BAUSCH Health

Bausch + Lomb And Nicox Announce FDA Approval Of VYZULTA™ (latanoprostene Bunod Ophthalmic Solution), 0.024%

November 02, 2017

LAVAL, Quebec and SOPHIA ANTIPOLIS, France, Nov. 2, 2017 /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: FR0013018124, COX), an international ophthalmic company, today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for VYZULTA™ (latanoprostene bunod ophthalmic solution, 0.024%). VYZULTA, the first prostaglandin analog with one of its metabolites being nitric oxide (NO), is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.[1]

"With today's approval of VYZULTA, our customers and their patients with glaucoma now have a new treatment option that can help provide consistent and sustained IOP lowering, the only modifiable risk factor that can help slow down the progression of the disease," said Joseph C. Papa, chairman and CEO, Valeant. "We expect to make this new advancement available for those who suffer with glaucoma before the end of the year."

Following topical administration, VYZULTA, a once daily monotherapy with a dual mechanism of action, works by metabolizing into two moieties, latanoprost acid, which primarily works within the uveoscleral pathway to increase aqueous humor outflow, and butanediol mononitrate, which releases NO to increase outflow through the trabecular meshwork and Schlemm's canal. The most common ocular adverse events include conjunctival hyperemia, eye irritation, eye pain and instillation site pain. Increased pigmentation of the iris and periorbital tissue and growth of eyelashes can occur.

In glaucoma patients, damage to the trabecular meshwork, through which the majority of the aqueous humor passes, can lead to reduced drainage and as a result elevated IOP. Lowering IOP, even in patients with normal baseline levels, can delay, or even prevent damage to optic nerves, helping to reduce the risk of glaucomatous visual field loss.

"VYZULTA represents the first FDA-approved therapy developed through our proprietary NO-donating research platform," said Michele Garufi, chairman and CEO of Nicox. "We look forward to continuing to leverage our platform in the development of additional innovative ophthalmic compounds."

Preclinical studies have shown that NO plays a role in controlling IOP in normal eyes by increasing aqueous humor outflow through the trabecular meshwork and Schlemm's canal. Studies have also demonstrated that patients with glaucoma have reduced levels of NO signaling in their eyes, providing a rationale for the therapeutic value of NO-releasing molecules for patients with open-angle glaucoma or ocular hypertension.

"The safety and efficacy of VYZULTA has been well-established through multiple clinical studies, which have demonstrated positive results, including statistically significant differences in IOP

lowering compared to timolol and latanoprost," said Robert N. Weinreb, M.D., chairman and distinguished professor of Ophthalmology and director, Hamilton Glaucoma Center at the University of California San Diego. "As one molecule with a dual mechanism of action, VYZULTA™ provides a new treatment option that works to reduce IOP by increasing the outflow through both the trabecular meshwork and the uveoscleral pathways."

VYZULTA was licensed on a global basis to Bausch + Lomb from Nicox. As a result of this approval, Nicox will receive $17.5 million from Bausch + Lomb and will make a $15 million payment to Pfizer under a previous license agreement.

VYZULTA™ COMPREHENSIVE CLINICAL TRIALS

VYZULTA™ vs. Timolol Study: Non-Inferior & Superior to Timolol 0.5% (32% Mean Diurnal IOP Reduction)
The efficacy and safety of VYZULTA were evaluated in two randomized, multi-center, double-masked, parallel-group Phase 3 studies,
APOLLO
and
LUNAR
, comparing VYZULTA with timolol maleate ophthalmic solution 0.5% in subjects (N=831) with open-angle glaucoma or ocular hypertension. The primary objective of these studies was to demonstrate that the mean IOP reduction over 3 months of treatment with VYZULTA once daily (QD) in the evening was non-inferior to timolol 0.5% twice daily (BID). A secondary objective was to demonstrate the superiority of VYZULTA QD to timolol 0.5% BID. In both studies, VYZULTA met the primary efficacy endpoint. VYZULTA also demonstrated significantly greater IOP lowering than timolol 0.5% throughout the day at 3 months of treatment resulting in a reduction in mean diurnal IOP of 32% from baseline.[2,3,4] The most common ocular adverse events included conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%).[1] No unexpected safety concerns were raised as a result of any of the ocular sign assessments or vital sign measurements.[2,3]

VYZULTA™ vs. Latanoprost Study: Greater Mean IOP Reduction vs. Latanoprost
In the
Phase 2 VOYAGER study
, designed to identify the appropriate dose of VYZULTA for the reduction of IOP in addition to assessing safety and efficacy, 413 patients across 23 sites in the United States and Europe were randomized to receive either latanoprostene bunod (various concentrations) or Xalatan (latanoprost ophthalmic solution 0.005%) once a day in the evening for 28 days. Two of the four doses tested, including the FDA approved dose for VYZULTA (latanoprostene bunod ophthalmic solution), 0.024%, showed greater IOP reduction compared with Xalatan (latanoprost ophthalmic solution 0.005%), with the differences reaching 1.23 mm Hg (p=0.005) for VYZULTA. In addition, 68.7% of subjects treated with the FDA approved dose for VYZULTA (latanoprostene bunod ophthalmic solution), 0.024%, compared to 47.5% of subjects treated with Xalatan (latanoprost ophthalmic solution 0.005%), achieved a mean diurnal IOP ≤18 mm Hg (p<0.05).[5]

52-Week Safety Study: VYZULTA™ Reduced Mean IOP to 14.4 mm Hg in Subjects with Mean Low Baseline IOP of 19.6 mm Hg
The long-term safety of VYZULTA was assessed in
JUPITER
, a single-arm, multicenter, open-label Phase 3 study of one-year duration in Japanese subjects (N=130) with open-angle glaucoma (including normotensive, pigmentary and pseudoexfoliative glaucoma) or ocular hypertension. The efficacy endpoints of the JUPITER study were to evaluate the absolute IOP level and its reduction from baseline over a 52-week period. The mean baseline IOP in the study eye in the JUPITER study was 19.6 mm Hg. Treatment with VYZULTA resulted in a 22% mean reduction in IOP at Week 4 which was sustained through Week 52. Mean IOP was

14.4 mm Hg at Week 52 representing a 26% reduction from baseline in the study eye.[6] The most common ocular adverse events were conjunctival hyperemia, growth of eyelashes, iris pigmentation, blepharal pigmentation, eye irritation, and eye pain.

24-hour IOP Lowering Study: VYZULTA Demonstrated Better 24-hour IOP Control than Timolol

Another study,
CONSTELLATION
, compared the effect of VYZULTA dosed QD with timolol maleate ophthalmic solution 0.5% dosed BID in reducing IOP measured over a 24-hour period in subjects with open-angle glaucoma or ocular hypertension (N=25). The results of this randomized, single-center, open-label, 2-month crossover study demonstrated that VYZULTA lowered IOP over 24-hours, with a significantly greater nocturnal IOP reduction vs. timolol (p<0.004). The study also compared ocular perfusion pressure (OPP) in VYZULTA-treated subjects vs. timolol-treated subjects over a 24-hour period. VYZULTA improved daytime OPP vs. baseline (p<0.001) and nocturnal OPP vs. timolol 0.5% (p=0.01).[7]

Important Risk Information about VYZULTA

INDICATION AND USAGE

VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024% is a prostaglandin analog indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

- Increased pigmentation of the iris, periorbital tissue (eyelid), and eyelashes can occur. Iris pigmentation is likely to be permanent
- Gradual changes to eyelashes, including increased length, increased thickness, and number of eyelashes, may occur. These changes are usually reversible upon treatment discontinuation
- Most common ocular adverse reactions with incidence ≥2% are conjunctival hyperemia (6%), eye irritation (4%), eye pain (3%), and instillation site pain (2%)

Please see full prescribing information at
www.bausch.com/vyzulta
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About Nicox

Nicox S.A. (Euronext Paris: FR0013018124, COX) is an international ophthalmic company developing innovative solutions to help maintain vision and improve ocular health. By leveraging its proprietary expertise in NO donation and other technologies, the Company is developing an extensive portfolio of novel drug candidates that target multiple ophthalmic conditions, including glaucoma. Nicox currently has two products with approved NDAs, VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024%, licensed worldwide to Bausch + Lomb, and ZERVIATE™ (cetirizine ophthalmic solution) 0.24% licensed in the U.S. to Eyevance. In addition, its promising drug-candidate pipeline includes clinical stage assets based both on its proprietary NO-donating research platform and on the repurposing of existing molecules as well as a next-generation of stand-alone NO donors and exploratory novel NO-donating compounds with the potential to offer novel approaches to treat a range of ophthalmic conditions. 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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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. Its core businesses include over-the-counter supplements, eye care products, ophthalmic pharmaceuticals, contact lenses, lens care products, ophthalmic surgical devices and instruments. Bausch + Lomb develops, manufactures and markets one of the most comprehensive product portfolios in our industry, which is available in more than 100 countries.

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
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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.

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