

# Bausch Health Statement on Selection of XIFAXAN® (rifaximin) for Inflation Reduction Act's Medicare Negotiation Program

January 17, 2025

LAVAL, Quebec, January 17, 2025 – Bausch Health Companies Inc. (NYSE:BHC)(TSX:BHC) and its gastroenterology (GI) business, Salix Pharmaceuticals, today acknowledged that the Centers for Medicare and Medicaid Services (CMS) has selected XIFAXAN® (rifaximin) 550 mg tablets as one of the medicines for the second round of negotiation as part of the Inflation Reduction Act with an initial price applicability in 2027 of the Drug Price Negotiation program.

We look forward to engaging in open and transparent conversations with CMS, where we will share information on the value that XIFAXAN® delivers for the healthcare system in addition to sharing recommendations from The American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL) who gave XIFAXAN® the highest possible recommendation (Grade I, A,1) via their practice guidelines. We will continue to be driven by our commitment to patients in advocating for a healthcare environment that supports patient access to critical medications as well as encouraging future innovation.

## **About XIFAXAN**

### **INDICATION**

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.

### **IMPORTANT SAFETY INFORMATION**

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.
- Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued.
- There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.
- Caution should be exercised when concomitant use of XIFAXAN and P-glycoprotein (P-gp) and/or OATPs inhibitors is needed. Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs, significantly increased the systemic exposure of rifaximin. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin.
- In clinical studies, the most common adverse reactions for XIFAXAN (alone or in combination with lactulose) were:
  - HE ( $\geq 10\%$ ): Peripheral edema (17%), constipation (16%), nausea (15%), fatigue (14%), insomnia (14%), ascites (13%), dizziness (13%), urinary tract infection (12%), anemia (10%), and pruritus (10%)

- IBS-D ( $\geq 2\%$ ): Nausea (3%), ALT increased (2%)
- INR changes have been reported in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be required.
- XIFAXAN may cause fetal harm. Advise pregnant women of the potential risk to a fetus. To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

Please  
[click here](#)  
for full Prescribing Information.

### **About Bausch Health**

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global, diversified pharmaceutical company enriching lives through our relentless drive to deliver better health care outcomes. We develop, manufacture and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, international pharmaceuticals and eye health, through our controlling interest in Bausch + Lomb Corporation. Our ambition is to be a globally integrated healthcare company, trusted and valued by patients, HCPs, employees and investors. Our gastroenterology business, Salix Pharmaceuticals, is one of the largest specialty pharmaceutical businesses in the world and has licensed, developed and marketed innovative products for the treatment of gastrointestinal diseases for more than 30 years. For more information about Salix, visit [www.Salix.com](http://www.Salix.com)

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### **Forward-looking Statements**

This news release may contain forward-looking statements within the meaning of applicable securities laws, including the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding the value or benefits of our pharmaceutical products. Forward-looking statements may generally be identified by the use of the words "will," "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "subject to" and variations or similar expressions. These statements are neither historical facts nor assurances of future performance, 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. 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 and quarterly reports 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. Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. The Company undertakes no obligation to update any of these forward-looking statements

to reflect events, information or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

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