



Phathom Pharmaceuticals Provides Update on Litigation Filed by BDR Pharmaceuticals against FDA

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FLORHAM PARK, N.J., Oct. 23, 2026 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a biopharmaceutical company focused on commercializing and developing novel treatments for gastrointestinal (GI) diseases, announced today that BDR Pharmaceuticals International Pvt. Ltd. (BDR) has filed suit against the U.S. Food and Drug Administration (FDA) and related Federal Defendants in the United States District Court for the District of Columbia, principally challenging FDA's alleged refusal to receive an abbreviated new drug application (ANDA) referencing Phathom's new drug application (NDA) for VOQUEZNA®. In the suit, BDR alleges that FDA has improperly applied the GAIN Act to extend Phathom's New Chemical Entity (NCE) exclusivity for VOQUEZNA (vonoprazan fumarate) tablets. Phathom is evaluating the BDR filings, but believes that FDA carefully and correctly evaluated this issue in its June 6, 2025 grant of Phathom's December 11, 2024 Citizen Petition, in which FDA recognized 10 years of NCE exclusivity for VOQUEZNA tablets through May 3, 2032. Phathom intends to take appropriate action to protect its statutory exclusivities.

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; the expected duration of NCE exclusivity for VOQUEZNA tablets; and the potential timing and outcome of the litigation filed by BDR. 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 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; 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 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 litigation; 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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