BAUSCH Health

Bausch + Lomb And Nicox Resubmit US New Drug Application For Novel Glaucoma Candidate Latanoprostene Bunod

February 27, 2017

LAVAL, Quebec and SOPHIA ANTIPOLIS, France, Feb. 27, 2017 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc.'s (NYSE: VRX and TSX: VRX) wholly owned subsidiary, Bausch + Lomb, and Nicox S.A. (NYSE Euronext Paris: COX) today announced the resubmission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval 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).

The data submitted in the NDA support latanoprostene bunod as the first nitric-oxide donating prostaglandin F2α analog for ophthalmic use.

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 F2α 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, eye health, neurology and

branded generics. More information about Valeant Pharmaceuticals International, Inc. 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. 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 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
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Forward-looking Statements

This press release contains forward-looking statements. 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.

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