BAUSCH Health

Valeant Pharmaceuticals Receives Complete Response Letter from the FDA for Latanoprostene Bunod Ophthalmic Solution, 0.024% NDA

August 07, 2017

LAVAL, Quebec, Aug. 7, 2017 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) today announced it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for latanoprostene bunod ophthalmic solution, 0.024%, an investigative intraocular pressure lowering single-agent eye drop for patients with open angle glaucoma or ocular hypertension.

The CRL from the FDA only refers to a Current Good Manufacturing Practice (CGMP) inspection at Bausch + Lomb's manufacturing facility in Tampa, Fla. The FDA did not identify any efficacy or safety concerns with respect to the NDA or additional clinical trials needed for the approval of the NDA for latanoprostene bunod ophthalmic solution, 0.024%.

Valeant will work closely with the FDA to determine the appropriate next steps for the NDA.

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
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Forward-looking Statements
This press release may contain forward-looking statements which may generally be identified by the use of the words "anticipates", "if approved", "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 Contacts:
Arthur Shannon
arthur.shannon@valeant.com

514-856-3855

877-281-6642 (toll free)

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

908-927-0617

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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

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