45.5% for placebo.

- **Onset of Effect:** Separation from placebo was observed after the first dose, with 45.3% of VOQUEZNA 10 mg and 52.4% of VOQUEZNA 20 mg patients experiencing a heartburn-free night after the first dose vs. 32.1% on placebo.

- **Patient-Reported Outcomes:** As measured by the validated Nocturnal Gastroesophageal Reflux Disease Symptom Severity and Impact Questionnaire (N-GSSIQ), treatment with VOQUEZNA was associated with improvements from baseline versus placebo in total N-GSSIQ score, and in the subscales of nocturnal symptom severity and concern about nocturnal GERD, but not on morning impact. Improvements with VOQUEZNA were sustained through the 20-week extension treatment period.

- **Durability:** VOQUEZNA demonstrated sustained nocturnal symptom relief throughout the full treatment period, consistent with the 24-hour heartburn relief observed in the full pHalcon-NERD-301 trial. Median heartburn-free nights remained above 70% across all treatment groups through the 20-week active extension.

- **Generally Well Tolerated:** VOQUEZNA was generally well tolerated in both phases of the trial. The most common adverse events (≤3%) in the 4-week period were nausea, abdominal pain, constipation, diarrhea, and urinary tract infection; in the 20-week extension, most common adverse events (≤5%) included upper respiratory tract infection, sinusitis, influenza, urinary tract infection, nasopharyngitis, nausea, and gastroenteritis.

“The publication of these data in *The American Journal of Gastroenterology* adds to the growing body of clinical evidence evaluating VOQUEZNA as a novel potassium-competitive acid blocker with the potential to address the unmet needs for patients with GERD, including those with bothersome nighttime symptoms who often have been inadequately managed by existing therapies,” said Eckhard Leifke, MD, Chief Medical Officer at Phathom. “The results provide additional insights into a challenging and under-recognized aspect of GERD and further contribute to the clinical understanding of this first-in-class medicine.”

About Non-Erosive Reflux Disease

Non-Erosive GERD is the largest subcategory of gastroesophageal reflux disease (GERD) and is characterized by reflux-related symptoms in the absence of esophageal mucosal erosions. There are an estimated 38 million U.S. adults living with Non-Erosive GERD, of these approximately 15 million are treated with a prescription medicine annually. Symptoms can impact overall quality of life and may include episodic heartburn, especially at night, regurgitation, problems swallowing, and chest pain.

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. VOQUEZNA is approved in the U.S. for the treatment of adults with Erosive Esophagitis, also known as Erosive GERD, the relief of heartburn associated with Erosive GERD, the relief of heartburn associated with Non-Erosive GERD, and for the treatment of *H. pylori* infection in combination with either amoxicillin or amoxicillin and clarithromycin. 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.

INDICATIONS AND USAGE

VOQUEZNA® (vonoprazan) is a potassium-competitive acid blocker (PCAB) indicated 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.
- to maintain healing of all grades of Erosive GERD and relief of heartburn associated with Erosive GERD.
- for the relief of heartburn associated with Non-Erosive GERD.

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 4 weeks 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 (≥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 (≥3% of patients in the VOQUEZNA arm) include gastritis (6%), abdominal pain (4%), dyspepsia (4%), hypertension (3%), and urinary tract infection (3%).

Relief of Heartburn Associated with Non-Erosive GERD: The most common adverse reactions (≥2% of patients in the VOQUEZNA arm) include abdominal pain (2%), constipation (2%), diarrhea (2%), nausea (2%), and urinary tract infection (2%).

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 click here to see full Prescribing Information for VOQUEZNA.

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), for the U.S., Europe and Canada. Phathom currently markets vonoprazan in the United States as VOQUEZNA® (vonoprazan) tablets for the relief of heartburn associated with Non-Erosive GERD in adults, the healing and maintenance of healing of Erosive GERD in adults and relief of associated heartburn, and as part of 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 follow on LinkedIn and X.

Forward-Looking Statements
This press release contains forward-looking statements, including without limitation statements regarding: the potential clinical profile of VOQUEZNA; our estimates as to the size of certain patient populations and unmet need in GERD; our business strategy, goals, mission and vision; and our other expectations, forecasts and predictions as to future performance, results and likelihood of success. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including the risk that: the unmet need for new treatment options in GERD may not be as high as we anticipate; our estimates of the number of patients with GERD or subsets of such patients may not be accurate; the efficacy profile for VOQUEZNA in clinical practice may be different than the results discussed in this press release; we may encounter unexpected adverse side effects for VOQUEZNA in commercial use or future clinical development; we may encounter setbacks in market acceptance for VOQUEZNA or commercialization that significantly impair our business strategy or efforts to achieve our goals, mission or vision; and any of the foregoing or other factors may negatively impact our ability to achieve our plans, goals, mission, vision and potential. For additional discussion of these and other risks, see the risk disclosure in our filings with the Securities and Exchange Commission (SEC), including our 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 we undertake no obligation to revise or update this presentation to reflect events or circumstances 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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