Bausch Health Responds to Norwich Pharmaceuticals Tentative FDA Approval for a 200 mg Rifaximin

September 09, 2022

LAVAL, QC, Sept. 9, 2022 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("the Company"), and its gastroenterology business Salix Pharmaceuticals, today responded to the U.S. Food and Drug Administration's (FDA) tentative approval of the Norwich Pharmaceuticals rifaximin 200 mg product.

The Company understands this was a Paragraph III filing. A Paragraph III filing is made when an Abbreviated New Drug Application (ANDA) applicant does not intend to market its generic product until the patent expiration. The FDA will therefore not grant full approval until the expiry of the last of the Company's Orange Book listed patents for the XIFAXAN® (rifaximin) 200 mg product on July 24, 2029.

XIFAXAN 200 mg is indicated for travelers' diarrhea and currently contributes less than 1 percent of Salix revenues.

About XIFAXAN

XIFAXAN (rifaximin) 200 mg tablets are indicated for travelers' diarrhea.
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 whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, international pharmaceuticals and eye health, through our approximately

90% ownership of Bausch + Lomb Corporation. With our leading durable brands, we are delivering on our commitments as we build an innovative company dedicated to advancing global health. For more information, visit
www.bauschhealth.com
and connect with us on
Twitter
and
LinkedIn
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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 "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "subject to" and variations or similar expressions, including statements about the Company's intentions to file an appeal with respect to, and take actions 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 amended ANDA and as to the outcome of any appeal. 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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