Salix Pharmaceuticals To Share New Data At Digestive Disease Week® 2022

May 18, 2022

XIFAXAN® (rifaximin), TRULANCE® (plecanatide) and PLENVU® Research Posters Will Be Presented

LAVAL, Quebec, May 18, 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 diseases and disorders, today announced seven posters on behalf of XIFAXAN® (rifaximin), TRULANCE® (plecanatide) and PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution), will be shared at
Digestive Disease Week® (DDW) 2022
, which is being held virtually and in-person in San Diego, Calif., from May 21-24, 2022. The posters will be accessible on DDW's ePoster's website beginning Saturday, May 21, 2022.

The full list of Salix research to be featured at DDW 2022 is as follows:

XIFAXAN

- Bajaj, Jasmohan S. et al. "*Rifaximin Plus Lactulose is More Efficacious than Lactulose Alone for Risk Reduction of Overt Hepatic Encephalopathy Recurrence: A Subgroup Analysis by Viral or Alcohol Cirrhosis Etiology*"
- Lacy, Brian et al. "*A New Trisymptom Composite Endpoint to Evaluate the Efficacy of Rifaximin for the Multiple Symptoms of Irritable Bowel Syndrome with Diarrhea (IBS-D): A Pooled Analysis of Two Randomized Phase 3 Trials*"

TRULANCE

- Shah, Eric et al. *"Plecanatide Produces A More Rapid and Sustained Clinical Response Compared to Placebo in Patients with Irritable Bowel Syndrome with Constipation"*

PLENVU

- Brooks, D. Cash et al. "*Low Risk of Hypokalemia in Adults Treated with the 1 Liter Polyethylene Glycol–Based Bowel Preparation NER1006: A Pooled Analysis of Two Randomized Phase 3 Trials*"
- Epstein, Michael S. et al. "*NER1006, A 1 Liter Polyethylene Glycol–Based Bowel Preparation, is an Independent Predictor of Adequate and High-Quality Cleansing Success in Adults Undergoing Colonoscopy: A Pooled Analysis of Two Randomized Phase 3 Trials*"

- Epstein, Michael S. et al. "*Same-Day Morning-Only Dosing Of 1 Liter NER1006, A Polyethylene Glycol Bowel Preparation, Nearly Doubles the Chance of High-Quality Cleansing Versus Standard 2 Liter Polyethylene Glycol and Ascorbate*"
- Poppers, David et al. "*Asymmetrically Dosed 1 Liter Polyethylene Glycol Bowel Preparation Plus Ascorbic Acid Demonstrates High-Quality Cleansing Efficacy Compared with Comparator Solutions Across Clinical Trials*"

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 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).

Please also see the
full Prescribing Information
, including BOXED Warning, for additional risk information.

About PLENVU

PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution) is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults.

IMPORTANT SAFETY INFORMATION

- PLENVU is contraindicated in patients with gastrointestinal (GI) obstruction, bowel perforation, gastric retention, ileus, toxic megacolon, and hypersensitivity to any of its ingredients.
- Advise patients to hydrate adequately before, during, and after the use of PLENVU. It is encouraged that patients drink additional clear liquids to help avoid cases of fluid and electrolyte abnormalities. Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures, and renal impairment.

- There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. These occur predominantly in patients with underlying cardiac risk factors and electrolyte disturbances. Consider obtaining ECGs in patients at an increased risk of serious cardiac arrhythmias.
- Use PLENVU with caution in patients with a history of seizures and those at an increased risk of seizures, including patients taking medications that lower the seizure threshold, patients withdrawing from alcohol or benzodiazepines, or patients with hyponatremia.
- Use PLENVU with caution in patients with renal impairment or those taking concomitant medications that affect renal function. Advise these patients to adequately hydrate before, during, and after the use of PLENVU and consider performing laboratory tests in these patients.
- Do not administer PLENVU to patients with GI obstruction or perforation. If GI obstruction or perforation is suspected, perform appropriate diagnostic studies prior to administering PLENVU.
- Use caution in patients with severe ulcerative colitis.
- Patients with impaired gag reflex or those prone to regurgitation or aspiration should be observed during the administration of PLENVU.
- Use PLENVU with caution in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- Phenylalanine can be harmful to patients with phenylketonuria (PKU). PLENVU contains phenylalanine, a component of aspartame. Each PLENVU treatment contains 491 mg of phenylalanine.
- PLENVU contains polyethylene glycol and may cause serious hypersensitivity reactions including anaphylaxis, angioedema, rash, urticaria, and pruritus. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should signs and symptoms occur.
- In clinical trials, the most common adverse reactions (>2% of patients taking PLENVU) were nausea, vomiting, dehydration, and abdominal pain/discomfort. Adverse reactions were similar between the two dosing regimens.

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 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 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.

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