New Analysis Indicates That a Majority of Overt Hepatic Encephalopathy (OHE) Patients May Face Delays in Treatment Initiation and Gaps During Treatment for Access to Treatment Indicated to Reduce Risk for OHE Recurrence

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Hurdles Led to Almost All Patients Having At Least One Day Delay to Receive Treatment with Xifaxan®

LAVAL, Quebec, October 17, 2023 –– Bausch Health Companies Inc. (NYSE/TSX: BHC) and its gastroenterology business, Salix Pharmaceuticals, today announced findings from a retrospective database analysis of adjudicated claims data that examined the impact of access barriers for commercially-insured adults prescribed Xifaxan® (rifaximin) for reduction in risk of overt hepatic encephalopathy (OHE) recurrence in adults. Results suggest potentially critical treatment gaps due to access barriers, which may result in increased rates of OHE-related hospitalizations. Findings from the analysis, "Assessment of Access Barriers to Rifaximin Among Patients with Overt Hepatic Encephalopathy Using Adjudicated Claims Data," were presented today at the AMCP Nexus 2023 meeting.

"This study was designed to identify barriers to Xifaxan access among patients with OHE. The study results highlight that rejection of Xifaxan claims led to delay in treatment initiation as well as gaps in active treatment. Such access barriers to Xifaxan may result in increased rates of OHE related hospitalizations," said Arun Jesudian, MD, Director of Inpatient Liver Services at NYPH/Weill Cornell in New York who led the analysis.

Treatment gaps were assessed across a 12-month period that began at the first observed attempt to access rifaximin, which is defined as a paid, reversed or rejected prescription claim.

- Across the study period, patients had 8.8 average attempts to access rifaximin with an average 6.4 claims paid, 1.5 rejected and 0.9 reversed
- Nearly all patients (97.0%) experienced a treatment gap of at least one day, with an average of 2.9 gaps per patient leading to a total duration of 157.4 days without exposure to rifaximin (medication possession ratio: 56.9%)
- Treatment-initiated delays in receiving rifaximin were experienced by 34.8% of patients with more than three-quarters (77.7%) of initiation delays experienced due to rejected claims with the most common rejection reported as Prior Authorization (PA) Required (61.8%)
- Following initial paid claim, active treatment gaps were experienced by nearly three-quarters of patients (72.7%) with an average gap duration of 22.9 days

"Xifaxan is the only FDA-approved medicine indicated for the reduction in risk of overt hepatic encephalopathy recurrence in adults and this analysis shows that many OHE patients continue to face barriers in receiving the vital care they may require," said Nicola Kayel, Senior Vice President, Marketing, Salix. "For the Salix team, our highest priority is patient care. Patients living

with OHE continue to be at risk for recurrence and we are committed to understanding and improving the patient journey."

The retrospective database analysis used the IQVIA PharMetrics Plus database linked with Longitudinal Access and Adjudicated Data and identified 1,711 commercially insured adults (aged 18-64) with OHE who had at least one paid rifaximin prescription fill and 12-month continuous eligibility.

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 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.

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 management 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
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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 approximately 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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