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Salix Receives FDA Approval For PLENVU®, Next Generation 1-Liter Bowel Cleansing Preparation For Colonoscopies

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BRIDGEWATER, N.J., May 7, 2018 /PRNewswire/ -- Salix Pharmaceuticals, Ltd. ("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 Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX), and its partner Norgine B.V. ("Norgine") announced today that the U.S. Food and Drug Administration (FDA) has approved PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution), a lower-volume (1L) polyethylene glycol based (PEG) bowel preparation.

Colorectal cancer is the third leading cause of cancer-related deaths in women and the second leading cause in men in the United States. The American Cancer Society estimates that there are approximately 97,000 new cases of colon cancer and 43,000 new cases of rectal cancer each year.[1] It is also shown that successful colorectal cancer screening can help save lives.[1]

"With the FDA approval of PLENVU®, physicians can now offer their patients a new preparation option for colonoscopies that features a lower-volume, one-liter PEG bowel preparation," said Mark McKenna, senior vice president and general manager, Salix Pharmaceuticals. "Studies have shown that high-volume bowel preparations can often be a deterrent to patients fully completing their preparation regimen. In contrast, PLENVU® is the lowest, total-volume preparation bowel cleanser available in the United States."

According to patients' experiences and reported barriers to colonoscopy, most patients perceived the bowel preparation to be the most burdensome part of colonoscopy.[2] Complaints regarding bowel preparation typically relate to the large volumes necessary to consume and the unpleasant taste. By reducing the volume of solution patients must consume for effective bowel cleansing to only one liter of active solution, Salix hopes to improve the patient colonoscopy preparation experience with PLENVU®.

"Often considered to be the gold standard, colonoscopy is the most effective screening method for the detection and prevention of colon cancer. With today's approval, we have a next-generation, one liter low volume option while still providing adequate and effective cleansing," said Philip Schoenfeld, M.D.

The approval was based on multiple Phase 3 clinical trials, including the NOCT study,[3] which compares 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 plus Good' cleansing of the ascending colon. PLENVU® is also the only FDA-approved bowel cleanser to offer split dosing on the same day as the colonoscopy procedure.

PLENVU® was licensed by Salix from Norgine in August 2016 for introduction to the U.S. market and will be available in the U.S market in the third quarter of 2018.

In Europe, PLENVU® is approved and available through Norgine.

About PLENVU® (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution)
PLENVU® (NER1006) is a low-volume (1L) polyethylene glycol based bowel preparation that has been developed to provide whole bowel cleansing, with an additional focus on the ascending colon.

PLENVU® Phase 3 Clinical Trial Program

- NOCT study. A U.S. study that compared PLENVU® to a trisulfate bowel cleansing solution using a two-day evening/morning split-dosing regimen in adults. Both primary endpoints were met. PLENVU® was as effective as a trisulfate solution in achieving overall bowel cleansing success and 'high quality' cleansing of the right colon.[3]
- MORA study. A European study that compared PLENVU® to MOVIPREP® using a two-day evening/morning split-dosing regimen and a one-day morning only split-dosing regimen in adults. The study met both of its primary endpoints. When administered using either dosing regimen, PLENVU® was as effective as MOVIPREP® in achieving overall bowel cleansing success, and superior to MOVIPREP® in achieving 'high quality' cleansing of the right colon using the Harefield Cleansing Scale (HCS).[4]

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 per cent.
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

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 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, 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.

Forward-looking Statements
This press 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 Company'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 press release or to reflect actual outcomes, unless required by law.

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[1] American Cancer Society
https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html

[2] Patients' experiences and reported barriers to colonoscopy in the screening context--a systematic review of the literature. Retrieved from
https://www.ncbi.nlm.nih.gov/pubmed/21640543
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[3] DeMicco MP, Clayton LB, Pilot J *et al*. Novel 1 L polyethylene glycol-based bowel preparation NER1006 for overall and right-sided colon cleansing: a randomized controlled phase 3 trial versus trisulfate. *Gastrointest Endosc* 2017; 87(3):677-687

[4] Bisschops R, *et al*. Tu2084 Efficacy and Safety of the Novel 1L PEG and Ascorbate Bowel Preparation NER1006 Versus Standard 2L PEG With Ascorbate in Overnight or Morning Split-Dosing Administration: Results from the Phase 3 Study MORA. Gastroenterology, Volume 150, Issue 4, Supplement 1, April 2016, Pages s1269-s1270.

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