

# Salix Announces Issuance of an Additional XIFAXAN® Patent

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LAVAL, Quebec, Oct. 31, 2019 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health" or the "Company") and its gastroenterology business, Salix Pharmaceuticals, ("Salix"), one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases, announced that the U.S. Patent and Trademark Office has issued an additional patent covering the use of XIFAXAN® (rifaximin) 550 mg tablets to treat symptoms of Irritable Bowel Syndrome (IBS). The patent issued is United States Patent No. 10,456,384, entitled "Methods for Treating Irritable Bowel Syndrome (IBS)." Final expiry of the new patent covering IBS is in February 2029.

"We have always been confident in the strength of the XIFAXAN patents, and the addition of this new patent specific to the treatment of IBS further strengthens our XIFAXAN intellectual property," said Joseph C. Papa, chairman and CEO, Bausch Health. "We will continue to vigorously defend our intellectual property."

XIFAXAN is now protected by 23 patents covering the composition of matter and the use of XIFAXAN listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book.

## About XIFAXAN

XIFAXAN (rifaximin) 550 mg tablets are indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults and for the reduction in risk of overt hepatic encephalopathy (HE) recurrence 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 in IBS-D ( $\geq 2\%$ ) were nausea (3%) and ALT increased (2%).
- In clinical studies, the most common adverse reactions for XIFAXAN in HE ( $\geq 10\%$ ) were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascities (11%).

- 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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

### **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 30 years, Salix has licensed, developed, and marketed innovative products to improve patients' lives and arm healthcare providers with life-changing solutions for many chronic and debilitating conditions. Salix currently markets its product line to U.S. healthcare providers through an expanded sales force that focuses on gastroenterology, hepatology, pain specialists, and primary care. Salix is headquartered in Bridgewater, N.J.

### **About Bausch Health**

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at [www.bauschhealth.com](http://www.bauschhealth.com).

### **Forward-looking Statements**

This news release may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. 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. These risks and uncertainties include, but are not limited to, risks and uncertainties discussed in the Company's most recent annual or quarterly report and detailed from time to time in the Company's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. The Company believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but 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. Bausch Health undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

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