

Valeant Pharmaceuticals Receives Complete Response Letter From The FDA

July 22, 2016

No Safety or Efficacy Concerns or Additional Clinical Trials Identified for Approval of Latanoprostene Bunod

FDA Letter Related to CGMP at Bausch + Lomb Facility

LAVAL, Quebec, July 22, 2016 /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 intraocular pressure lowering single-agent eye drop for patients with open angle glaucoma or ocular hypertension. The concerns raised by the FDA pertain to a Current Good Manufacturing Practice (CGMP) inspection at Bausch + Lomb's manufacturing facility in Tampa, Florida where some deficiencies were identified by the FDA. The FDA's letter 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 intends to meet with the FDA as soon as possible to work on a resolution and address these concerns.

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 contains forward-looking statements, including statements regarding the resolution of concerns raised by the FDA and the approval of the NDA for latanoprostene bunod ophthalmic solution 0.024%. Forward-looking statements 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 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.

Contact Information:

Laurie W. Little
laurie.little@valeant.com

or

Elif McDonald
elif.mcdonald@valeant.com

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

Media:

Renée Soto
or
Chris Kittredge/Jared Levy
Sard Verbinnen & Co.
212-687-8080

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**Investor Inquiries**

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

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Media inquiries

Corporate.communications@bauschhealth.com
908-569-3692

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