



## Phathom Pharmaceuticals to Present Data at DDW 2022 Annual Meeting

May 17, 2022

- New investigational data evaluating vonoprazan in erosive esophagitis (EE)
- Research highlights real-world evidence of unmet needs that exists for the treatment of *Helicobacter pylori* (*H. pylori*) infection
- Phathom research recognized with multiple “posters of distinction” by American Gastroenterological Association (AGA) Institute

FLORHAM PARK, N.J., May 17, 2022 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), an innovative biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, announced today the company will present findings from multiple studies at Digestive Disease Week® (DDW) 2022, being held May 21-24 in person in San Diego, CA and virtually.

The clinical data from Phathom being presented during the congress include Phase 3 results evaluating vonoprazan as investigational monotherapy in erosive esophagitis (EE) and data on the pharmacodynamics and pharmacokinetics of vonoprazan compared to lansoprazole, a proton pump inhibitor. An analysis of *H. pylori* diagnosis and treatment patterns will also be presented, among other important clinical developments.

“The breadth of data being presented at this year’s DDW highlights Phathom’s continued commitment to improving the lives of patients affected by acid-related gastrointestinal disorders,” said Eckhard Leifke, M.D., Chief Medical Officer at Phathom. “We look forward to sharing new data that explores unmet medical needs, as well as important analyses of treatment patterns and healthcare resource utilization. We are also excited that key data evaluating vonoprazan will be highlighted in several posters of distinction and in oral presentations.”

In addition to seven poster sessions and two oral presentations, Phathom will also have a physical presence on the exhibit floor at booth #1731 and throughout the conference. See below for full list of scientific data being presented on behalf of Phathom at DDW 2022.

### Phathom’s Scientific Presentations at DDW 2022

**Sunday, May 22, 2022**

- **Pharmacodynamics and Pharmacokinetics of the Potassium-Competitive Acid Blocker Vonoprazan and the Proton Pump Inhibitor Lansoprazole in Healthy U.S. Subjects**
  - 12:30 PM to 1:30 PM PDT
  - Presentation #: Su1202
  - Poster Session (Poster of Distinction\*)
- **Novel Approach to Evaluate the Impact of Moderate and Strong CYP3A Inducers on Vonoprazan Exposure**
  - 12:30 PM to 1:30 PM PDT
  - Presentation #: Su1203
  - Poster Session (Poster of Distinction\*)
- **A Clinical Drug Interaction Study to Assess the Effect of Vonoprazan on the Pharmacokinetics of Midazolam**
  - 12:30 PM to 1:30 PM PDT
  - Presentation #: Su1205
  - Poster Session
- **Diagnosis and Treatment Patterns Among Patients with Helicobacter Pylori Infection in the United States: A Linked EMR-Claims Database Analysis**
  - 12:30 PM to 1:30 PM PDT
  - Presentation #: Su1114
  - Poster Session

**Monday, May 23, 2022**

- **Vonoprazan is Associated with Lower Healthcare Resource Utilization and Costs Than PPI-Based Therapy for the Treatment of Helicobacter Pylori Infection in Japan**
  - 4:30 PM to 4:45 PM PDT
  - Presentation #: 817
  - Oral Presentation by Colin W. Howden, M.D.

**Tuesday, May 24, 2022**

- **Double-Blind Randomized Trial of the Potassium-Competitive Acid Blocker Vonoprazan vs. the Proton Pump Inhibitor Lansoprazole in U.S. and European Patients with Erosive Esophagitis**
  - 9:15 AM to 9:30 AM PDT
  - Presentation #: 883
  - Oral Presentation by Loren Laine, M.D.
- **Comparative Efficacy of Helicobacter Pylori Eradication Therapies: A Network Meta-Analysis**
  - 12:30 PM to 1:30 PM PDT
  - Presentation #: Tu1072
  - Poster Session
- **Comparative Efficacy of Acid Suppression Backbones for Helicobacter Pylori Eradication: Results of a Network Meta-Analysis**
  - 12:30 PM to 1:30 PM PDT
  - Presentation #: Tu1071
  - Poster Session (Poster of Distinction\*)
- **Global Temporal Trends in the Efficacy of Clarithromycin-Containing Regimens in Helicobacter Pylori Eradication**
  - 12:30 PM to 1:30 PM PDT
  - Presentation #: Tu1069
  - Poster Session (Poster of Distinction\*)

**\*Poster of Distinction: Abstract rated in the top 10% of all AGA abstracts selected for poster presentation at DDW**

Following the meeting, abstracts will be available on the [Phathom's publications and scientific section](#) of the company website.

#### **About VOQUEZNA TRIPLE and DUAL PAKs**

VOQUEZNA TRIPLE PAK (vonoprazan, amoxicillin, clarithromycin) and VOQUEZNA DUAL PAK (vonoprazan, amoxicillin) contain vonoprazan, an oral small molecule potassium-competitive acid blocker (PCAB) co-packaged with antibiotics. PCABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown the potential to provide acid suppression that can achieve pH levels that are important in enhancing antibiotic effectiveness. Phathom in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda, which completed 19 Phase 3 trials for vonoprazan and received marketing approval in Japan and numerous other countries in Asia and Latin America.

#### **Indication and Important Safety Information**

##### **INDICATIONS AND USAGE**

VOQUEZNA™ TRIPLE PAK™ is a co-packaged product containing vonoprazan, a potassium-competitive acid blocker (PCAB), amoxicillin, a penicillin-class antibacterial, and clarithromycin, a macrolide antimicrobial. VOQUEZNA™ DUAL PAK™ is a co-packaged product containing vonoprazan and amoxicillin. Both products are indicated for the treatment of *Helicobacter pylori* infection in adults.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of VOQUEZNA TRIPLE PAK, VOQUEZNA DUAL PAK and other antibacterial drugs, both products should be used only to treat or prevent infections that are proven or strongly suspected of being caused by bacteria.

##### **IMPORTANT SAFETY INFORMATION**

##### **CONTRAINDICATIONS**

VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK are contraindicated in patients with known hypersensitivity to vonoprazan or amoxicillin, any other components of the formulation, any other beta-lactams, or in patients receiving rilpivirine-containing products.

Due to the clarithromycin component, VOQUEZNA TRIPLE PAK is also contraindicated in patients with any known hypersensitivity to clarithromycin or any macrolide antibiotic, in patients receiving pimozide, lomitapide, lovastatin, simvastatin, ergotamine, dihydroergotamine, colchicine in patients with renal or hepatic impairment, or those with a history of cholestatic jaundice/hepatic dysfunction.

##### **WARNINGS AND PRECAUTIONS**

**Hypersensitivity Reactions:** Serious and occasionally fatal reactions (e.g., anaphylaxis) have been reported with components of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK. If hypersensitivity reactions occur, discontinue use and institute immediate therapy (e.g., anaphylaxis management).

**Severe Cutaneous Adverse Reactions (SCAR):** Discontinue use of VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK at first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation. SCAR, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the components of both products. In addition, drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) have been reported with amoxicillin and clarithromycin.

**Clostridioides difficile-associated diarrhea (CDAD):** Evaluate if diarrhea occurs with VOQUEZNA TRIPLE PAK or VOQUEZNA DUAL PAK. CDAD has been reported with use of acid suppressing therapies and nearly all antibacterial agents, and may range in severity from mild diarrhea to fatal colitis. If CDAD is confirmed, discontinue therapy and treat appropriately.

**VOQUEZNA TRIPLE PAK Warnings or Precautions Due to the Clarithromycin Component:**

**QT Prolongation:** Avoid VOQUEZNA TRIPLE PAK in patients with known QT prolongation or receiving drugs known to prolong the QT interval, ventricular arrhythmia (*torsades de pointes*), hypokalemia/hypomagnesemia, significant bradycardia, or taking Class IA or III antiarrhythmics.

**Hepatotoxicity:** Discontinue use of VOQUEZNA TRIPLE PAK if signs and symptoms of hepatitis occur.

**Serious adverse reactions due to concomitant use with other drugs:** 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, hypoglycemic agents including insulin,

quetiapine, warfarin, benzodiazepines, and other drugs.

**Embryo-Fetal Toxicity:** VOQUEZNA TRIPLE PAK is not recommended for use in pregnancy as clarithromycin may cause fetal harm.

**Myasthenia Gravis:** Exacerbation of myasthenia gravis can occur with VOQUEZNA TRIPLE PAK since it has been reported in patients receiving clarithromycin tablets.

#### **ADVERSE REACTIONS**

The most common adverse reactions ( $\geq 2\%$ ) include diarrhea, dysgeusia, vulvovaginal candidiasis, abdominal pain, headache, hypertension, and nasopharyngitis.

#### **DRUG INTERACTIONS**

Components of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK have the potential for clinically important drug interactions. See full Prescribing Information for important drug interactions.

#### **USE IN SPECIFIC POPULATIONS**

**Lactation:** Breastfeeding not recommended during treatment, but a lactating woman can pump and discard breast milk during treatment and for 2 days after VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK administration.

**Geriatrics:** VOQUEZNA TRIPLE PAK increased risk of *torsades de pointes* due to clarithromycin.

**Renal and Hepatic Impairment:** Avoid use in patients with severe renal impairment and avoid use 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](http://www.fda.gov/medwatch).**

Please see full [Prescribing Information](#) for VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK.

#### **About Phathom Pharmaceuticals, Inc.**

Phathom Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases and disorders. 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). Vonoprazan-based regimens are approved in the U.S. as part of a co-packaged product in combination with antibiotics for the treatment of *H. pylori* infection in adults, marketed as VOQUEZNA™ TRIPLE PAK™ (vonoprazan, amoxicillin, clarithromycin) and VOQUEZNA™ DUAL PAK™ (vonoprazan, amoxicillin). Phathom has submitted a New Drug Application to the FDA for vonoprazan in erosive esophagitis (EE) and is studying the use of vonoprazan for the treatment of non-erosive reflux disease (NERD). 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 [Twitter](#).

#### **About DDW**

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and virtual meeting from May 21-24, 2022. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at [www.ddw.org](http://www.ddw.org).

#### **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 vonoprazan as monotherapy for the treatment of erosive esophagitis. 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: Phathom's ability to access additional capital under the term loan facility is subject to certain conditions; 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 QIDP designations may not actually lead to extended exclusivity; Phathom's ability to obtain and maintain intellectual property protection for vonoprazan; Phathom's ability to comply with its license agreement with Takeda; Phathom's ability to maintain uninterrupted business operations due to the ongoing spread of the COVID-19 coronavirus, including delaying or otherwise disrupting its clinical trials, manufacturing and supply chain, 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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