Phathom Pharmaceuticals Announces Initiation of Registrational Phase 3 Study of VOQUEZNA® (vonoprazan) for As-Needed Treatment of Non-Erosive GERD

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- *Initiation of registrational Phase 3 study of VOQUEZNA® (vonoprazan) for as-needed (PRN) use in Non-Erosive Reflux Disease (NERD) builds on previously reported positive Phase 2 data*
- *Topline results expected in the first quarter of 2028*
- *pHalcon-NERD-302, if successful, is intended to support a potential VOQUEZNA label expansion to include as-needed treatment of heartburn episodes in patients with Non-Erosive GERD, a treatment regimen of interest to patients for which proton pump inhibitors (PPIs) are not currently approved in the U.S.*

FLORHAM PARK, N.J., Sept. 29, 2026 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases, today announced the initiation of patient screening in pHalcon-NERD-302, a registrational Phase 3 study evaluating an as-needed (PRN or on-demand) investigational dosing regimen of VOQUEZNA® (vonoprazan) tablets in adults with Non-Erosive Gastroesophageal Reflux Disease, or Non-Erosive GERD (NERD). Topline results are expected in the first quarter of 2028. If successful, the study is intended to support a potential regulatory submission seeking a label expansion for VOQUEZNA tablets for this treatment regimen.

“With pHalcon-NERD-302, we are studying what we believe could be an important new treatment approach for patients with Non-Erosive GERD. The study is designed to assess whether as-needed VOQUEZNA can provide rapid relief of heartburn when symptoms occur, with relief sustained over 24 hours. We have heard from many physicians and patients about the desire for an as-needed option. If successful, this study could support a potential label expansion for VOQUEZNA and an important opportunity to potentially broaden how VOQUEZNA may be used in the future to meet the needs of patients with Non-Erosive GERD,” said **Steve Basta, President and Chief Executive Officer of Phathom Pharmaceuticals**.

VOQUEZNA Phase 3 As-Needed Program
Building on previously reported positive Phase 2 results, pHalcon-NERD-302 is a multicenter, randomized, double-blind, placebo-controlled Phase 3 study investigating VOQUEZNA 10 mg as an as-needed treatment in adults with Non-Erosive GERD. The Phase 3 pHalcon-NERD-302 study is expected to enroll approximately 500 adults with Non-Erosive GERD who report heartburn at least four days per week. The study is planned to be conducted at approximately 80 sites in the U.S. Following a four-week, open-label run-in period with VOQUEZNA 10 mg once daily, patients without heartburn during the final seven days of the run-in period will be randomized 1:1 to receive VOQUEZNA 10 mg or placebo, as-needed, for 24 weeks of treatment. The primary endpoint, assessed at Week 12, is the percentage of heartburn episodes in which patients experience complete relief within two hours and sustained relief for 24 hours post-dosing.

“Non-Erosive GERD is characterized by episodic, often unpredictable heartburn. Proton-pump inhibitor acid-suppressing therapies generally rely on continuous daily use,” said **Ronnie Fass, M.D., Division Director of Gastroenterology and Hepatology and Medical Director of the Digestive Health Center at MetroHealth Medical Center, Professor of Medicine at Case Western Reserve University School of Medicine, and an investigator for pHalcon-NERD-302.** “An as-needed treatment approach would need to provide acid suppression that starts rapidly and is sustained long enough to control heartburn over 24 hours. The results from the earlier Phase 2 as-needed study of VOQUEZNA provide a strong rationale for evaluating its efficacy and safety in this Phase 3 trial.”

“One of the practical questions in managing Non-Erosive GERD is whether patients with intermittent symptoms need continuous daily therapy. This registrational study is designed to evaluate whether an as-needed treatment approach can provide effective heartburn relief when symptoms occur,” said **Philip O. Katz, M.D., Professor of Medicine in the Division of Gastroenterology and Hepatology at Weill Cornell Medicine, gastroenterologist at NewYork-Presbyterian/Weill Cornell Medical Center, and an investigator for pHalcon-NERD-302.** Dr. Katz serves as a consultant for Phathom Pharmaceuticals.

For more information about the pHalcon-NERD-302 study (NCT07752407), visit ClinicalTrials.gov.

About Non-Erosive Gastroesophageal Reflux Disease
Non-Erosive Gastroesophageal Reflux Disease (NERD) is the largest subcategory of gastroesophageal reflux disease (GERD) and is characterized by reflux-related

symptoms in the absence of esophageal mucosal erosions. More than 22 million U.S. patients are estimated to be treated annually with prescription medication for GERD, and approximately 15 million of these patients are believed to have NERD. Symptoms of NERD may impact overall quality of life and can include episodic heartburn, regurgitation, problems swallowing, and chest pain.

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

Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VOQUEZNA during pregnancy. Healthcare providers are encouraged to register patients by calling 1-866-609-1612 or visiting https://voqueznapregnancyregistry.com/.

Lactation: There are no data on the effects of vonoprazan on the breastfed child or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VOQUEZNA and any potential adverse effects on the breastfed child from VOQUEZNA or from the underlying maternal condition.

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 click here to 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 fact contained in this press release, including statements regarding: our plans, expectations, and goals for the development of VOQUEZNA for as-needed use in Non-Erosive GERD (NERD); potential timelines for the pHalcon-NERD-302 study (the "Study"), including timelines for site activation, screening, enrollment and reporting of topline results; the potential for the Study to be successful and to support the filing and approval of a label expansion for VOQUEZNA as an as-needed treatment in NERD; the potential role and need for an as-needed treatment option in the treatment of NERD; the potential of VOQUEZNA as such a treatment option, if the Study is successful and an expanded label is approved; our plans, expectations and strategies with respect to our business, goals, mission and vision; and our 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 the conduct of the Study that delay our timelines, including slower than expected site activation or enrollment, or issues with study conduct or data analysis; the Study may not replicate the results of our Phase 2 study; the Study may produce negative, mixed or otherwise inconclusive results; regulatory authorities may not agree that the results are sufficient to support a regulatory submission or approval of a label expansion for as-needed use in NERD; even if the results of the Study are positive, we may decide not to seek a label expansion; the success of the program may be impacted by potential safety or tolerability issues, competition from other therapies, treatment approaches, or ongoing clinical trials of other treatments; we may encounter manufacturing or other technical issues that negatively impact our conduct of the Study; 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.

MEDIA CONTACT
Nick Benedetto
1-877-742-8466
media@phathompharma.com

INVESTOR CONTACT
Eric Sciorilli
1-877-742-8466

ir@phathompharma.com