BAUSCH Health

Bausch + Lomb Announces U.S. FDA Filing Acceptance For Loteprednol Etabonate Ophthalmic Gel, 0.38%

July 09, 2018

PDUFA Date Set for February 25, 2019

LAVAL, Quebec , July 9, 2018 /PRNewswire/ -- – Bausch + Lomb, a leading global eye health company and wholly owned subsidiary of Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX), today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for its sub-micron loteprednol etabonate ophthalmic gel, 0.38% with a Prescription Drug User Fee Act (PDUFA) action date of February 25, 2019. If approved, the product would be the lowest concentrated loteprednol ophthalmic corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery.

"The sub-micron loteprednol etabonate ophthalmic gel, 0.38% will offer eye care professionals and their patients a lower concentration formulation with less frequent dosing compared to currently available formulations of loteprednol," said Tracy Valorie, senior vice president, U.S. Pharmaceuticals and Surgical, Bausch + Lomb. "We are committed to developing innovative ophthalmic treatment options to help serve the needs of patients and look forward to bringing this new product to market."

This investigative product utilizes a novel submicron particle to help increase ocular penetration and residence time in anterior segment tissues.

About Bausch + Lomb
Bausch + Lomb, a Valeant Pharmaceuticals International, Inc. company, is a leading global eye health organization that is solely focused on protecting, enhancing and restoring people's eyesight. Its core businesses include over-the-counter supplements, eye care products, ophthalmic pharmaceuticals, contact lenses, lens care products, ophthalmic surgical devices and instruments. Bausch + Lomb develops, manufactures and markets one of the most comprehensive product portfolios in the industry, which is available in more than 100 countries.

About Valeant
Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at www.valeant.com.

Forward-looking Statements
This news release may contain forward-looking statements which may generally be identified by the use of the words "anticipates," "expects," "look forward," "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 Valeant'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 news release or to reflect actual outcomes, unless required by law.

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