Bausch Health Announces Updates Related to Norwich XIFAXAN Matters

May 14, 2024

LAVAL, QC, May 14, 2024 – Bausch Health Companies Inc. (NYSE/TSX: BHC) and its gastroenterology business Salix Pharmaceuticals, today announced certain updates related to its litigation with Norwich Pharmaceuticals, Inc.

With respect to the April 11, 2024, decision of the US Court of Appeals for the Federal Circuit, both Bausch Health and Norwich have filed petitions for panel rehearing or rehearing en banc. The Company anticipates a decision on whether a rehearing will be granted within the next three months.

The Company has also received notice of a new Paragraph IV certification (the "Notice"), dated May 10, 2024, from Norwich advising that it has submitted to the U.S. Food and Drug Administration (FDA) an amendment to an Abbreviated New Drug Application (ANDA) requesting approval to market a generic version of XIFAXAN® (rifaximin) 550 mg tablets for the treatment of irritable bowel syndrome with diarrhea in adults.

Bausch Health is reviewing the Notice and has 45 days from receipt of the Notice to commence a patent infringement lawsuit against Norwich. Bausch Health understands that such a lawsuit would automatically preclude the FDA from approving Norwich's ANDA for up to 30 months or until the issuance of a decision by the district court in this matter that is adverse to Bausch Health, whichever occurs first.

Bausch Health intends to vigorously enforce its intellectual property rights relating to XIFAXAN®.

About XIFAXAN

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults and for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

About Salix

Salix Pharmaceuticals is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For more than 30 years, Salix has licensed, developed and marketed innovative products to improve patients' lives and arm health care providers with life-changing solutions for many chronic and debilitating conditions. Salix currently markets its product line to U.S. health care providers through an expanded sales force that focuses on gastroenterology, hepatology, pain specialists and primary care. Salix is headquartered in Bridgewater, New Jersey. For more information about Salix, visit www.Salix.com
and connect with us on
Twitter
and
LinkedIn

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About Bausch Health

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global diversified pharmaceutical company enriching lives through our relentless drive to deliver better health care outcomes. We develop, manufacture and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, medical aesthetic devices, international pharmaceuticals and eye health, through our controlling interest in Bausch + Lomb. Our ambition is to be a globally integrated healthcare company, trusted and valued by patients, HCPs, employees and investors. For more information, visit
www.bauschhealth.com
and connect with us on
LinkedIn.

Forward-looking Statements

This news release may contain forward-looking statements about the future performance of Bausch Health, which may generally be identified by the use of the words "will," "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "subject to" and variations or similar expressions, including statements about the Company's actions and plans to vigorously defend its intellectual property. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. In particular, Bausch Health can offer no assurance as to the timing of any approval by the FDA of any ANDA or as to the outcome of any patent litigation. Actual results are subject to other risks and uncertainties that relate more broadly to Bausch Health's overall business, including those more fully described in Bausch Health's most recent annual report on Form 10-K and detailed from time to time in Bausch Health's other filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference.

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