BAUSCH Health

Salix Pharmaceuticals To Deliver Podium Presentation At Digestive Disease Week® 2023

May 08, 2023

Five XIFAXAN® (rifaximin) and TRULANCE® (plecanatide) Research Posters Also to Be Presented

LAVAL, Quebec, May 8, 2023 – Bausch Health Companies Inc. (NYSE/TSX: BHC) and its gastroenterology business, Salix Pharmaceuticals, ("Salix"), the gastroenterology (GI) business of Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") and one of the largest specialty pharmaceutical companies in the world committed to the management and treatment of gastrointestinal diseases, today will deliver a podium presentation of its research titled *"Impact of Rifaximin Use During The 30-Day Post-Discharge Period Following an Overt Hepatic Encephalopathy Hospitalization on Healthcare Utilization And Costs"* during Digestive Disease Week® (DDW) 2023, which will be held virtually and in-person in Chicago, IL through Tuesday, May 9, 2023.

The study led by Arun Jesudian, MD, Director of Inpatient Liver Services at NYPH/Weill Cornell, describes and compares healthcare resource utilization, including the rate of overt hepatic encephalopathy (OHE) hospitalizations, and costs during the 30-day period following an OHE hospitalization among patients who are treated with Xifaxan versus those who are not. Results showed that initiation of Xifaxan after an OHE hospitalization resulted in reduced OHE-related hospitalizations in the 30-day period following an OHE hospitalization. Further, initiation of Xifaxan immediately upon discharge after the OHE hospitalization showed a high quality of care, with a lower rate of OHE-related hospitalizations. Additionally, reduced medical costs associated with fewer hospitalizations offset the increased pharmacy costs of Xifaxan.

"The research was designed to help establish optimal clinical practices and patient health outcomes post an OHE-related hospitalization," said Dr. Jesudian. "Adding to a growing body of evidence, the study supports the use of Xifaxan to both reduce re-hospitalizations and their associated medical costs after an initial OHE-related hospitalization."

In addition, on Sunday, May 7, lead author Robert Wong, MD, MS Clinical Associate Professor (Affiliated) of Medicine in the division of Gastroenterology and Hepatology at the Stanford University School of Medicine and Staff Physician in the Gastroenterology Section at the Veterans Affairs Palo Alto Healthcare System, presented a poster titled "Real-World Trends in The Prevalence of Cirrhosis and Rates of Overt Hepatic Encephalopathy Among Commercially Insured Adults in The United States From 2006-2020" that showed an increasing trend in the prevalence of diagnosed cirrhosis from 0.20% in 2006 to 0.45% in 2020. Among adults with cirrhosis, the rate of decompensation increased by 27% from 35.6% in 2006 to 45.2% in 2020 and the rate of OHE nearly doubled from 11.8% in 2006 to 21.4% in 2020. Based on the study findings, there were approximately 900,000 adults with cirrhosis, 450,000 with decompensated cirrhosis, and 200,000 with OHE in the US in 2020.

A complete list of research being presented by Salix at DDW 2023 on behalf of XIFAXAN® (rifaximin) and TRULANCE® (plecanatide), includes:

HEALTH POLICY

- Wong, Robert. et al. "Real-World Trends in the Prevalence of Cirrhosis and Rates of Hepatic Encephalopathy Among Commercially Insured Adults in the United States From 2006-2020"
  - May 7, 2023 – 12:30 –1:30 PM (CDT); Embargo Time-12:01 a.m. CDT May 7
  - Abstract #-3859401 / Poster #-Su1546
- Jesudian, Arun. et al. *"Perception of Moderate to High Risk Factors for Developing Overt Hepatic Encephalopathy Across Physician Specialties in The United States"*
  - May 9, 2023 – 12:30 –1:30 PM (CDT); Embargo Time- 12:01 a.m. CDT May 9
  - Abstract #-3853017 / Poster #-Tu1524

XIFAXAN

- Kowdley, Kris. et al. *"Rifaximin Plus Lactulose Is More Efficacious Than Lactulose Alone for The Prevention of Overt Hepatic Encephalopathy in Patients With Or Without Ascites"*
  - May 7, 2023 – 12:30-1:30 PM (CDT); Embargo Time-12:01 a.m. CDT May 7
  - Abstract #-3862864 / Poster #-Su1548
- Jesudian, Arun. et al. *"Impact of Rifaximin Use During The 30-Day Post-Discharge Period Following an Overt Hepatic Encephalopathy Hospitalization on Healthcare Utilization And Costs"*
  - May 8, 2023 – 2:30-2:45 PM (CDT); Embargo Time-12:01 a.m. CDT May 8
  - Abstract #-3857579
- Gagnon-Sanschagrin, Patrick. et al.*"Long Term Care Services Use Among Medicare Patients Treated with Rifaximin for Overt Hepatic Encephalopathy"*
  - May 9, 2023 – 12:30 –1:30 PM (CDT); Embargo Time-12:01 a.m. CDT May 9
  - Abstract #-3862445 / Poster #-Tu1522

TRULANCE

- Brenner, Darren. et al. *"Plecanatide Improves Abdominal Pain, Bloating, And Straining Symptoms in Adults with Irritable Bowel Syndrome with Constipation (IBS-C): A New Composite Endpoint Analysis of Two Randomized, Phase 3 Trials"*
  - May 9, 2023 – 12:30-1:30 PM (CDT); Embargo Time- 12:01 a.m. CDT May 9
  - Abstract #-3860993 / Poster #-Tu1617

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 TRULANCE

Trulance (plecanatide) 3 mg tablets is indicated in adults for the treatment of Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C).

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

Trulance® is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Use of Trulance should be avoided in patients 6 years to less than 18 years of age. The safety and efficacy of Trulance have not been established in pediatric patients less than 18 years of age.

Contraindications

- Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- Trulance is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Risk of Serious Dehydration in Pediatric Patients

- Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid secretion as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than older patients to develop severe diarrhea and its potentially serious consequences.
- Use of Trulance should be avoided in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young mice and the lack of clinical safety and efficacy data in pediatric patients, use of Trulance should be avoided in patients 6 years to less than 18 years of age.

Diarrhea

- Diarrhea was the most common adverse reaction in the four placebo-controlled clinical trials for CIC and IBS-C. Severe diarrhea was reported in 0.6% of Trulance-treated CIC patients, and in 1% of Trulance-treated IBS-C patients.

- If severe diarrhea occurs, the health care provider should suspend dosing and rehydrate the patient.

Adverse Reactions

- In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence ≥2% and greater than in the placebo group) was diarrhea (5% vs 1% placebo).
- In the two combined IBS-C clinical trials, the most common adverse reaction in Trulance-treated patients (incidence ≥2% and greater than in the placebo group) was diarrhea (4.3% vs 1% placebo).

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 also see the
full Prescribing Information
, including BOXED Warning, for additional risk 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
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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 controlling interest in Bausch + Lomb. 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
and connect with us on
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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. 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. 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.

About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 6-9, 2023. The meeting showcases more than 3,100 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org

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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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Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
908-569-3692