Phathom Pharmaceuticals Submits Citizen Petition to FDA Seeking Correction of Orange Book Listings for VOQUEZNA® (vonoprazan) Tablets

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- *Citizen Petition seeks correction of expiration date for New Chemical Entity (NCE) exclusivity on VOQUEZNA (vonoprazan) tablets Orange Book listings*
- *Phathom believes applicable law mandates a 10-year NCE exclusivity period (from date of first approval of drug containing vonoprazan) benefitting all vonoprazan-based products, with exclusivity until May 3, 2032*

FLORHAM PARK, N.J., Dec. 11, 2024 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal (GI) diseases, announced today it has submitted a Citizen Petition (CP) with the U.S. Food and Drug Administration (FDA). The petition formally requests correction of the Orange Book listings for VOQUEZNA (vonoprazan) 10 mg and 20 mg tablets to accurately reflect the full 10-year NCE exclusivity period until May 3, 2032.

The update would align the VOQUEZNA tablets Orange Book listings to reflect the same period of NCE exclusivity that was granted upon approval of vonoprazan-based VOQUEZNA TRIPLE PAK® and VOQUEZNA DUAL PAK® in May 2022. The statutory 10-year exclusivity period encompasses the five-year standard exclusivity period for NCEs as extended by the additional five years by operation of the Generating Antibiotic Incentives Now (GAIN) Act. As VOQUEZNA tablet products contain the same drug substance with the active moiety, vonoprazan, they should be entitled to the same protection.

The main points addressed in Phathom's Citizen Petition include:

- **New Chemical Entity Exclusivity Provisions:** The approval of VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK in May 2022 triggered a 10-year NCE exclusivity period by operation of the GAIN Act, tied to the drug substance containing vonoprazan, which had never previously been approved. This exclusivity period expires in May 2032. Under the law and FDA's longstanding interpretations of it, NCE exclusivity precludes the submission of any Abbreviated New Drug Application (ANDA) or 505(b)(2) New Drug Application (NDA) referencing any drug containing vonoprazan for the NCE exclusivity period, including VOQUEZNA tablets.
- **The GAIN Act:** The NCE exclusivity period awarded upon approval of VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK is 10 years. This is because the GAIN Act's application to the approval of VOQUEZNA DUAL PAK and VOQUEZNA TRIPLE PAK was to extend, by five years, the underlying NCE exclusivity tied to the drug substance containing vonoprazan. While the GAIN Act includes certain limitations on the application of the extension, none of these exceptions have any effect on the 10-year NCE exclusivity period already awarded and honored by the FDA, and such 10-year NCE exclusivity period equally benefits any vonoprazan-containing products, including VOQUEZNA tablets.
- **Established and Sound Public Policy:** As mandated by the plain language of the applicable statutes and the FDA's longstanding interpretations, Phathom requests that the FDA promptly correct the Orange Book to accurately reflect the statutorily-required 10-year period of NCE exclusivity for vonoprazan in the Orange Book listings for the VOQUEZNA tablet products, identifying the correct expiry date of May 3, 2032.

"We are committed to ensuring VOQUEZNA tablets receive the full exclusivity protections in accordance with the FDA's longstanding policies and the clear language of the law," said Terrie Curran, President and Chief Executive Officer of Phathom Pharmaceuticals. "We remain confident in our position that VOQUEZNA tablets are entitled to the full ten-years of NCE exclusivity on the basis of the approval of vonoprazan in VOQUEZNA TRIPLE PAK and DUAL PAK. If corrected, we expect NCE exclusivity for VOQUEZNA tablets until May 3, 2032, which is an enhancement to our patent term exclusivity that is expected to be extended into 2030."

Phathom expects the CP and related docket information to be made available on the www.regulations.gov website in the coming days. The FDA must provide a response to the petition within 180 days from the date of submission. The response will either approve the petition, deny or dismiss the petition, or provide a tentative

response indicating why the agency hasn't been able to reach a decision. The Company believes that a CP affords the FDA the ability to analyze the request under an established framework, and ultimately formalize its decision in accordance with its procedural regulations.

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.

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) that is currently marketed in the United States as VOQUEZNA® (vonoprazan) tablets for the treatment 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, in addition to 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. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about: the ultimate decision by the FDA on the action requested in the CP and the timing any FDA action regarding the CP; the possible extension of NCE exclusivity to VOQUEZNA tablets; and the expected duration of patent term extension for VOQUEZNA. 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: the FDA may reject our request to correct the Orange Book listings identifying the expiration date for the NCE exclusivity period on the VOQUEZNA tablets Orange Book listings; the FDA may take longer that we expect to act on our CP, if at all; members of the public may comment on our CP which may influence the FDA's decision; our ability to obtain and maintain intellectual property protection, including patent term extensions, and non-patent regulatory exclusivity for vonoprazan; we may face competition earlier than expected if we lose or fail to obtain any of our patent protection or non-patent regulatory exclusivity for VOQUEZNA tablets; 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 most recent 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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