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# SALIX ANNOUNCES FILING ACCEPTANCE FOR PLENVU®\* NEXT GENERATION BOWEL CLEANSING PREPARATION FOR COLONOSCOPIES

# **Expects FDA Decision in First-Quarter 2018**

BRIDGEWATER, N.J. – June 28, 2017 – Valeant Pharmaceuticals International, Inc.'s (NYSE: VRX AND TSX: VRX) wholly owned subsidiary, Salix Pharmaceuticals, a leading specialty pharmaceutical company committed to the prevention and treatment of gastrointestinal disorders, today announced that the U.S. Food and Drug Administration (FDA) accepted the New Drug Application for NER1006 (PLENVU®\*) a novel, lower-volume polyethylene glycol based bowel preparation that has been developed to help provide complete bowel cleansing, with an additional focus on the ascending colon. As high preparation volumes can often be a deterrent in patients fully completing their regimen, PLENVU®, when approved, will offer the lowest total volume of solution for an FDA-approved bowel cleanser in the market.

Colorectal cancer is the third leading cause of cancer-related deaths in women in the United States and the second leading cause in men, and successful colorectal cancer screening can save lives.<sup>1</sup>

"Effective bowel preparation is an important factor for a successful colonoscopy and for detecting adenomas and polyps," said Mark McKenna, senior vice president and general manager, Salix Pharmaceuticals. "If approved, PLENVU® may enhance bowel cleansing and the overall bowel prep experience relating to a colonoscopy."

PLENVU® was licensed by Norgine B.V. to Salix in August 2016. PLENVU® is not a U.S.- approved drug.

# **About PLENVU® (NER1006)**

PLENVU® (NER1006) is a novel, 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. This low-volume solution is developed not only to support improved patient acceptability and compliance but also to contribute to effectiveness of colonoscopy procedures at detecting colon cancer and for optimized bowel surveillance, through effective bowel cleansing.



### **About Norgine**

Norgine is a leading European specialist pharmaceutical company with a direct commercial presence in all major European markets. In 2016, Norgine's total revenue was EUR 368 million. 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 <a href="https://www.norgine.com">www.norgine.com</a>

#### **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, a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX), is headquartered in Bridgewater, New Jersey.

#### **Forward-looking Statements**

This press release contains forward-looking statements. Forward-looking statements may generally be identified by the use of the words "anticipates," "expects,", "can", "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 and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. 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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<sup>1</sup>American Cancer Society (2017) Key Statistics for Colorectal Cancer. Retrieved from https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html

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<sup>\*</sup>Provisionally approved name