Bausch Health Brings Patent Infringement Lawsuit Against Norwich Pharmaceuticals

June 20, 2024

LAVAL, QC, June 20, 2024 – Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health" or the "Company") and its gastroenterology business, Salix Pharmaceuticals, today announced that it has filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Norwich Pharmaceuticals, Inc.

This lawsuit was filed in connection with the Notice of Paragraph IV Certification, dated May 10, 2024, received 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 diarrhea-predominant irritable bowel syndrome (IBS-D).

Bausch Health continues to defend challenges to its XIFAXAN® intellectual property. In the first Norwich lawsuit, the U.S. District Court for the District of Delaware issued a ruling in August 2022 that barred Norwich's first ANDA for XIFAXAN® 550 mg from approval by the U.S. Food and Drug Administration until October 2029. On appeal, the ruling was confirmed.

Since the District Court's ruling, Bausch Health received additional patents related to XIFAXAN® 550 mg that protect the innovative treatment of IBS-D. As part of the applications to the U.S. Patent and Trademark Office the Company provided information related to the ongoing dispute between the Company and Norwich, including the District Court's August 2022 decision.

As a leader in gastrointestinal health, Bausch Health will continue to vigorously defend our intellectual property and is committed to advocating for the safety of patients who have benefited from continued access to XIFAXAN®. We look forward to continuing to serve our patients, as every patient deserves better health outcomes and the chance to make the most of life.

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
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Forward-looking Statements

"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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