BAUSCH Health

Salix To Highlight New Clinical Data During Digestive Disease Week

May 31, 2018

Oral Presentation and Eight Posters to be Featured

BRIDGEWATER, N.J., May 31, 2018 /PRNewswire/ -- Salix Pharmaceuticals, a leading specialty pharmaceutical company committed to the prevention and treatment of gastrointestinal disorders and a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX), will present new scientific data, including one podium presentation and eight 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 Digestive Disease Week (DDW) in Washington, D.C., from June 2-5, 2018.

"Salix will be presenting multiple, new data sets at DDW, the world's largest gathering of physicians and researchers in gastroenterology. We remain committed to advancing GI research that meets the needs of both the scientific and medical community, and the patients and families we serve," said Mark McKenna, senior vice president and general manager, Salix Pharmaceuticals.

The full schedule of research to be presented includes:

XIFAXAN (Rifaximin)-Related Presentations

- Pimentel, Mark. "*Rifaximin Repeat Treatment for Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D) and Impact on Clostridium Difficile Infection Development*." Poster available Saturday, June 2
- Weinstock, Leonard. "*Characterization of Long-Term Rifaximin Responders from a Phase 3, Randomized, Double Blind, Placebo-Controlled Repeat Treatment Trial for Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D)*." Poster available Saturday, June 2
- Lacy, Brian. "*Efficacy of Rifaximin on Bloating in Patients with Diarrhea–Predominant Irritable Bowel Syndrome (IBS–D): A Pooled Analysis of Three Phase 3, Randomized, Placebo–Controlled Trials*." Poster available Saturday, June 2
- Lembo, Anthony. "*Efficacy of Rifaximin in Patients with Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D) and Prior Use of IBS Medications*." Poster available Saturday, June 2
- Pimentel, Mark. "*Lack of Development of Opportunistic Infections, Including Candidiasis, in Patients with Diarrhea-Predominant Irritable Bowel Syndrome Receiving Repeat Treatment with Rifaximin*." Sunday, June 3 at 5:00 p.m.; Room 201

PLENVU®, also known as NER1006,-Related Presentations

- Epstein, Michael. "*Assessment of Patient Satisfaction with NER1006 and Trisulfate Bowel Preparations for Colonoscopy: A Phase 3, Randomized, Multicenter Trial*." Poster available Tuesday, June 5
- Epstein, Michael. "*Impact of Time Interval Between the Second Dose of a Split-Dose Regimen of NER1006 Versus Trisulfate and Start of Colonoscopy: Evaluation of Colon Cleansing Rates*." Poster available Tuesday, June 5
- Epstein, Michael. "*Comparative Assessment of Bowel Cleansing of 1 L Polyethylene Glycol Plus Ascorbate NER1006 Compared with 2 L Polyethylene Glycol Plus Ascorbate: A Phase 3, Randomized, Multicenter Trial*." Poster available Tuesday, June 5
- Hassan, Cesare. "*Impact of Cleansing Quality Using the Harefield Cleansing Scale and Polyp and Adenoma Detection Rates: A Post Hoc Analysis of Three Phase 3 Randomized Trials*." Poster available Tuesday, June 5

About XIFAXAN

XIFAXAN® (rifaximin) 550 mg tablets are indicated 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 in IBS-D (≥2%) were nausea (3%) and 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.

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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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 Salix

Salix Pharmaceuticals 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, a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc., is headquartered in Bridgewater, New Jersey.

About Valeant

Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) 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.valeant.com .

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 Valeant's most recent annual or quarterly report and detailed from time to time in Valeant's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. 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. Valeant 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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