BAUSCH Health

Statement Regarding Xifaxan Intellectual Property Litigation

May 17, 2017

LAVAL, Quebec, May 17, 2017 /PRNewswire/ -- Salix Pharmaceuticals, Inc. and parent Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) ("Valeant") and Actavis Laboratories, Inc., at Actavis' request, have agreed to stay outstanding litigation and extend the 30-month stay regarding Actavis' Abbreviated New Drug application (ANDA) for a generic version of Xifaxan (rifaximin) 550 mg tablets.

Valeant initiated the litigation against Actavis on March 23, 2016. Additionally, Valeant filed a Citizen Petition with the U.S. Food and Drug Administration (FDA) on Oct. 17, 2016, requesting changes to previously recommended standards for approval of generic versions of Xifaxan. On March 16, 2017, the FDA answered the Citizen Petition and issued its revised draft guidance regarding the recommended standards for approval of ANDAs for generic versions of Xifaxan.

Legal action is stayed through April 30, 2018 and cannot be lifted prior to Oct. 31, 2017. All currently scheduled litigation activities, including the January 2018 trial date, have been indefinitely removed from the Court docket.

The parties agree and the Court ordered that Actavis' 30-month regulatory stay shall be extended from Aug. 12, 2018 until no earlier than Feb. 12, 2019 and could be longer if the litigation stay lasts for more than 6 months.

Valeant remains confident in the strength of the Xifaxan patents and will defend its intellectual property vigorously.

About Valeant
Valeant Pharmaceuticals International, Inc. (NYSE/TSX:VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, gastrointestinal disorders, eye health, neurology and branded generics. More information about Valeant can be found at www.valeant.com
.

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.

Investor Contact:
Elif McDonald
elif.mcdonald@valeant.com

514-856-3855
877-281-6642 (toll free)

Media Contact:
Lainie Keller
lainie.keller@valeant.com

908-627-0917

To view the original version on PR Newswire, visit:
http://www.prnewswire.com/news-releases/statement-regarding-xifaxan-intellectual-property-litigation-300458920.html

SOURCE Valeant Pharmaceuticals International, Inc.

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
848-264-0934

LEGAL NOTICE PRIVACY POLICY

EMAIL ALERTS EMAIL PAGE RSS FEED

Use of this site signifies your agreement to the Legal Notice and Privacy Policy.
©2026 Bausch Health Companies Inc. All rights reserved. MTB.0230.USA.18 V2.0

CALIFORNIA RESIDENTS: DO NOT SELL MY PERSONAL INFORMATION

Powered by SITECORE