# U.S. District Court Upholds Final Judgment for XIFAXAN® 550 mg That Prevents FDA Approval of Norwich's Abbreviated New Drug Application Until 2029

May 17, 2023

**LAVAL, Quebec, May 17, 2023** – Bausch Health Companies Inc. (NYSE/TSX: BHC), and its gastroenterology business Salix Pharmaceuticals, today announced that the U.S. District Court of Delaware in the matter of *Salix Pharmaceuticals, LTD et al v. Norwich Pharmaceuticals, Inc.*, has denied Norwich Pharmaceuticals' motion to modify the Court's final judgment that prevents the U.S. Food and Drug Administration (FDA) from approving Norwich's abbreviated new drug application (ANDA) for XIFAXAN® (rifaximin) 550 mg before Oct. 2, 2029. As a result of this decision, Norwich's ANDA cannot be approved until Oct. 2, 2029.

"This decision is important for patients who continue to depend on a proven and highly effective drug to treat gastro-intestinal disorders," Thomas J. Appio, Chief Executive Officer stated. "It is our long- standing position that the XIFAXAN patent claims are valid and infringed by Norwich's ANDA. We will continue to advocate for the safety of patients who have benefited from the continued access to XIFAXAN, and we look ahead to the appeal process."

To date, Norwich has not received tentative or final approval of its ANDA from the FDA.

### **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 controlling ownership interest 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

# **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 appeal with respect to, and 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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