BAUSCH Health

Salix to Present Clinical Data for XIFAXAN® (RIFAXIMIN) and PLENVU® at the American College of Gastroenterology Annual Meeting

October 08, 2018

Oral Presentation and Five Posters to be Featured

BRIDGEWATER, N.J., Oct. 8, 2018 /PRNewswire/ -- Salix Pharmaceuticals ("Salix"), one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases and a wholly owned subsidiary of Bausch Health Companies Inc. ("Bausch Health") (NYSE/TSX: BHC), will present scientific data, including one podium presentation and five posters, evaluating investigative data on the safety and efficacy of XIFAXAN® (rifaximin) and PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution) at the American College of Gastroenterology (ACG) annual meeting in Philadelphia from Oct. 5-10, 2018.

"We look forward to presenting clinical study research elements of our portfolio at one of the most preeminent GI conferences, such as ACG," said Mark McKenna, president, Salix Pharmaceuticals. "We remain committed to improving understanding of the science and impact of GI therapies. This commitment emerges from our mission, values and expectations — all the factors that have made us a leading GI company for nearly 30 years."

"We believe that the new PLENVU data presented by our partner, Salix, at ACG will be important to help further educate physicians as they offer this product, given the recent U.S. launch in September 2018," said Peter Martin, chief operating officer, Norgine. "Together, we continuously strive to reinforce the benefits of PLENVU to improve cleansing of the colon before colonoscopy."

The full schedule of research to be presented includes:

XIFAXAN (rifaximin)-Related Presentations

- Anthony Lembo. "*Characterization of Abdominal Pain Response to Rifaximin in Patients with Irritable Bowel Syndrome with Diarrhea (IBS-D), by Baseline Pain Severity*." Poster #P0337; Sunday, October 7, 3:30 p.m. – 7:00 p.m.; Exhibit Halls DE (level 200)
- Brian Lacey. "*Rifaximin for Improving Abdominal Pain and Bloating Symptoms in Patients with Irritable Bowel Syndrome with Diarrhea (IBS-D) Using Modified Definitions of Pain Response*." Poster #P1231; Monday, October 8, 10:30 a.m. – 4:15 p.m.; Exhibit Halls DE (level 200)
- Ali Rezaie. "*Lactulose Breath Testing Predicts Response to Rifaximin for Cardinal Irritable Bowel Syndrome With Diarrhea (IBS-D)*." Poster #P2105; Tuesday, October 9, 10:30 a.m. – 4:00 p.m.; Exhibit Halls DE (level 200)
- Steven Flamm. "*Efficacy and Safety of Rifaximin Treatment for Reducing the Risk of Overt Hepatic Encephalopathy by Baseline Hepatic Impairment*." Wednesday, October 10, 9:00 a.m. – 9:10 a.m.; Terrace Ballroom 4 (level 400)

PLENVU®, also known as NER1006,-Related Presentations

- Neal Osborn. "*Safety of 1 L Polyethylene Glycol-Based Bowel Preparation, NER1006, for Colon Cleansing Before Colonoscopy: A Pooled Analysis of Three Phase 3 Randomized Controlled*

Trials." Poster #P1249; Monday, October 8, 10:30 a.m. – 4:15 p.m.; Exhibit Halls DE (level 200)

- Cesare Hassan. "*Impact of Cleansing Quality Using the Boston Bowel Preparation Scale on Polyp and Adenoma Detection Rates: A Post Hoc Analysis of Three Phase 3 Randomized Trials*." Poster #P1120; Monday, October 8, 10:30 a.m. – 4:15 p.m.; Exhibit Halls DE (level 200)

Salix licensed the commercial rights of PLENVU for the United States and Canada from Norgine B.V. in August 2016.

About XIFAXAN

XIFAXAN (rifaximin) 550 mg tablets are indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults and for the reduction in risk of overt hepatic encephalopathy (HE) recurrence 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 in IBS-D (≥2%) were nausea (3%) and ALT increased (2%).
- In clinical studies, the most common adverse reactions for XIFAXAN in HE (≥10%) were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascities (11%).
- 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.

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 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.

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About Norgine

Norgine is a leading European specialist pharmaceutical company with a direct commercial presence in all major European markets. In 2017, Norgine's total net sales were EUR 345 million, up 17 percent. Norgine employs over 1,000 people across its commercial, development and manufacturing operations and manages all aspects of product development, production, marketing, sale and supply. Norgine specialises in gastroenterology, hepatology, cancer and supportive care.

Norgine is headquartered in the Netherlands. For more information, please visit

www.norgine.com

In 2012, Norgine established a complementary business Norgine Ventures, supporting innovative healthcare companies through the provision of debt-like financing in Europe and the US. For more information, please visit
www.norgineventures.com
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About Salix
Salix is one of the largest specialty pharmaceutical companies in the world committed to the prevention and treatment of gastrointestinal diseases. For almost 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.

About Bausch Health
Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at
www.bauschhealth.com
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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," "expects," "intends," "plans," "should," "could," "would," "may," "will," "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, risks and uncertainties discussed in the Bausch Health's most recent annual or quarterly report and detailed from time to time in Bausch Health's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. In addition, certain material factors and assumptions have been applied in making these forward-looking statements, including that the risks and uncertainties outlined above will not cause actual results or events to differ materially from those described in these forward-looking statements. Bausch Health believes that the material factors and assumptions reflected in these forward-looking statements are reasonable, but 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 and Salix undertake 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 product and the XIFAXAN trademark are licensed by Alfasigma S.P.A. to Salix Pharmaceuticals or its affiliates. PLENVU is a trademark of the Norgine group of companies.
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