U.S. FDA grants Priority Review for Nicox's AC-170 New Drug Application

FDA assigns Prescription Drug User Fee Act (PDUFA) goal date of October 18, 2016

June 21, 2016

Sophia Antipolis, France.

Nicox S.A. (Euronext Paris: FR0000074130, COX), the international ophthalmic company, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for AC-170, a novel, proprietary, cetirizine eye drop formulation, for the treatment of ocular itching associated with allergic conjunctivitis. The FDA also granted Priority Review and has assigned a Prescription Drug User Fee Act (PDUFA) goal date of October 18, 2016. Such date is indicative and contingent upon the information (including data) to be eventually provided by Nicox in the review period.

The October PDUFA date means Nicox now has decisions expected from the FDA on two of its compounds, AC-170 and latanoprostene bunod, by the end of 2016.

About AC-170

AC-170 is a novel formulation of cetirizine, the active ingredient in Zyrtec®[1], which has been developed for the first time for topical application in the eye for the treatment of ocular itching associated with allergic conjunctivitis. Cetirizine is a second generation antihistamine and mast cell stabilizer that binds competitively to histamine receptor sites to reduce swelling, itching and vasodilation. Cetirizine, as an approved oral drug, has a well-characterized systemic safety and efficacy profile with worldwide exposure representing more than 300 million patient-years[2-3-4]. AC-170 is covered by two granted U.S. patents expiring in 2030 and 2032.

Approval of the AC-170 NDA prior to 1st December 2016 will trigger a milestone payment of $35 million in Nicox shares to ex-Aciex shareholders or $10 million in Nicox shares if approval of the NDA is received after this date. AC-170 was developed by Aciex Therapeutics, Inc., which became a wholly-owned subsidiary of Nicox in October 2014 and was subsequently renamed Nicox Ophthalmics, Inc.

About allergic conjunctivitis

Allergic conjunctivitis occurs when an allergic reaction causes conjunctivitis. Conjunctivitis is an inflammation of the thin layer of tissue that lines the white surface of the eye and the inner surface of the eyelids. It is a common eye disease, especially in children, and may affect one or both eyes. The signs and symptoms may include eye redness, excessive watering, itchy burning eyes, discharge, blurred vision and increased

sensitivity to light. Conjunctivitis can be caused by a viral or bacterial infection, or can be the result of an allergic reaction.

It is estimated that more than 75 million people suffer from allergic conjunctivitis in the U.S.[5] and the prevalence ranges from 20% to 40%[6-7]. The annual U.S. market for the treatment of allergic conjunctivitis totals more than $800 million[8].

References

1. Zyrtec® is a trademark of UCB Pharma SA or GlaxoSmithKline.
2. Zyrtec® (Cross-discipline team-leader review).
3. Charlesworth, E.N., et al., Effect of cetirizine on mast cell-mediator release and cellular traffic during the cutaneous late-phase reaction. J Allergy Clin Immunol, 1989. 83(5): p. 905-12.
4. Levi-Schaffer, F. and R. Eliashar, Mast cell stabilizing properties of antihistamines. J Invest Dermatol, 2009. 129(11): p. 2549-51.
5. Global Data: Allergic Conjunctivitis Market Analysis, September 2014.
6. Nathan RA, Meltzer EO, et al. Prevalence of allergic rhinitis in the United States. J Allergy Clin Immunol 1997; 99(6)2:S808-S814.
7. Singh K, et al. Epidemiology of ocular and nasal allergy in the United States, 1988-1994. Journal of Allergy and Clinical Immunology; 2010. 126: 778–783.
8. IMS April 2014.

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 NDA was submitted to the FDA for the treatment of ocular itching associated with allergic conjunctivitis in April 2016, 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 CAC Healthcare, CAC Pharma & Bio and Next 150 indexes. For more information on Nicox, its commercial products or pipeline, please visit: www.nicox.com.

Analyst coverage

Bryan, Garnier & Co	Hugo Solvet	Paris, France
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Upcoming 2016 events

Financial and business conferences

June 28	SGCIB Healthcare & Biotechnology conference	Paris, France
July 12-13	Cantor Fitzgerald's 2nd Annual Healthcare conference	New York, US
September 11-13	Rodman & Renshaw Annual Healthcare conference	New York, US
October 5-6	Large & Midcap Event	Paris, France

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This press release contains certain forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these 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, which is available on Nicox's website (www.nicox.com).