BAUSCH Health

Bausch + Lomb Announces PDUFA Date For New OTC Redness Reliever, Brimonidine Tartrate Ophthalmic Solution, 0.025%

May 08, 2017

PDUFA date set for December 27, 2017

LAVAL, Quebec, May 8, 2017 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc.'s (NYSE: VRX and TSX: VRX) wholly owned subsidiary, Bausch + Lomb, a leading global eye health company, today announced that the U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for brimonidine tartrate ophthalmic solution, 0.025% (Luminesse™*), and set a PDUFA action date of December 27, 2017. Luminesse is a topical vasoconstrictor formulation to be used Over-the-Counter (OTC) as an eye drop to relieve redness of the eye due to minor eye irritations. If approved, this will be the first OTC product developed with brimonidine tartrate for the treatment of ocular redness.

"The filing acceptance of Luminesse brings us one step closer to bringing a new treatment option to potentially help patients in the more than 14 million households who use OTC eye drops to treat ocular redness," said Joseph C. Papa, Chairman and CEO of Valeant. "If approved, Luminesse may provide patients with ocular redness significant benefits versus other competing redness reliever products currently available."

Six clinical studies were conducted to evaluate the safety and effectiveness of low-dose Luminesse in relieving ocular redness, including a study to demonstrate the absence of IOP-lowering potential of low-dose brimonidine. Bausch + Lomb also conducted a comprehensive review of all post-marketing safety data, as the active ingredient brimonidine tartrate is typically found to be used in prescription ophthalmic products. The drug was found to be highly efficacious and safe with low risk of tachyphylaxis (tolerance or loss of effectiveness) and rebound congestion, which are both common to currently available OTC redness reliever eye drops.

Luminesse was licensed by Eye Therapies, Inc., to Bausch + Lomb.

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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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 our industry, which is available in more than 100 countries.

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.

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