BAUSCH Health

Valeant Receives FDA Confirmation Of Voluntary Action Indicated (VAI) Inspection Classification For Tampa Facility

August 16, 2017

LAVAL, Quebec, Aug. 16, 2017 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) ("Valeant" or the "Company") today announced the U.S. Food and Drug Administration (FDA) confirmed it intends to issue a Voluntary Action Indicated (VAI) inspection classification for its Bausch + Lomb manufacturing facility in Tampa, Fla. as part of a forthcoming Establishment Inspection Record for the facility. With this confirmation, manufacturing uncertainties related to current and upcoming regulatory submissions will be eliminated for products manufactured at the Tampa facility.

"Following continued close collaboration with FDA inspectors, today, the FDA confirmed that all issues related to a Current Good Manufacturing Practice inspection at the Tampa facility are being satisfactorily resolved, and VAI status will soon be granted to the facility. We expect this to facilitate our current and upcoming regulatory submissions of products manufactured at the facility," said Joseph C. Papa, chairman and CEO, Valeant.

As further evidence of the progress made at the Tampa facility, the Company received approval yesterday for a Supplemental New Drug Application for the facility to be a release testing facility for drug substance for Alaway® (ketotifen fumarate ophthalmic solution), 0.035%.

A VAI inspection classification occurs when objectionable concerns were observed by FDA inspectors at a facility, but the problems do not meet the threshold of regulatory significance.[1]

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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https://www.fda.gov/downloads/aboutfda/transparency/publicdisclosure/glossaryofacronymsandabbreviations/ucm212061.pdf

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:	**Media Contact:**
Arthur Shannon	Lainie Keller
arthur.shannon@valeant.com	lainie.keller@valeant.com
(514) 856-3855	(908) 927-0617

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