# Bausch Health Responds to Norwich's ANDA Tentative Approval and Lawsuit Against United States Food and Drug Administration

June 06, 2023

**LAVAL, Quebec, June 6, 2023** – Bausch Health Companies Inc. (NYSE/TSX: BHC), and its gastroenterology business Salix Pharmaceuticals, understand that in a June 2, 2023, letter, the U.S. Food and Drug Administration (FDA) granted Norwich Pharmaceuticals Inc. Tentative Approval of its Abbreviated New Drug Application (ANDA) for XIFAXAN® (rifaximin) 550 mg. At the same time, the FDA confirmed in its Letter that it *cannot* grant Final Approval until Oct. 2, 2029 – the date specified by the presiding judge in his Final Judgment in *Salix Pharmaceuticals, LTD et al. v. Norwich Pharmaceuticals, Inc*.

Having recently failed in its attempt to modify the Final Judgment (see May 17 Press Release), Norwich has now sued the FDA in the United States District Court for the District of Columbia requesting that the Court direct the FDA to immediately grant Final Approval to the ANDA. Like its failed motion for modification of the Final Judgment, Norwich's lawsuit is another attempt to avoid the Final Judgment.

Bausch Health intends to intervene in Norwich's lawsuit against the FDA and will continue to take all steps to vigorously defend its intellectual property.

**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

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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 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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