BAUSCH Health

Bausch + Lomb and Nicox Announce the Publication of Latanoprostene Bunod Ophthalmic Solution 0.024% Phase 3 Study Results in American Journal of Ophthalmology

July 06, 2016

Second Published Phase 3 Trial to Demonstrate Significantly Greater Efficacy vs. Timolol Maleate 0.5%

LAVAL, Quebec and SOPHIA ANTIPOLIS, France, July 6, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc.'s (NYSE: VRX and TSX: VRX) wholly owned subsidiary, Bausch + Lomb, a leading global eye health company, and Nicox S.A. (Euronext Paris: COX) today announced that the results of a Phase 3 study for latanoprostene bunod (LBN) ophthalmic solution 0.024% have been
published
in the *American Journal of Ophthalmology*. LBN 0.024% is an intraocular pressure (IOP) lowering single-agent eye drop dosed once daily for patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

In the eye, LBN 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–cyclic guanosine-3',5'-monophosphate signaling pathway. Latanoprostene bunod is thought to lower intraocular pressure by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes.

The results of this study, called LUNAR, demonstrated that LBN 0.024% administered once daily (QD) in the evening was not only non-inferior to timolol maleate 0.5% dosed twice daily (BID) in subjects with OAG or OHT over 3 months of treatment, but also provided significantly greater IOP reduction ($P \leq 0.025$) at all but the earliest time point evaluated.[1]

"This is the second phase 3 clinical trial published in which latanoprostene bunod has effectively lowered IOP," said Robert N. Weinreb, M.D., chairman & distinguished professor of Ophthalmology and director, Hamilton Glaucoma Center at the University of California San Diego. "If approved, this therapy would offer a new therapeutic alternative for physicians and their patients with open angle glaucoma or ocular hypertension."

A prospective, double-masked, parallel group, clinical trial, LUNAR compared the IOP lowering effect of LBN 0.024% with timolol maleate 0.5% in adults with OAG or OHT. Subjects from 46 clinical sites in the U.S. and Europe were randomized to administer LBN QD in the evening or timolol BID for 3 months. Intraocular pressure was measured at 9 time points (Week 2, Week 6 and Month 3; 8am, 12pm and 4pm each visit). The primary objective was to demonstrate non-inferiority to timolol, while the secondary objective was to demonstrate superiority.[2]

The results of this study showed that mean IOP was significantly lower in the LBN 0.024% group than in the timolol 0.05% group at all time points (range 17.7 - 18.7 mm Hg for LBN 0.024%; 18.8-19.6 mm Hg for timolol 0.5%; $P \leq 0.025$) except for at Week 2, 8am (19.2 mm Hg for LBN

0.024% vs 19.6 mm Hg for timolol 0.5%; *P*=0.216). These differences corresponded to a reduction from baseline ranging from 29.1% to 32.1% in the LBN 0.024% group and 25.2% to 28.7% in the timolol group.[3]

Adverse events, though uncommon, were slightly higher in the LBN group. They included conjunctival hyperemia, eye irritation, and eye pain and were mostly mild-to-moderate in severity.[4]

A second similarly designed study, published in the May issue of *Ophthalmology*, also demonstrated the efficacy of LBN 0.024% for IOP lowering. In this randomized, controlled, multicenter, double-masked, parallel-group, non-inferiority clinical study, called APOLLO, the primary efficacy end point was IOP in the study eye measured at the same 9 assessment time points as LUNAR. Results showed that the mean IOP in the study eye was significantly lower in the LBN 0.024% group (range, 17.8-18.7 mm Hg) than in the timolol 0.5% group (range, 19.1-19.8 mm Hg) at all 9 efficacy time points assessed.[5]

In July 2015, Bausch + Lomb submitted a New Drug Application (NDA) to the United States Food and Drug Administration (FDA). The FDA accepted its application and set an action date of July 21, 2016 to complete its review, as per the Prescription Drug User Fee Act (PDUFA). If approved, LBN will be the first nitric oxide donating prostaglandin F2α analog available for this indication.

About Glaucoma

Glaucoma is a group of eye diseases that 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

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

.

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 latanoprostene bunod for the lowering of intra-ocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension, for which a New Drug Application (NDA) was submitted to the FDA by the Company's licensee Bausch + Lomb, Valeant Pharmaceuticals International, Inc.'s, wholly owned subsidiary. The Company's pipeline also features AC-170, for which the FDA granted priority review for the NDA 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 next generation ophthalmology-focused candidates, which utilize its proprietary nitric oxide (NO)-donating research platform. The Group has operations in Europe and the United States.

Nicox is listed on Euronext Paris (Category B: Mid Caps) and is part of the Russell Global, 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 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.

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 2015 » filed with the French Autorité des Marchés Financiers (AMF) on April 15, 2016 and available on Nicox' website (
www.nicox.com
) and on the AMF's website (
www.amf-france.org
).

Contact Information:

Valeant Pharmaceuticals International, Inc.
Investors:
Laurie W. Little
laurie.little@valeant.com

or

Elif McDonald
elif.mcdonald@valeant.com

514-856-3855
877-281-6642 (toll free)

Media:
Renée Soto
or
Chris Kittredge/Jared Levy
Sard Verbinnen & Co.
212-687-8080

Bausch + Lomb
Kristy Marks
Sr. PR Product Manager, Bausch + Lomb
(908) 927-0683 or
kristy.marks@bausch.com

Teresa Panas
BioComm Network, on behalf of Bausch + Lomb
(973)-809-8590 or
tpanas@biocommnetwork.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

[1] Medeiros FA, Martin KR, Peace J, Sforzolini BS, et al. Comparison of Latanoprostene Bunod 0.024% and Timolol Maleate 0.5% in Open-Angle Glaucoma or Ocular Hypertension: The LUNAR Study. *Am J Ophthalmol* 2016 May 19 doi:10.101016/j.ajo.2016.05.012 [Epub ahead of print].

[2] Ibid.
[3] Ibid.
[4] Ibid.
[5] Weinreb RN, Scassellati Sforzolini B, Vittitow J, Liebmann J. Latanoprostene bunod 0.024% vs timolol maleate 0.5% in subjects with open-angle glaucoma or ocular hypertension: the APOLLO study. *Ophthalmology* 2016;123(5):965-73.

Logo -
http://photos.prnewswire.com/prnh/20160705/386355LOGO

To view the original version on PR Newswire, visit:
http://www.prnewswire.com/news-releases/bausch--lomb-and-nicox-announce-the-publication-of-latanoprostene-bunod-ophthalmic-solution-0024-phase-3-study-results-in-american-journal-of-ophthalmology-300294296.html

SOURCE Valeant Pharmaceuticals International, Inc.

908-569-3692