BAUSCH + Health

Bausch + Lomb and Nicox Announce FDA Acceptance of New Drug Application for Novel Glaucoma Candidate VESNEO™ (latanoprostene bunod)

September 22, 2015

PDUFA date is July 21, 2016

LAVAL, Quebec and SOPHIA ANTIPOLIS, France, Sept. 22, 2015 /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 that the U.S. Food and Drug Administration (FDA) has accepted for review its New Drug Application (NDA) for *VESNEO*™ (latanoprostene bunod ophthalmic solution 0.024%), an intraocular pressure (IOP) lowering single-agent eye drop dosed once daily, for patients with open angle glaucoma or ocular hypertension. If approved, *VESNEO* will be the first nitric oxide donating prostaglandin receptor agonist available for the above indication.

Upon instillation in the eye, latanoprostene bunod is rapidly metabolized to two actives: latanoprost acid, a prostaglandin analog, and nitric oxide. Nitric oxide is an important physiological signaling molecule, which plays a key role in IOP regulation in healthy eyes. *VESNEO* is thought to increase aqueous humor outflow by acting on both the uveoscleral (non-conventional) pathway via latanoprost acid, and trabecular meshwork and Schlemm's canal (conventional pathway) via nitric oxide signaling.

VESNEO was licensed by Nicox to Bausch + Lomb.

"The acceptance for review of the *VESNEO NDA* by the FDA marks an important milestone in our effort to bring a new treatment to patients with open angle glaucoma and ocular hypertension," stated J. Michael Pearson , chairman and chief executive officer of Valeant. "It is also another illustration of how Valeant's robust pipeline continues to be filled by a commitment to innovation driven by significant R&D programs and partnerships focused on the needs of medical professionals and their patients around the world."

"If granted, the FDA's approval of *VESNEO* will clear the way for the first truly novel IOP-lowering medication in years," said Michele Garufi , chairman and CEO of Nicox. "Open angle glaucoma and ocular hypertension represent significant unmet medical needs. The clinical advancement of *VESNEO* is particularly gratifying as it validates the therapeutic and commercial potential of our proprietary nitric oxide-donating R&D platform, which we will continue to leverage in the development of additional innovative ophthalmic compounds."

The FDA has set an action date of July 21, 2016 to complete its review, as per the Prescription Drug User Fee Act (PDUFA).

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 usually 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. 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 Pharmaceuticals International, Inc.

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 disease, eye health, neurology and branded generics. More information about Valeant Pharmaceuticals International, Inc. can be found at 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 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 are available in more than 100 countries.

About Nicox

Nicox (Bloomberg: COX:FP, Reuters: NCOX.PA) is an international commercial-stage company focused on the ophthalmic market. With a heritage of innovative R&D, business development and marketing expertise, Nicox is building a diversified portfolio of ophthalmic products that can help people enhance their sight.

Nicox's advanced pipeline features VESNEO™ for the lowering of intra-ocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension, and for which a New Drug Application (NDA) was recently submitted to the FDA by the Company's licensee Valeant. Our pipeline also features AC-170, a pre-NDA candidate for the treatment of ocular itching associated with allergic conjunctivitis, as well as two pre-MAA candidates in Europe: AzaSite® for bacterial conjunctivitis and BromSite™ for pain and inflammation after cataract surgery. Beyond these late-stage candidates, Nicox is developing a pipeline of ophthalmology-focused candidates which utilize its proprietary nitric oxide (NO)-donating research platform. The Group operates directly in six countries, including the United States. It has proprietary commercial operations in Europe's five largest markets complemented by an expanding international network of distributors.

Nicox is headquartered in France and has more than 130 staff worldwide. It is listed on Euronext Paris (Category B: Mid Caps) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes. For more information on Nicox, its commercial products or pipeline, please visit www.nicox.com

.

Valeant Forward-looking Statements

This press release may contain forward-looking statements, including, but not limited to, statements regarding expected regulatory filings, commercialization plans, product potential, future investment in R&D programs and the related benefits and effects of such programs. Forward-looking statements may be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential,"

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 filed with the Securities and Exchange Commission ("SEC") and other risks and uncertainties detailed from time to time in the Company's filings with the SEC 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. 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.

Nicox Forward-looking Statement

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated in the forward-looking statements.

Risks factors which are likely to have a material effect on Nicox's business are presented in the 4th chapter of the << Document de reference, rapport financier annuel et rapport de gestion 2014 >> filed with the French Autorite des Marches Financiers (AMF) on April 10, 2015 and available on Nicox' website (
www.nicox.com
) and on the AMF's website (
www.amf-france.org
).

®/™ are trademarks of Bausch & Lomb Incorporated and its affiliates.
© 2015 Bausch & Lomb Incorporated.

Contacts:

Valeant Pharmaceuticals International, Inc.
Investors:
Laurie Little
SVP, Investor Relations
(949) 461-6002 or
laurie.little@valeant.com

Financial Media:
Renee E. Soto / Meghan Gavigan
Sard Verbinnen & Co.
212-687-8080or
rsoto@sardverb.com

Kristy Marks
Public Relations Product Manager, Bausch + Lomb
(585) 338-8095 or
kristy.marks@bausch.com

Nicox S.A.
Gavin Spencer Executive Vice President Corporate Development, Nicox
+33 (0)4 97 24 53 00 or
communications@nicox.com

Media Relations in the United States
Argot Partners, Eliza Schleifstein
(917)-763-8106 or
eliza@argotpartners.com

Media Relations in the United Kingdom
Jonathan Birt
+44 7860 361 746 or
jonathan.birt@ymail.com

Media Relations in France
NewCap, Nicolas Merigeau
+33 (0)1 44 71 94 98 or
nicox@newcap.fr

Investor Relations in the United States
Argot Partners, Melissa Forst
(212)-600-1902 or
melissa@argotpartners.com

Investor Relations in Europe
NewCap, Julien Perez and Valentine Brouchot
+33 (0)1 44 71 94 94 or
nicox@newcap.fr

To view the original version on PR Newswire, visit:
http://www.prnewswire.com/news-releases/bausch--lomb-and-nicox-announce-fda-acceptance-of-new-drug-application-for-novel-glaucoma-candidate-vesneo-latanoprostene-bunod-300146826.html
SOURCE Valeant Pharmaceuticals International, Inc.

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
848-264-0934

LEGAL NOTICE PRIVACY POLICY

EMAIL ALERTS EMAIL PAGE RSS FEED

Use of this site signifies your agreement to the Legal Notice and Privacy Policy.
©2026 Bausch Health Companies Inc. All rights reserved. MTB.0230.USA.18 V2.0

CALIFORNIA RESIDENTS: DO NOT SELL MY PERSONAL INFORMATION

Powered by SITECORE