

# Bausch Health to Appeal XIFAXAN® Patent Decision to U.S. Court of Appeals for the Federal Circuit

August 10, 2022

LAVAL, Quebec, Aug. 10, 2022 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC), and its gastroenterology business Salix Pharmaceuticals, today announced that, consistent with the company's July 28, 2022, press release, the U.S. District Court of Delaware has issued a decision in the matter of *Salix Pharmaceuticals, Ltd. et al v. Norwich Pharmaceuticals, Inc.* finding certain XIFAXAN® (rifaximin) 550 mg HE patents valid and infringed and certain XIFAXAN composition and IBS-D patents invalid. As previously stated, the Company will appeal this decision to the U.S. Court of Appeals for the Federal Circuit and it expects an appeal decision to issue within 12 to 18 months.

To date, Norwich has not received tentative or final approval of its ANDA from the FDA. Unless and until FDA approves a revised Norwich ANDA that omits the XIFAXAN HE indication, and any injunction issued by the Court is modified, Norwich is not permitted to launch a generic equivalent of XIFAXIN.

## **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](http://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](http://www.bauschhealth.com)

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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.

**Investor Contact:**

**Media Contacts:**

Christina Cheng

Kevin Wiggins

[ir@bauschhealth.com](mailto:ir@bauschhealth.com)

[corporate.communications@bauschhealth.com](mailto:corporate.communications@bauschhealth.com)

(514) 856-3855

(848) 541-3785

(877) 281-6642 (toll free)

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**Investor Inquiries**

[ir@bauschhealth.com](mailto:ir@bauschhealth.com)

877-281-6642

514-856-3855 (Canada)

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**Media inquiries**

[Corporate.communications@bauschhealth.com](mailto:Corporate.communications@bauschhealth.com)

908-569-3692

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