# Bausch Health Provides Update Following Oral Order in XIFAXAN® Patent Litigation

July 28, 2022

**-- Company to Appeal Expected Court Decision on Certain XIFAXAN® Patents –**

LAVAL, Quebec, July 28, 2022 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC), and its gastroenterology business Salix Pharmaceuticals, today announced the U.S. District Court of Delaware issued an Oral Order in the matter of *Salix Pharmaceuticals, Ltd. et al v. Norwich Pharmaceuticals, Inc.* regarding the infringement and validity of certain U.S. Patents protecting the composition and use of XIFAXAN® (rifaximin) 550 mg tablets for the treatment of irritable bowel syndrome with diarrhea (IBS-D) and reduction in risk of overt hepatic encephalopathy (HE) recurrence.

The Oral Order indicates that the Court will find certain U.S. Patents protecting the use of XIFAXAN® (rifaximin) 550 mg tablets for the reduction in risk of HE recurrence valid and infringed and U.S. Patents protecting the composition, and use of XIFAXAN® for treating IBS-D invalid. While the Court has not yet entered any final judgement, absent Norwich's removal of the HE indication and data from their Abbreviated New Drug Application (ANDA), it is expected that the Court will enjoin Norwich's pending ANDA until expiration of the XIFAXAN® HE Patents in 2029. The Company intends to vigorously oppose any attempt by Norwich to remove the HE safety data from its ANDA in an effort to avoid the XIFAXAN® HE Patents.

The FDA has stated that they plan to make a major revision to the rifaximin product specific guidance to add an *in vivo* bioequivalency study. Until an approval of a revised ANDA is granted by the FDA and the expected injunction modified by the Court, Norwich is not permitted to launch a generic equivalent of XIFAXAN®.

When the Court enters a final order, Bausch Health will consider all available options to vigorously defend the intellectual property protecting XIFAXAN® and will appeal the Court's decision to the U.S. Court of Appeals for the Federal Circuit.

"We are disappointed with today's development. We strongly disagree with any conclusion that our patents are not valid and intend to file an appeal to any such order," 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. We intend to vigorously pursue all available options to challenge any final ruling, while also continuing to drive growth and innovation for our XIFAXAN® franchise."

Bausch Health has previously entered into settlement agreements with Teva, Sun Pharmaceuticals, and Sandoz to permit a generic rifaximin product entry in 2028 or upon an earlier approval and launch of a generic rifaximin product. Until, and if, Norwich secures FDA approval for its generic rifaximin product and subsequently launches a generic rifaximin product, Teva, Sun Pharmaceuticals, and Sandoz will not be permitted to launch a generic version of XIFAXAN® tablets before 2028.

The Company intends to file an appeal immediately after any final order is issued, assuming it is

consistent with the Oral Order.

## 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 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 timing and details of the future plans for Solta and its future performance. 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 that the Court will issue a final judgment consistent with the Oral Order, 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 | corporate.communications@bauschhealth.com |
| (514) 856-3855 | 848) 541-3785 |
| (877) 281-6642 (toll free) | |



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**Investor Inquiries**
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

**Media inquiries**
Corporate.communications@bauschhealth.com
848-264-0934

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