Bausch Health Announces Patent Lawsuit Against Amneal Pharmaceuticals

April 05, 2024

LAVAL, QC, April 5, 2024 – Bausch Health Companies Inc. (NYSE/TSX: BHC) along with its gastroenterology business, Salix Pharmaceuticals, Inc., announced that it filed a lawsuit today in the United States District Court for the District of New Jersey against Amneal Pharmaceuticals of New York, LLC, Amneal EU, Limited, Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals Private Limited, and Amneal Pharmaceuticals, Inc. This lawsuit follows receipt of a Notice of Paragraph IV Certification stating that Amneal submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) seeking approval to market a generic version of XIFAXAN® (rifaximin) 550 mg tablets. Amneal asserts that certain patents listed in the FDA's Orange Book for XIFAXAN® are unenforceable, invalid, and/or not infringed by Amneal's ANDA product. This action formally initiates the litigation process under the Hatch-Waxman Act and triggers a 30-month stay of any potential FDA approval for Amneal's ANDA.

"Bausch Health remains confident in its XIFAXAN® intellectual property and we will continue to defend our XIFAXAN® franchise for the benefit of patients," Thomas J. Appio, CEO, Bausch Health said. "As a leader in gastrointestinal health, protecting our intellectual property is essential to our ability to continue to develop innovative therapies."

Bausch Health has previously received Paragraph IV Certifications for XIFAXAN® (rifaximin) 550 mg tablets from Teva Pharmaceuticals, Sandoz Inc., Sun Pharmaceuticals and Norwich Pharmaceuticals. The Company has since settled the matters with Teva, Sandoz and Sun in September 2018, May 2020 and September 2020, respectively, while litigation with Norwich remains ongoing.

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.

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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