BAUSCH Health

Salix Pharmaceuticals to Present New Clinical Data at the American College of Gastroenterology (ACG) Annual Meeting

October 28, 2019

TRULANCE® (plecanatide) Poster Presentation Recognized with Presidential Poster Award Distinction

BRIDGEWATER, N.J., Oct. 28, 2019 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) 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, is presenting new scientific data, including seven posters at the American College of Gastroenterology (ACG) 2019 Annual Scientific Meeting in San Antonio (Oct. 25 – 30, 2019). One of the presentations evaluating investigative data on the safety and efficacy of TRULANCE® (plecanatide) was selected as a Presidential Poster Award recipient.

"It is our ongoing commitment to R&D that has enabled Salix to produce what the ACG Committee recognizes as high-quality, novel, unique and interesting research," said Howard Franklin, MD, vice president of Medical Affairs and Strategy, Salix Pharmaceuticals. "We're especially pleased that a poster presentation featuring TRULANCE®, the newest addition to our portfolio, received the Presidential Poster Award, a distinction that is reserved for only a small percentage of accepted abstracts."

The ACG Abstract Selection Committee reviewed over 2,700 abstracts in advance of this year's Annual Scientific Meeting. Each year less than five percent of accepted abstracts receive the Presidential Poster Award distinction.

The complete list of all Salix poster presentations at ACG is as follows:

TRULANCE® (Plecanatide)

- Darren M. Brenner, MD. "*Impact of Plecanatide on Symptoms and Quality of Life for Patients with Chronic Idiopathic Constipation: Analysis of PAC-SYM and PAC-QOL From Two Phase III Clinical Trials.*" Poster #P0341; Sunday, Oct. 27, 3:30 p.m. – 7:00 p.m. CT; Exhibit Halls 3 and 4 (street level); Recipient of the Presidential Poster Award
- Gregory Sayuk, MD. "*Plecanatide for Patients with Chronic Idiopathic Constipation and Irritable Bowel Syndrome-Constipation: Analysis of Abdominal Bloating from Four Randomized Phase 3 Clinical Trials."* Poster #P2157; Tuesday, Oct. 29, 10:30 a.m. – 4:00 p.m. CT; Exhibit Halls 3 and 4 (street level)

XIFAXAN® (Rifaximin)

- Brian Lacy, PhD, MD. "*Impact of Colonoscopy Timing on Rifaximin in Patients with Irritable Bowel Syndrome with Diarrhea (IBS-D).*" Poster #P2164; Tuesday, Oct. 29, 1:00 p.m. – 2:15 p.m. CT; Exhibit Halls 3 and 4 (street level)

PLENVU®(polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution), also known as NER1006

- Michael S. Epstein, MD, FACG*; "Electrolyte Shifts of NER1006 Bowel Preparation for Colonoscopy in the Elderly Are Transient and Well-Tolerated."* Poster #P0368; Sunday, Oct. 27, 3:30 p.m. – 7:00 p.m. CT; Exhibit Halls 3 and 4 (street level)

- Michael S. Epstein, MD, FACG*, "1 L NER1006 Improves High-Quality Colon Cleansing and Mean Polyp Detection versus Oral Sulfate Solution and 2 L Polyethylene Glycol Plus Ascorbate."* Poster #P2030; Tuesday, Oct. 29, 10:30 a.m. – 4:00 p.m. CT; Exhibit Halls 3 and 4 (street level)
- Michael S. Epstein, MD, FACG*, "In Patients with an Overall Cleansing Success the 1L Polyethylene Glycol NER1006 Achieves More High-Quality Cleansed Segments per Patient Than Three Standard Bowel Preparations."* Poster #2031; Tuesday, Oct. 29, 10:30 a.m. – 4:00 p.m. CT; Exhibit Halls 3 and 4 (street level)
- Brooks D. Cash, MD, FACG. *"Patient Experience with NER1006 as a Bowel Preparation for Colonoscopy: A Prospective, Multicenter U.S. Survey."* Poster #P0372; Sunday, Oct. 27, 3:30 p.m. – 7:00 p.m. CT; Exhibit Halls 3 and 4 (street level)

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 click
here
for full Prescribing Information, including Box Warning, for additional risk information.

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.

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 ascites (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.

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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
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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 30 years, Salix has licensed, developed, and marketed innovative products to improve patients' lives and arm healthcare providers with life-changing solutions for many chronic and debilitating conditions. Salix currently markets its product line to U.S. healthcare providers through an expanded sales force that focuses on gastroenterology, hepatology, pain specialists, and primary care. Salix is headquartered in Bridgewater, N.J.

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 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 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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