

# Salix Announces U.S. Launch of PLENVU®, the First and Only 1-Liter PEG Bowel Cleansing Preparation for Colonoscopies

September 11, 2018

## **PLENVU Offers Same-Day Morning-of-Colonoscopy and 2-Day Split-Dosing<sup>1</sup>**

BRIDGEWATER, N.J., Sept. 11, 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), and its partner Norgine B.V. ("Norgine") today announced the U.S. launch and availability of PLENVU (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution). PLENVU is now the lowest total volume requirement compared to any other prescription bowel prep.

Please see the Important Safety Information and the full U.S. Prescribing Information below.

Colorectal cancer is the second leading cause of cancer-related deaths in the United States. The American Cancer Society estimates colorectal cancer is expected to cause 50,630 deaths during 2018. It is commonly known that successful colorectal cancer screening can help save lives.<sup>2</sup>

"When detected early, colorectal cancer is one of the most preventable and treatable forms of cancer,"<sup>3</sup> said Mark McKenna, president, Salix Pharmaceuticals. "Our hope is that by offering physicians and patients this new and innovative colonoscopy prep, we will further support successful cancer screenings, which may ultimately help save lives."

According to patients' experiences and reported barriers to colonoscopy, most patients perceive the bowel preparation to be the most burdensome part of colonoscopy.<sup>4</sup> Complaints regarding bowel preparation typically relate to the large volumes of fluid necessary to consume and the unpleasant taste.<sup>5</sup>

"PLENVU is an important advancement in bowel preparation products. By reducing both the volume of solution and addressing product palatability, PLENVU may make it easier for patients to cleanse their colon prior to colonoscopy," said Philip Schoenfeld, Adjunct Professor of Medicine, Division of Gastroenterology, University of Michigan School of Medicine. "I am also pleased that the FDA has approved PLENVU for same-day dosing so that patients have the option to drink all of the bowel prep on the morning of the colonoscopy and have the colonoscopy performed later that day."

The U.S. Food and Drug Administration (FDA) approved PLENVU in May 2018. The approval was based on multiple Phase 3 clinical trials, including the NOCT study,<sup>6</sup> which compared PLENVU versus a trisulfate bowel cleansing solution (SUPREP®) using a two-day split-dosing regimen in adults. Both primary endpoints were met, achieving non-inferior overall bowel cleansing success and 'Excellent' and 'Good' cleansing of the ascending colon. PLENVU is also the only FDA-approved bowel cleanser to offer a same-day morning-of-colonoscopy dose.

## About PLENVU (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution)

### Indications

PLENVU is a prescription medication used by adults to clean the colon before a colonoscopy.

### Important Safety Information for Patients

- 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.
- It is important to drink sufficient clear liquids before, during, and after the use of PLENVU. Be sure to consume additional clear liquids after the first dose and second dose of PLENVU. Stop drinking liquids 2 hours prior to colonoscopy.
- Before you take PLENVU, talk to your doctor if you:
  - Have problems with serious loss of body fluid (dehydration) and changes in blood salts (electrolytes).
  - Have heart problems or take medication that affects your heart. Your doctor may consider obtaining an electrocardiogram (ECG) test if you are at an increased risk for heart rhythm abnormalities, of seizures or take antiseizure medication.
  - Have kidney problems or take medication that affects kidney function. Your doctor may want to perform blood testing before and after your colonoscopy.
  - Have a history of stomach or bowel problems, such as ulcerative colitis, a bowel blockage, or a suspected opening in the wall of your stomach or intestine.
  - Have problems swallowing, heartburn (gastric reflux), or if you inhale food or fluid into your lungs when eating or drinking (aspirate).
  - Have a condition that destroys red blood cells, called glucose-6-phosphate dehydrogenase (G6PD) deficiency.
  - Have phenylketonuria (PKU). PLENVU contains aspartame equivalent to 491 mg of phenylalanine per treatment.
- PLENVU may affect how other medications work. Tell your doctor about all other medications (including prescription and nonprescription medicines, vitamins, and herbal supplements) you take before you take PLENVU. Do not take oral medications within 1 hour before or after starting each dose of PLENVU.
- Symptoms of serious allergic reactions may include skin rash, itching, raised red patches on your skin (hives), swelling of the face, lips, tongue, and throat, and kidney problems.
- In clinical studies with PLENVU, the most common side effects in patients taking PLENVU were nausea, vomiting, dehydration, and abdominal pain/discomfort.

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

For product information, adverse event reports, and product complaint reports, please contact:

Salix Product Information Call Center

Phone: 1-800-321-4576

Fax: 1-510-595-8183

Email:

[salixmc@dlss.com](mailto:salixmc@dlss.com)

Please click

[here](#)

for full Prescribing Information.

### 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. Norgine owns a R&D site in Hengoed, Wales and two manufacturing sites in Hengoed, Wales and Dreux, France. For more information, please visit [www.norgine.com](http://www.norgine.com)

### **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](http://www.bauschhealth.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 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.

### **References**

- The "One-Day Morning Dosing Regimen" (as it is labeled in the Prescribing Information) is referred to as "Same-Day Morning-of-Colonoscopy Dosing."
- National Cancer Institute  
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- Optimizing bowel preparation for colonoscopy: a guide to enhance quality of visualization. Retrieved from [www.ncbi.nlm.nih.gov/pmc/articles-PMC4805732-.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles-PMC4805732-.pdf)
- Hengoed, UK: Norgine Ltd; 2018

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PLV.0103.USA.18*

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