Phathom Pharmaceuticals Announces First Patient Dosed in Phase 2 Study of VOQUEZNA® (vonoprazan) in Eosinophilic Esophagitis (EoE)

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- *First patient dosed, with topline results expected in 2027*
- *pHalcon-EoE-201 is the first large, well-controlled clinical trial of an acid secretory treatment in EoE*

FLORHAM PARK, N.J., Nov. 04, 2025 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal (GI) diseases, today announced the first patient has been dosed in its Phase 2 pHalcon-EoE-201 clinical trial evaluating VOQUEZNA® (vonoprazan) tablets as an investigational treatment for eosinophilic esophagitis (EoE) in adults.

“The initiation of the pHalcon-EoE-201 study reflects Phathom’s commitment to advancing care for patients with gastrointestinal diseases and our development strategy to expand VOQUEZNA’s clinical potential,” said Steve Basta, President and Chief Executive Officer at Phathom. “This trial represents an important opportunity to address significant unmet needs in the treatment of EoE while potentially generating data to support discussions on a pediatric program that could ultimately extend VOQUEZNA’s regulatory exclusivity and strengthen our long-term growth strategy as leaders in GI.”

“Despite advances in understanding eosinophilic esophagitis, treatment options remain limited, with only two approved therapies currently available,” said Evan S. Dellon, MD, MPH, Professor of Medicine in the Division of Gastroenterology and Hepatology, and Director of the Center for Esophageal Diseases and Swallowing at the University of North Carolina School of Medicine, Chapel Hill, and principal investigator of the pHalcon-EoE-201 study. “Proton pump inhibitors (PPIs) are traditionally used as first-line treatment for EoE, but none are FDA approved for this indication, and supporting data come primarily from uncontrolled studies. VOQUEZNA’s acid suppression profile could potentially offer an oral, non-steroidal treatment approach for patients with EoE.”

Phathom’s Phase 2 EoE study is a two-part, randomized, double-blind, placebo-controlled study. The first part will enroll 80 adults with endoscopic-confirmed EoE and dysphagia, or trouble swallowing, to be randomized evenly to receive VOQUEZNA 20 mg or placebo, once daily for 12 weeks. Patients who complete the initial 12-week treatment period will be eligible to enter Part 2, a 12-week extension phase, where all subjects will receive VOQUEZNA 20 mg for the remainder of the study.

Topline primary and secondary results are anticipated to be available in 2027.

For more information about the pHalcon-EoE-201 study (NCT06851559), visit ClinicalTrials.gov.

About pHalcon-EoE-201

pHalcon-EoE-201 (NCT06851559) is a Phase 2, randomized, double-blind, placebo-controlled study evaluating VOQUEZNA® (vonoprazan) 20 mg in approximately 80 adults with eosinophilic esophagitis (EoE) across approximately 40 U.S. sites. In Part 1, participants with endoscopically-confirmed EoE and dysphagia will receive once-daily VOQUEZNA or placebo for 12 weeks. Those who complete Part 1 may enter Part 2, a 12-week extension period, during which all patients will receive VOQUEZNA 20 mg once daily.

About Eosinophilic Esophagitis

Eosinophilic esophagitis (EoE) is a chronic, immune condition of the esophagus where white blood cells called eosinophils build up in the lining, causing inflammation and potential difficulty or painful swallowing, choking or food impaction. Additional symptoms may also include chest pain, heartburn, regurgitation, and vomiting. Although the exact cause is unknown, it is believed to be triggered by a variety of stimuli including certain foods and environmental allergens. Identifying EoE can be complex and delayed diagnosis is common among patients. If left untreated, the inflammation of EoE can worsen and narrow the esophagus, further exacerbating symptoms.

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.
- in combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori* (*H. pylori*) infection.
- in combination with amoxicillin for the treatment of *H. pylori* infection.

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.

For information about contraindications of antibacterial agents (clarithromycin and amoxicillin) indicated in combination with VOQUEZNA, refer to the *Contraindications* section of the corresponding prescribing information.

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.

CDAD has been reported with use of nearly all antibacterial agents. For more information specific to antibacterial agents (clarithromycin and amoxicillin) indicated for use in combination with VOQUEZNA, refer to *Warnings and Precautions* section of the corresponding prescribing information.

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%).

Treatment of *H. pylori* Infection (VOQUEZNA and Amoxicillin): The most common adverse reactions (≥2% in any treatment arm) include diarrhea (5%), abdominal pain (3%), vulvovaginal candidiasis (2%), nasopharyngitis (2%), dysgeusia (1%), headache (1%), and hypertension (1%).

Treatment of *H. pylori* Infection (VOQUEZNA, Amoxicillin and Clarithromycin): The most common adverse reactions (≥2% in any treatment arm) include dysgeusia (5%), diarrhea (4%), vulvovaginal candidiasis (3%), headache (3%), abdominal pain (2%), hypertension (2%), and nasopharyngitis (<1%).
For more information on adverse reactions and laboratory changes with amoxicillin or clarithromycin, refer to *Adverse Reactions* section of the corresponding prescribing information.

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.

For information about drug interactions, contraindications, and warnings and precautions of antibacterial agents (amoxicillin or clarithromycin) indicated in combination with VOQUEZNA, refer to their corresponding prescribing information.

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). Use of VOQUEZNA is not recommended for the treatment of *H. pylori* infection in patients with severe renal impairment.

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). Use of VOQUEZNA is not recommended for the treatment of *H. pylori* infection in patients with moderate to severe hepatic impairment.

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 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 rights to vonoprazan for the U.S., Europe and Canada 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), 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 and follow on LinkedIn and X.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained in this press release, including statements regarding: our plans, expectations, and goals for development of VOQUEZNA in eosinophilic esophagitis (EoE); potential timelines for the pHalcon-EoE-201 study (the "Study"), including timelines for reporting of topline results; the potential for the Study to support discussions on a pediatric program that could extend regulatory exclusivity; the unmet need for additional options in the treatment of EoE and the potential of VOQUEZNA as a treatment option; and our plans, expectations and strategies with respect to our business, goals, mission and vision; and as to future performance, results and likelihood of success, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential", "guidance", or "continue" or the negative of these terms or other similar expressions. 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: we may encounter issues with conduct of the Study that delay our timelines, including slower than expected enrollment or issues with conduct of the study or data analysis; we may receive negative or mixed results from the Study that are not sufficient to advance the program; even if the results of the Study are positive, we may decide not to advance the EoE program and we may decide not to conduct a pediatric program in EoE; if we decide to conduct a pediatric program in EoE, the studies we conduct may not meet the requirements or timelines for receiving an extension of our regulatory exclusivity for VOQUEZNA; the data from the Study or any future studies we may conduct in EoE may not support the potential for VOQUEZNA as a treatment option in this indication; the success of the EoE program may be impacted by potential safety or tolerability issues, competition from other therapies or treatment approaches, or technical issues; future cash needs may cause us to change our plans; 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 press release 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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