Nicox exercises option to co-promote latanoprostene bunod with Bausch + Lomb in the US

August 8, 2014.

Sophia Antipolis, France.

Nicox S.A. (NYSE Euronext Paris: COX), the international ophthalmic company, today announced it has notified Bausch + Lomb (B+L), a division of Valeant Pharmaceuticals International, Inc., of its decision to exercise the option to co-promote latanoprostene bunod in the United States. Latanoprostene bunod is a nitric oxide (NO)-donating prostaglandin F2-alpha analog in phase 3 clinical development for the potential treatment of glaucoma and ocular hypertension which was licensed by Nicox to B+L in 2010.

B+L's phase 3 clinical program includes two studies, APOLLO and LUNAR, which are pivotal for registration in the US. Valeant recently said that it expects to receive top-line efficacy results from the first of these phase 3 studies in the third quarter of 2014, and from the second of these studies in the fourth quarter of 2014.[1] Valeant also said latanoprostene bunod could be launched in the US in 2016, pending approval from the US Food and Drug Administration (FDA).[1]

Under the licensing agreement signed in 2010, Nicox had an option to co-promote latanoprostene bunod products in the US. Nicox has notified B+L on August 6, 2014 of its decision to exercise this option. Nicox and B+L will now start negotiating a co-promotion agreement which will be signed at a later stage.

Latanoprostene bunod clinical program

In January 2013, B+L initiated a phase 3 clinical program for latanoprostene bunod. The initiation of this program started with two pivotal studies, APOLLO and LUNAR, for registration in the US. These studies are designed to compare the efficacy and safety of latanoprostene bunod administered once daily (QD) with timolol maleate 0.5% administered twice daily (BID) in lowering intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. The primary endpoint of both studies, which will include a combined total of approximately 800 patients, is the reduction in mean IOP measured at specified time points during three months of treatment.

In July 2013, B+L also initiated two studies in Japan, the second largest ophthalmic market in the world. JUPITER is a Phase 3 study enrolling approximately 130 subjects. Its purpose is to demonstrate the clinical safety of latanoprostene bunod 0.024% administrated once daily (QD) over a one-year treatment period. KRONUS is a Phase 1 study. Its primary objective is to evaluate the effect of latanoprostene bunod 0.024% administered once daily (QD) in reducing IOP measured over a 24-hour period in approximately 24 healthy male Japanese subjects. A confirmatory efficacy study is expected to be required for the Japanese registration of latanoprostene bunod.

Clinical and preclinical results obtained with latanoprostene bunod were presented by B+L at the Association for Research in Vision and Ophthalmology (ARVO) 2014 annual meeting in Orlando, Florida, including results from two clinical studies (CONSTELLATION and KRONUS) as well as some preclinical results on the effect of latanoprostene bunod on primary human trabecular meshwork cell contractility and underlying signaling pathways[2].

Nicox and B+L 2010 worldwide licensing agreement

In March 2010, B+L signed a worldwide licensing agreement with Nicox for latanoprostene bunod, and made an initial license payment of $10 million. B+L made an additional $10 million milestone payment in April 2012 following their decision to pursue further development of latanoprostene bunod. If certain regulatory, commercialization and sales milestones for latanoprostene bunod are met, Nicox stands to receive from B+L additional potential payments which, over time, could total $162.5 million. Nicox will also receive tiered double-digit royalties on the sales of latanoprostene bunod. If Nicox intends to promote an ophthalmic product in the US which is competitive with a B+L product, it must give B+L at least 12 months' notice before launch of that product and B+L then has the right to terminate the co-promotion agreement. Under the terms of the contract signed with Pfizer in August 2009, by which Nicox recovered the rights to latanoprostene bunod, Nicox has to pay Pfizer two undisclosed milestones payments (the first linked to regulatory approvals and the second to certain sales levels) as well as royalties on potential future sales.

Reference

1. See Valeant's 'Second Quarter 2014 Financial Results Conference Call' available on Valeant's website (http://ir.valeant.com/investor-relations/events-and-presentations/default.aspx)
2. The abstracts are available on the ARVO 2014 Online Planner (http://www.arvo.org/ARVO_2014_Mobile_App/).

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 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.

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 2, 2014 and available on Nicox's website (www.nicox.com) and on the AMF's website (www.amf-france.org).

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