

Phathom[®]

PHARMACEUTICALS

Phathom Pharmaceuticals Provides Update on FDA Litigation

October 26, 2026

FLORHAM PARK, N.J., Oct. 26, 2026 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on commercializing and developing novel treatments for gastrointestinal (GI) diseases, today announced the U.S. Food and Drug Administration's (FDA's) establishment of a public docket (Docket No. FDA-2026-N-13038) to solicit comment on legal and regulatory questions regarding certain issues raised by a filer of an abbreviated new drug application (ANDA) referencing VOQUEZNA[®] (vonoprazan) tablets, BDR Pharmaceuticals, International Pvt. Ltd. (BDR), in litigation brought against the FDA following FDA's rejection of the ANDA. The litigation was brought to challenge FDA's June 6, 2025 decision granting Phathom's Citizen Petition, which agreed with Phathom that VOQUEZNA benefits from 10 years of New Chemical Entity (NCE) exclusivity through May 3, 2032. The deadline for comments submitted to the public docket is November 23, 2026.

"FDA carefully reviewed the NCE exclusivity period applicable to VOQUEZNA through a full public process, and we believe reached the right decision," said **Steve Basta, President and Chief Executive Officer of Phathom**. "We will make that case clearly in our comments to FDA and in any appropriate court proceeding, and our team remains focused on bringing VOQUEZNA to patients."

Phathom has also moved to intervene in the litigation filed by BDR to continue to enforce its statutory exclusivities.

A second purported ANDA filer, Saba Ilac Sanayii Ve Ticaret AS, has filed a notice in the BDR litigation claiming to have a pending related case, and that it intends to move to consolidate its case with BDR's.

About Phathom Pharmaceuticals, Inc.

Phathom Pharmaceuticals is a biopharmaceutical company focused on the commercialization and development 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[®] DUAL PAK[®] (vonoprazan tablets, amoxicillin capsules) and VOQUEZNA[®] TRIPLE PAK[®] (vonoprazan tablets, amoxicillin capsules, clarithromycin tablets) 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, including without limitation statements regarding: Phathom's belief that FDA correctly evaluated and recognized the GAIN Act extension of the NCE exclusivity for VOQUEZNA tablets; Phathom's intent to take appropriate actions to protect its statutory exclusivities, including intervening in the litigation and submitting comments on the FDA docket; the expected duration of NCE exclusivity for VOQUEZNA tablets; the potential timing and outcome of the litigation filed by BDR (and the second purported ANDA filer); and the timing and potential impact of the FDA public docket and potential decisions FDA may make in light of the comments received. 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: BDR (and the second purported ANDA filer) may succeed in its challenge to FDA's recognition of the GAIN Act extension of NCE exclusivity for VOQUEZNA tablets which would result in a reduction in the period of regulatory exclusivity and permit FDA to receive and potentially approve ANDAs referencing VOQUEZNA tablets earlier than currently anticipated; members of the public may comment on the public docket in a manner adverse to Phathom's position which may influence the FDA's decision and FDA may, in light of those comments or otherwise, reconsider, modify or reverse its prior decision recognizing the GAIN Act extension of NCE exclusivity for VOQUEZNA tablets; the litigation, including any appeals, may be lengthy, costly and distracting to management, and its timing and outcome are uncertain; developments in the litigation or related to FDA's request for comments, or public perception of them, may hurt Phathom's stock price, VOQUEZNA sales, or Phathom's business, financial condition and prospects; Phathom may not be able to obtain and maintain intellectual property protection, including patent term extensions, and may not be able to maintain non-patent regulatory exclusivity for VOQUEZNA for the time periods it expects or at all; Phathom may be unsuccessful in defending its Orange Book-listed patents against challenges by third parties; Phathom may face competition earlier than expected if it loses any of regulatory or patent protection or non-patent regulatory exclusivity for VOQUEZNA tablets, including as a result of an adverse outcome in the BDR and related litigation or an adverse FDA decision; and other risks described in Phathom's prior press releases and 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 revise or update such statements 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.

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