

Phathom[®]

PHARMACEUTICALS

Phathom Pharmaceuticals Announces FDA Correction to Orange Book Listing, Confirming 10 Years of Regulatory Exclusivity for VOQUEZNA[®] (vonoprazan) Tablets Through May 3, 2032

June 16, 2025

FLORHAM PARK, N.J., June 16, 2025 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal (GI) diseases, today announced that the U.S. Food and Drug Administration (FDA) has updated the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") to accurately reflect the full 10-year period of non-patent New Chemical Entity (NCE) exclusivity for VOQUEZNA® (vonoprazan) 10 mg and 20 mg tablets.

The corrected Orange Book listing confirms that VOQUEZNA is entitled to NCE regulatory exclusivity through May 3, 2032, aligning with statutory requirements and reinforcing the long-term commercial runway for the first-in-class product.

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 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, 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 Phathom's commercialization plans. 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 expected duration of patent term extension for VOQUEZNA; we may not be able to successfully commercialize VOQUEZNA, VOQUEZNA TRIPLE PAK and VOQUEZNA DUAL PAK, 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; 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 obtain and maintain intellectual property protection, including patent term extensions, and non-patent regulatory exclusivity for vonoprazan; Phathom may face competition earlier than expected if it loses or fails to obtain any of its patent protection or non-patent regulatory exclusivity for VOQUEZNA tablets; Phathom's ability to obtain and maintain intellectual property protection and non-patent regulatory exclusivity for vonoprazan; 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.

MEDIA CONTACT

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

INVESTOR CONTACT

Eric Sciorilli
1-877-742-8466
ir@phathompharma.com

© 2025 Phathom Pharmaceuticals. All rights reserved.

VOQUEZNA, VOQUEZNA DUAL PAK, VOQUEZNA TRIPLE PAK, Phathom Pharmaceuticals, and their respective logos are registered trademarks of Phathom Pharmaceuticals, Inc.