Phathom Pharmaceuticals Announces Commercial Availability of VOQUEZNA® (vonoprazan) Tablets, a Powerful First-In-Class PCAB for the Treatment of Erosive GERD and Relief of Associated Heartburn

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- *VOQUEZNA, the first and only FDA-approved potassium-competitive acid blocker (PCAB), is now available through major retail pharmacies and BlinkRx, an end-to-end digital fulfillment channel*
- *VOQUEZNA tablets in 30-count bottles are now commercially available for the healing and maintenance of healing of all severities of Erosive GERD, and relief of heartburn associated with Erosive GERD*[1]

FLORHAM PARK, N.J., Nov. 28, 2023 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal (GI) diseases, today announced the U.S. commercial availability of VOQUEZNA® (vonoprazan). VOQUEZNA is now available for the treatment of adults with Erosive Esophagitis, also known as Erosive GERD (gastroesophageal reflux disease), and the relief of heartburn associated with Erosive GERD.[1] As the first and only approved potassium-competitive acid blocker (PCAB) in the U.S., this milestone brings the power of a new class of acid suppression treatment to a disease with high unmet need.

“We are thrilled to announce the commercial availability of our first-in-class medication, VOQUEZNA, now available for the millions of people in the U.S. suffering from Erosive GERD,” said Martin Gilligan, Chief Commercial Officer at Phathom Pharmaceuticals. “For over three decades, there has been no major innovation in this category. We are excited to introduce VOQUEZNA to patients and healthcare providers, as it has been shown to provide rapid, potent, and durable acid suppression and has the power to help heal Erosive GERD for patients seeking a new and effective treatment option.”

The U.S. Food and Drug Administration (FDA) recently approved VOQUEZNA for the healing of all severities (grades) of Erosive GERD, maintenance of healing of all severities of Erosive GERD, and relief of heartburn associated with Erosive GERD in adults.[1] Its novel mechanism of action (MOA) provides rapid, potent, and durable acid suppression in a way that is distinct from other prescription and over-the-counter medications.[2] Additionally, VOQUEZNA does not have the burden of mealtime dosing, whereas most PPIs must always be taken with food.[1]

In a Phase 3, randomized clinical study, VOQUEZNA 20 mg met the primary endpoint of non-inferiority for complete healing by Week 8 in patients with all severities of Erosive GERD, demonstrating a strong healing rate of 93% compared to 85% for lansoprazole 30 mg, with superior rates of healing demonstrated in a secondary endpoint in patients with moderate-to-severe disease at Week 2 compared to lansoprazole (70% for VOQUEZNA 20 mg and 53% for lansoprazole 30 mg). In the maintenance phase of the study, VOQUEZNA 10 mg was superior to lansoprazole 15 mg in maintaining healing at six months in all randomized patients (79% for VOQUEZNA 10 mg, compared to 72% for lansoprazole 15 mg).

The most common side effects of VOQUEZNA for the treatment of Erosive GERD include stomach inflammation, diarrhea, stomach bloating, stomach pain, nausea, indigestion, high blood pressure, and urinary tract infection.

“Erosive GERD is a highly prevalent condition affecting over 20 million people in the U.S., [3,4] many of whom experience troubling symptoms, including painful heartburn. When not properly treated, Erosive GERD can lead to complications such as scarring, narrowing of the esophagus, and bleeding,[4]” said Colin Howden, M.D., Professor Emeritus, University of Tennessee College of Medicine. "With many patients unsatisfied with their current therapy,[5] the introduction of VOQUEZNA provides healthcare providers and patients with an important new treatment option that offers a novel mechanism of action and has demonstrated superiority in comparison to a standard-of-care PPI across several clinically meaningful endpoints.[2]"

Prescriptions for VOQUEZNA may be filled at major retail pharmacies and through BlinkRx, an end-to-end digital fulfillment channel. Phathom is 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.

In addition, VOQUEZNA® TRIPLE PAK® (vonoprazan tablets, amoxicillin capsules, clarithromycin tablets) and VOQUEZNA® DUAL PAK® (vonoprazan tablets, amoxicillin capsules), two treatment regimens for adults with *H. pylori* infection, are expected to be commercially available in mid-December 2023. VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK each contain 14-days of VOQUEZNA-based treatment co-packaged with antibiotics in convenient blister packs.

VOQUEZNA is marketed exclusively by Phathom Pharmaceuticals, Inc. Please visit www.voquezna.com to learn more about VOQUEZNA.

INDICATION AND IMPORTANT SAFETY INFORMATION

What is VOQUEZNA?
VOQUEZNA® (vonoprazan) is a prescription medicine used in adults:

- for 8 weeks to heal acid-related damage to the lining of the esophagus (called Erosive Esophagitis or Erosive Acid Reflux) and for relief of heartburn related to Erosive Acid Reflux.
- for up to 6 months to maintain healing of Erosive Acid Reflux and for relief of heartburn related to Erosive Acid Reflux.

It is not known if VOQUEZNA is safe and effective in children.

Do not take VOQUEZNA if you:

- are allergic to vonoprazan or any of the other ingredients in VOQUEZNA. Allergic reaction symptoms may include trouble breathing, rash, itching and swelling of your face, lips, tongue, or throat.
- are taking a medicine that contains rilpivirine (EDURANT, COMPLERA, JULUCA, ODEFSEY, CABENUVA) used to treat HIV-1 (Human Immunodeficiency Virus).

Before taking VOQUEZNA, tell your healthcare provider about all your medical conditions, including if you:

- have low magnesium, calcium, or potassium in your blood, or you are taking a medicine to increase urine (diuretic).
- have kidney or liver problems.
- are pregnant, think you may be pregnant, or plan to become pregnant. It is not known if VOQUEZNA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VOQUEZNA passes into your breast milk. You and your healthcare provider should decide if you will take VOQUEZNA or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

VOQUEZNA may affect how other medicines work, and other medicines may affect how VOQUEZNA works. Especially tell your healthcare provider if you take medicine that contains rilpivirine (EDURANT, COMPLERA, JULUCA, ODEFSEY, CABENUVA).

What are the possible side effects of VOQUEZNA?

VOQUEZNA may cause serious side effects including:

A type of kidney problem (acute tubulointerstitial nephritis): Some people who take VOQUEZNA may develop a kidney problem called acute tubulointerstitial nephritis. Call your healthcare provider right away if you have a decrease in the amount that you urinate or if you notice blood in your urine.

Diarrhea caused by an infection (*Clostridioides difficile*) in your intestines: Call your healthcare provider right away if you have watery stools, stomach pain, and fever that does not go away.

Bone fractures (hip, wrist, or spine): Bone fractures in the hip, wrist, or spine may happen in people who take multiple daily doses of another type of medicine that reduces acid in your stomach known as proton pump inhibitors (PPI medicines) for a long period of time (a year or longer). Tell your healthcare provider if you have a bone fracture, especially in the hip, wrist, or spine.

Severe skin reactions: VOQUEZNA can cause rare, but severe skin reactions that may affect any part of your body. These serious skin reactions may need to be treated in a hospital and may be life threatening:

- Skin rash which may have blistering, peeling, or bleeding on any part of your skin.
- You may also have fever, chills, body aches, shortness of breath, or enlarged lymph nodes.
- If you experience any of these symptoms, stop taking VOQUEZNA and call your healthcare provider right away. These symptoms may be the first sign of a severe skin reaction.

Low vitamin B-12 levels: VOQUEZNA lowers the amount of acid in your stomach. Stomach acid is needed to absorb Vitamin B12 properly. Tell your healthcare provider if you have symptoms of low vitamin B12 levels, including irregular heartbeat, shortness of breath, lightheadedness, tingling or numbness in the arms or legs, muscle weakness, pale skin, feeling tired, or mood changes. Talk with your healthcare provider about the risk of low vitamin B12 levels if you have been on VOQUEZNA for a long time.

Low magnesium levels in the body can happen in people who take VOQUEZNA. Tell your healthcare provider right away if you have symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, or spasms of hands, feet, or voice.

Stomach growths (fundic gland polyps): A certain type of stomach growth called fundic gland polyps may happen in people who take another type of medicine that reduces acid in your stomach known as proton pump inhibitors (PPI medicines) for a long time. Talk with your healthcare provider about the possibility of fundic gland polyps if you have been on VOQUEZNA for a long time.

The most common side effects of VOQUEZNA for treatment of Erosive Acid Reflux include:

- stomach inflammation
- diarrhea
- stomach bloating
- stomach pain
- nausea
- indigestion
- high blood pressure
- urinary tract infection

These are not all the possible side effects of VOQUEZNA. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects.

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 Patient Information and full Prescribing Information for VOQUEZNA.

What are VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK?

- VOQUEZNA® TRIPLE PAK® (vonoprazan tablets, amoxicillin capsules, clarithromycin tablets) and VOQUEZNA® DUAL PAK® (vonoprazan tablets, amoxicillin capsules) are co-packaged prescription medicines for the treatment of a *Helicobacter pylori (H. pylori)* bacterial infection in adults.
- It is not known if VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK are safe and effective in children.
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK and other antibacterial drugs, these products should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Do not take VOQUEZNA TRIPLE PAK if you

- are known to have an allergy or be sensitive to the components of VOQUEZNA TRIPLE PAK (vonoprazan, amoxicillin, clarithromycin), macrolide antibiotics (such as azithromycin and erythromycin), or penicillin.
- are taking:
  - medicines that contain rilpivirine (Edurant, Complera, Odefsey)
  - pimozide
  - colchicine, if you have kidney or liver problems
  - lomitapide, lovastatin, and simvastatin
  - ergot alkaloids (ergotamine or dihydroergotamine)
  - lurasidone
- have a history of yellowing of the skin (jaundice) or liver problems when taking clarithromycin.

Do not take VOQUEZNA DUAL PAK if you

- are known to have an allergy or be sensitive to the components of VOQUEZNA DUAL PAK (vonoprazan, amoxicillin) or penicillin.
- are taking medicines that contain rilpivirine (Edurant, Complera, Odefsey).

Before you take VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK, tell your healthcare provider about all of your medical conditions, including if you

- are breastfeeding. If breastfeeding, pump and discard breast milk during treatment and for 2 days after treatment.
- have severe kidney disease.
- have moderate to severe liver disease.
- have myasthenia gravis.

Additionally, do not take VOQUEZNA TRIPLE PAK if:

- you are pregnant or plan to become pregnant. Clarithromycin, a medicine in VOQUEZNA TRIPLE PAK may harm your unborn baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. There can be serious side effects when some are used in combination with this product. Serious adverse reactions can occur with VOQUEZNA TRIPLE PAK due to drug interactions of clarithromycin with colchicine, some lipid lowering agents, some calcium channel blockers, and other drugs.

What are the possible side effects of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK?

VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK can cause serious side effects including:

- **Allergic reactions (hypersensitivity):** Call your doctor right away if you have rash, hives, or other skin changes, face swelling or difficulty breathing.
- **Severe skin reactions:** VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK can cause severe skin reactions, such as skin rash or allergic reaction on or in any part of your body. Symptoms can also include, but are not limited to, fever, chills, body aches or shortness of breath. If you experience any of these symptoms, stop taking VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK immediately and call your doctor right away.
- **Severe diarrhea:** Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away while taking VOQUEZNA DUAL PAK or VOQUEZNA TRIPLE PAK or after therapy is completed.
- **Rash in patients with mononucleosis:** Amoxicillin (a component of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK) may cause a rash in patients who have mononucleosis. Stop taking VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK if you are diagnosed with mononucleosis and call your doctor right away.
- **Altered test results for some tumors:** VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK lower stomach acid which can cause increased levels of a certain protein (CgA) in your blood. When this level is increased it may alter test results for detecting some tumors. Notify your doctor of the use of VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK prior to blood tests.

Additionally, VOQUEZNA TRIPLE PAK can cause:

- **Irregular heartbeats:** Clarithromycin may cause irregular heartbeats. Call your doctor right away if you feel faint, light-headed, or feel your heart beating irregularly.
- **Liver problems:** Call your doctor right away if you have any of the following symptoms: weight loss, yellowing of the skin and eyes (jaundice), dark urine, rash, or pain on the right side of your abdomen.

The most common side effects may include:

- diarrhea
- temporary changes in sense of taste
- vaginal yeast infection
- stomach pain
- headache
- high blood pressure and
- cold-like symptoms

These are not all of the possible side effects of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. Call your healthcare provider for medical advice about side effects.

General information about the safe and effective use of VOQUEZNA.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK for a condition for which it was not prescribed. Do not give VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK to other people, even if they have the same symptoms you have. It may harm them.

For more information, ask your healthcare provider or pharmacist.

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 TRIPLE PAK AND VOQUEZNA DUAL PAK.

About Erosive GERD
Erosive GERD, also referred to as Erosive Esophagitis or Erosive Acid Reflux, is a major type of GERD that affects over 20 million people in the U.S. and is characterized by erosions in the gastric mucosa caused by acidic reflux of stomach contents into the esophagus.[3] There are estimated to be over 65 million individuals with GERD in the U.S., of which approximately 30% have erosive GERD.[4,6,7] In addition to experiencing troubling heartburn symptoms and painful erosions, patients with inadequately treated erosive GERD may progress to more severe diseases including Barrett's esophagus and esophageal cancer. [4]

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. Vonoprazan provides rapid, potent, and durable acid suppression. Phathom in-licensed the U.S., European, and Canadian 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 U.S., 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 and follow the Company on LinkedIn and X (formerly Twitter).

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 size of the Erosive GERD patient population and the potential of vonoprazan to satisfy the large unmet medical need. 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; future data generated from our stability program may be different from the data submitted to the FDA to date and may not demonstrate that our mitigation efforts will continue to maintain the level of the nitrosamine impurity below the acceptable intake (AI) level throughout the shelf life of products containing vonoprazan, which could result in market action or shelf life reduction; risks associated with product manufacturing or formulation changes required to be made in connection with achieving the AI; 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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