

# Bausch + Lomb and Nicox's Glaucoma Candidate VESNEO™ (latanoprostene bunod) Meets Primary Endpoint in Phase 3 Studies

September 25, 2014

**Expect to file in the U.S. in First Half of Q2 2015**

**Expect to launch in the U.S. in First Half of 2016**

**Peak US sales ~\$500 million+, Peak Global Sales ~\$1 billion+**

LAVAL, QUEBEC and SOPHIA ANTIPOLIS, FRANCE – September 25, 2014 - 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 positive top-line results from the pivotal Phase 3 studies conducted with VESNEO™ (latanoprostene bunod; previously known as BOL-303259-X and NCX 116) for the reduction of intraocular pressure (IOP) in patients with glaucoma or ocular hypertension. VESNEO™ is a novel nitric oxide-donating prostaglandin F2-alpha analog licensed by Nicox to Bausch + Lomb. These studies met their primary endpoint and showed positive results on a number of secondary endpoints. This product has peak sales potential of ~\$500 million+ in the U.S. alone and ~\$1 billion+ globally. These positive results follow three successful approvals from the Food and Drug Administration (FDA) in the last year, including approvals for Luzu™ (luliconazole) Cream Jublia® (efinaconazole 10% topical solution) and Retin-A Micro (tretinoin) Gel microsphere 0.08%, and further validate our unique output-driven approach to R&D.

"The results of these studies confirm the results observed in the phase 2b trials. VESNEO™ effectively lowered IOP, which is critical in the management of glaucoma or ocular hypertension, and was well-tolerated" said Robert N. Weinreb, M.D., chairman & distinguished professor of Ophthalmology and director, Hamilton Glaucoma Center at the University of California San Diego.

"Valeant is committed to innovation in healthcare and continues to fund important R&D programs that will bring benefits to physicians and the patients they serve," stated J. Michael Pearson, chairman and chief executive officer, Valeant Pharmaceuticals International, Inc. "We are pleased with the Phase 3 program top line results and look forward to continuing to advance the VESNEO™ program as part of this commitment. We are proud of our R&D Team who have worked diligently over the past four years to bring this program to successful completion. We are pursuing development plans and programs for other priority markets around the world."

"VESNEO™ was discovered in our Research Laboratories in Milan and we are encouraged by these promising results from Bausch + Lomb's pivotal Phase 3 studies," said Michele Garufi, chairman and CEO of Nicox. "The success of this program thus far highlights the promise of nitric oxide donation in the treatment of serious ophthalmic conditions and we are delighted by Valeant's commitment to bringing a new treatment option to patients."

## **Phase 3 study design and top-line results**

The pivotal Phase 3 program includes two separate randomized, multicenter, double-masked, parallel-group clinical studies, APOLLO and LUNAR, designed to compare the efficacy and safety of VESNEO™ administered once daily (QD) against timolol maleate 0.5% administered twice daily (BID) in lowering IOP in patients with open-angle glaucoma or ocular hypertension. The primary endpoint of both studies, which include a combined total of 840 patients, was the reduction in mean IOP measured at specified time points during three months of treatment. The collection of patient safety data for a total of up to 12 months is still ongoing. The Phase 3 studies are pivotal for U.S. registration and are being conducted in North America and Europe. Additional information about the studies can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

The primary endpoint of non-inferiority to timolol maleate 0.5% was achieved in both Phase 3 studies. Additionally, VESNEO™ showed a reduction in mean IOP of 7.5 to 9.1 mmHg from baseline between 2 and 12 weeks of treatment in the two Phase 3 studies. This IOP effect was statistically superior ( $p < 0.05$ ) to timolol in both studies. VESNEO™ also showed positive results on a number of secondary endpoints. There were no significant safety findings in either study.

Bausch + Lomb expects to submit a new drug application to the FDA for the approval of VESNEO™ in mid-2015.

## **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 if left untreated. Drug therapy is used to reduce IOP and therefore prevent further vision loss, typically through 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 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, eye health, neurology and branded generics. More information about Valeant Pharmaceuticals International, Inc. 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 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 emerging international company focused on the ophthalmic market. With a heritage of innovative R&D, business development and commercial expertise, the Nicox team is building a diversified portfolio of therapies and diagnostic tools that can help people to enhance their sight. The Company's commercial portfolio and near-term pipeline already include several innovative diagnostic tests intended for eye care professionals, as well as a range of eye care products. Nicox's key proprietary asset in ophthalmology is VESNEO (latanoprostene bunod) (latanoprostene bunod), a novel compound based on Nicox's proprietary nitric oxide (NO)-donating R&D platform, currently in Phase 3 clinical development in collaboration with Bausch + Lomb for the potential treatment of glaucoma and ocular hypertension. Further NO-donors are under development, notably through partners.

Nicox is headquartered in France, with research capabilities in Italy, a growing commercial infrastructure in North America and in the major European markets and an expanding international presence through partners. Nicox S.A. is listed on Euronext Paris (Compartment B: Mid Caps). For more information on Nicox or its products please visit [www.nicox.com](http://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 référence, rapport financier annuel et rapport de gestion 2013 » filed with the French Autorité des Marchés Financiers (AMF) on April 2nd, 2014 and available on Nicox' website ([www.nicox.com](http://www.nicox.com)) and on the AMF's website ([www.amf-france.org](http://www.amf-france.org)).

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### **Contacts:**

#### **Valeant Pharmaceuticals International, Inc.**

Investors:

Laurie Little

SVP, Investor Relations

(949) 461-6002 or [laurie.little@valeant.com](mailto:laurie.little@valeant.com)

Financial Media:

Renee E. Soto/Meghan Gavigan

Sard Verbinnen & Co.

212-687-8080

[rsoto@sardverb.com](mailto:rsoto@sardverb.com) / [mgavigan@sardverb.com](mailto:mgavigan@sardverb.com)

Kristy Marks

Public Relations Product Manager, Bausch + Lomb

(585) 338-8095 or [kristy.marks@bausch.com](mailto: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](mailto:communications@nicox.com)

Jonathan Birt, on behalf of Nicox

+44 7860 361 746 | [jonathan.birt@ymail.com](mailto:jonathan.birt@ymail.com)

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