Salix to Share New Data from XIFAXAN® (Rifaximin) Clinical Research at EASL's International Liver Congress™ 2022

June 20, 2022

LAVAL, QC, June 20, 2022 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") 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 (GI) and liver diseases and disorders, today announced its presence at the European Association for the Study of the Liver's (EASL) International Liver Congress™ (ILC) 2022 through the presentation of new XIFAXAN® (rifaximin) data that was selected for inclusion in the program.

ILC 2022 is being held virtually and in-person in London, United Kingdom, from June 22-26, 2022. The data will be presented in the Cirrhosis and its complications session on Saturday, June 25, 2022.

"As a leading pharmaceutical company specializing in hepatology, Salix continues to invest in research and development to address the scientific and clinical unmet needs in liver disease. We continue our close collaboration with the medical community to advance treatment of life-threatening conditions such as overt hepatic encephalopathy (OHE), improve standard of care and quality of life of liver patients. To this end, the work to be presented at EASL highlights the fact that early identification and management of OHE precipitating factors is an important component of an overall disease management strategy to reduce the risk of OHE recurrence and HE-related hospitalizations," said Tage Ramakrishna, M.D., chief medical officer and president of Research & Development, Bausch Health.

The research to be featured at ILC 2022 and available via the meeting's online platform is as follows:

XIFAXAN

- Bajaj, Jasmohan S. et al. *"Identification of overt hepatic encephalopathy precipitating factors: a pooled analysis of 3 clinical trials of rifaximin plus lactulose" Poster #SAT517*

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.

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 were:
  - HE (≥10%): Peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites (11%)
  - IBS-D (≥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
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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 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 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
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Forward-looking Statements

This news release may contain forward-looking statements, which may generally be identified by the use of the words "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "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, the risks and uncertainties discussed in the Bausch Health Companies Inc.'s (Bausch Health) 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. They also include, but are not limited to, risks and uncertainties caused by or relating to the evolving COVID-19 pandemic, and the fear of that pandemic and its potential effects, the severity, duration, and future impact of which are highly uncertain and cannot be predicted, and which may have a material adverse impact on Bausch Health, including but not limited to its project development timelines, and costs (which may increase). 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.

The XIFAXAN 550 mg product and the XIFAXAN trademark are licensed by Alfasigma S.p.A. to Salix Pharmaceuticals and its affiliates.
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