

# Bausch + Lomb And Nicox Announce PDUFA Date For Novel Glaucoma Candidate Latanoprostene Bunod

March 20, 2017

LAVAL, Quebec and SOPHIA ANTIPOLIS, France, March 20, 2017 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc.'s (NYSE: VRX and TSX: VRX) wholly owned subsidiary, Bausch + Lomb, and Nicox S.A. (Euronext Paris: FR0013018124, COX) today announced that the U.S. Food and Drug Administration (FDA) has set a PDUFA date of August 24, 2017 for its decision on the New Drug Application (NDA) for latanoprostene bunod ophthalmic solution, 0.024%. Latanoprostene bunod is an intraocular pressure (IOP) lowering single-agent eye drop dosed once daily, for patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

If approved, latanoprostene bunod would be the first nitric-oxide donating prostaglandin F2 $\alpha$  analog for ophthalmic use.

"This is an exciting development in our journey to bring this new treatment option to the more than 3 million<sup>1</sup> patients in the U.S. with open angle glaucoma and ocular hypertension, and address a significant unmet medical need," said Joseph C. Papa, Chairman and CEO of Valeant. "Valeant is committed to delivering therapies that make a difference in patients' lives, and our work on latanoprostene bunod is a strong example of that."

"If granted, the FDA's approval of latanoprostene bunod will allow for the introduction of the first truly novel medication for these patients in many years," said Michele Garufi, Chairman and CEO of Nicox. "Additionally, latanoprostene bunod would represent the first commercially available therapy to use our proprietary nitric oxide-donating R&D platform, which we will continue to apply in the development of future innovative ophthalmic compounds."

Latanoprostene bunod was licensed by Nicox to Bausch + Lomb.

## **About Latanoprostene Bunod**

Latanoprostene bunod ophthalmic solution, 0.024% is an IOP-lowering single-agent eye drop dosed once daily for patients with OAG or OHT. In the eye, latanoprostene bunod is metabolized to two moieties. The first, latanoprost acid, is an F2 $\alpha$  prostaglandin analog, while the second, butanediol mononitrate, releases nitric oxide, which activates the soluble guanylate cyclase-guanosine-3',5'-monophosphate signaling pathway. Latanoprostene bunod is believed to lower IOP by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes.

## **About Glaucoma**

Glaucoma is a group of eye diseases which can lead to the loss of peripheral vision and eventually total blindness. Glaucoma is frequently linked to abnormally high pressure in the eye (intraocular pressure, IOP), due to blockage or malfunction of the eye's drainage system. Abnormally high IOP does not cause any symptoms itself, however it can lead to optic nerve damage and vision loss over time if left untreated. Drug therapy is used to reduce IOP and therefore prevent further

vision loss, typically through either reducing aqueous humor production or by increasing the drainage of intraocular fluid by relaxing certain muscles in the eye. Several large trials have demonstrated that reducing IOP can prevent the progression of glaucoma in both early and late stages of the disease. A significant proportion of patients with elevated IOP require more than one medication to maintain their IOP within target levels, highlighting the need for more effective treatments.

### **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](http://www.valeant.com)

### **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. Our core businesses include over-the-counter supplements, eye care products, ophthalmic pharmaceuticals, contact lenses, lens care products, ophthalmic surgical devices and instruments. We develop, manufacture and market one of the most comprehensive product portfolios in our industry, which is available in more than 100 countries.

### **About Nicox**

Nicox S.A. (NYSE Euronext Paris: FR0013018124, COX) is an international ophthalmic R&D company utilizing innovative science to maintain vision and improve ocular health. By leveraging its proprietary expertise in nitric oxide donation and other technologies, the Company is developing an extensive portfolio of novel therapies that target multiple ophthalmic conditions, including glaucoma. Nicox currently has two products at the pre-approval stage with the U.S. Food and Drug Administration (FDA) and a promising pipeline including next-generation stand-alone nitric-oxide donors, with the potential to treat a range of ophthalmic indications. Nicox is headquartered in Sophia Antipolis, France, is listed on Euronext Paris (Compartment B: Mid Caps; Ticker symbol: COX) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes.

For more information on Nicox, its products or pipeline, please visit:

[www.nicox.com](http://www.nicox.com)

### **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 the management of Valeant and Nicox 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. Neither Valeant nor Nicox undertakes any 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.

<sup>1</sup>Glaucoma Facts and Stats. (2015, May 5). Retrieved from [www.glaucoma.org/glaucoma/glaucoma-facts-and-stats.php](http://www.glaucoma.org/glaucoma/glaucoma-facts-and-stats.php)

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<http://www.prnewswire.com/news-releases/bausch--lomb-and-nicox-announce-pdufa-date-for-no-vel-glaucoma-candidate-latanoprostene-bunod-300426306.html>

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