# Salix provides update on FDA submission for PLENVU®\*

February 09, 2018

BRIDGEWATER, N.J. – Feb. 9, 2018 – 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: VRX and TSX: VRX), and its partner Norgine B.V. ("Norgine") have received notice that the U.S. Food and Drug Administration (FDA) has extended the PDUFA action date for its review of the New Drug Application for PLENVU<sup>®\*</sup> (NER1006) by three months to May 13, 2018. The PDUFA action date has been extended to allow the FDA more time to review additional data that was recently provided at its request.

PLENVU<sup>®</sup> was licensed by Salix from Norgine in August 2016 for introduction to the U.S. market. Salix and Norgine will continue to work closely with the FDA to support the review of PLENVU<sup>®</sup>, a next-generation bowel cleansing preparation for colonoscopies.

## About PLENVU® (NER1006)

PLENVU® (NER1006) is an investigational, 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 by 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 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.

#### **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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\*Provisionally approved name

PLV.0016.USA.18





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