BAUSCH Health

ACG Presidential Plenary to Highlight Analysis of Xifaxan® (rifaximin) Risk Reduction of Overt Hepatic Encephalopathy (OHE) Recurrence

October 28, 2024

Additional ACG presentation to focus on impact of Xifaxan on OHE rehospitalizations

LAVAL, QC / ACCESSWIRE / October 27, 2024 / Bausch Health Companies Inc. (NYSE:BHC) (TSX:BHC) and its gastroenterology (GI) business, Salix Pharmaceuticals ("Salix"), announced that results of an analysis of Xifaxan® (rifaximin) monotherapy will be presented during a Presidential Plenary Session of The American College of Gastroenterology® 2024 Annual Scientific Meeting taking place October 25-30 in Philadelphia, PA. This post hoc analysis of data from two randomized trials evaluated the efficacy of Xifaxan monotherapy compared to lactulose monotherapy for risk reduction of overt hepatic encephalopathy (OHE) recurrence and all-cause mortality.

During ACG, Salix will also present new data on the impact of Xifaxan use on rehospitalizations following an OHE hospitalization discharge in both commercially insured and Medicare patient populations.

Two posters to be presented at the ACG meeting will also share findings for Plenvu® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride for oral solution) as a bowel preparation medication, including efficacy findings from colonoscopy patients who have either comorbid conditions or are taking concomitant medications that are known to impact bowel prep quality.

"These presentations at ACG 2024 can give healthcare professionals confidence that treatments from Salix have potential to improve outcomes for their patients" said Aimee Lenar, Executive Vice President, US Pharma at Bausch Health. "Bausch Health remains dedicated to pursuing life-changing solutions and continues to invest in expanding the body of evidence for our medicines today and in the future."

The complete list of Salix research and analyses to be presented at ACG 2024 is as follows:

XIFAXAN

- Bajaj, Jasmohan S. et.al. Rifaximin Monotherapy Is More Effective Than Lactulose Monotherapy for Reducing the Risk of Overt Hepatic Encephalopathy (OHE) Recurrence and All-Cause Mortality: An Analysis of Two Randomized Trials
    - Presidential Plenary Session 2; Presentation #9
    - Monday, October 28, 10:06 - 10:18 AM ET
- Jesudian, Arun B. et.al. Impact of Rifaximin Use on Overt Hepatic Encephalopathy (OHE) Rehospitalizations Post Discharge from an OHE Hospitalization in Commercially and Medicare

Insured Patients

- Poster #P1162
- Sunday, October 27, 3:30 PM - 7:00 PM ET

PLENVU

- Cash, Brooks D. et.al. Efficacy and Safety of the 1 Liter NER1006 Bowel Preparation for Colonoscopy in Adults With Comorbid Conditions That May Impact Prep Quality
  - Poster #P3667
  - Tuesday, October 29, 10:30 AM - 4:00 PM ET
- Poppers, David. et.al. One-Liter NER1006 Is Efficacious as a Bowel Preparation for Colonoscopy in Patients Taking Concomitant Medications Known to Impact Prep Quality
  - Poster #P3657
  - Tuesday, October 29, 10:30 AM - 4:00 PM ET

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 (≥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 (≥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 PLENVU

INDICATION

PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride for oral solution) is a prescription medication used by adults to clean the colon before a colonoscopy.

IMPORTANT SAFETY INFORMATION

- Do not take PLENVU® if you have a blockage in your intestine (bowel obstruction), an opening in the wall of your stomach or intestine (bowel perforation), problems with food or fluid emptying from your stomach (gastric retention), a problem with food moving too slowly through your intestines (ileus), a very dilated large intestine, or an allergy to any of the ingredients in PLENVU®.

- PLENVU® and other bowel preparations can cause serious side effects including loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood. These changes can cause abnormal heartbeats that may result in death, seizures (even if you have never had a seizure), or kidney problems. Your chance of having fluid loss and changes in body salts with PLENVU® is higher if you have heart problems, kidney problems, or take water pills, high blood pressure medicine, or non-steroidal anti-inflammatory drugs (NSAIDS).

- Your healthcare provider may do blood tests after you take PLENVU® to check your blood for changes. Tell your healthcare provider right away if you have any symptoms of too much fluid loss (dehydration) including vomiting, dizziness, heart problems, kidney problems, seizures, dry mouth, urinating less often than normal; headache, or feel faint, weak, or lightheaded, especially when you stand up.

- PLENVU® can cause ulcers of the bowel or bowel problems (ischemic colitis). Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal

bleeding.

- PLENVU® can cause serious allergic reactions that may include skin rash, itching, raised red patches on your skin (hives); swelling of the face, lips, tongue, and throat; and kidney problems.

- The most common side effects in patients taking PLENVU® were nausea, vomiting, dehydration, and stomach pain or discomfort.

- Tell your healthcare provider about all of your medical conditions and medicines you take, including prescription, nonprescription medicines, vitamins, and herbal supplements before you take PLENVU®

These are not all the possible side effects of PLENVU®. Ask your healthcare provider for more information.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit
www.fda.gov/medwatch
or call
1-800-FDA-1088
.

Please
click here
for full Prescribing Information.

About Bausch Health

Bausch Health Companies Inc. (NYSE:BHC)(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
and connect with us on
Twitter
and
LinkedIn.
For more information about Bausch Health, visit
www.bauschhealth.com
and connect with us on
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