Nicox receives Orphan Drug Designation from FDA for naproxcinod in Duchenne Muscular Dystrophy

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Sophia Antipolis, France

Nicox S.A. (Euronext Paris: COX) today announced that the United States Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for naproxcinod for the treatment of Duchenne Muscular Dystrophy (DMD). ODD is a status granted to drugs or biological products that treat rare diseases or conditions. The designation qualifies the sponsor of the drug for various development incentives, including a period of US marketing exclusivity upon marketing approval for the designated indication, potential tax credits and the waiver of certain fees[1].

Naproxcinod is a CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory candidate currently under evaluation by an undisclosed financial partner for potential clinical development in DMD[2]. Nicox has granted the undisclosed partner the exclusive right, should the results of the evaluation be satisfactory to the partner, to invest at the end of the evaluation period in naproxcinod and next generation nitric oxide (NO)-donors outside ophthalmology through an independent structure.

DMD is the most common and serious form of muscular dystrophy, a group of inherited diseases that cause muscle weakness and muscle loss. Naproxcinod already showed promising preclinical results in models of muscular dystrophy[3] and received a European Orphan Drug Designation for the treatment of DMD in October 2013.

References

1. For more information, please visit the FDA website: http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm.
2. See Nicox press release dated February 14, 2014.

3. Long-term treatment with naproxcinod significantly improves skeletal and cardiac disease phenotype in the mdx mouse model of dystrophy, Uaesoontrachoon K, Quinn JL, Tatem KS, Van der Meulen JH, Yu Q, Phadke A, Miller BK, Gordish-Dressman H, Ongini E, Miglietta D, Nagaraju K. *Hum Mol Genet.* 2014, 15; 23(12):3239-49.

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, we are building a diversified portfolio of ophthalmic products that can help people to enhance their sight.

Nicox's advanced pipeline features two pre-NDA candidates (Vesneo™ for glaucoma, partnered with Bausch + Lomb / Valeant and AC-170 for allergic conjunctivitis) as well as two pre-MAA candidates (AzaSite® for bacterial conjunctivitis and BromSite™ for pain and inflammation after cataract surgery). The Group operates directly in six countries, including the United States. It has proprietary commercial operations in Europe's five largest markets complemented by an expanding international network of distributors.

Nicox is headquartered in France and has more than 120 staff worldwide. It 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.

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; the '*Rapport semestriel financier et d'activité au 30 juin 2014*'; the 5th chapter of the '*Actualisation du Document de Référence 2013*' filed with the AMF on September 30, 2014; the Section B.1 of the '*Document E*' registered with the AMF on September 30, 2014; the 5th chapter of the '*Seconde Actualisation du Document de Référence 2013*' filed with the AMF on March 6, 2015 and the chapter 2 of the '*Note d'opération*' filed with the AMF on March 6, 2015 (visa n°15-080). All these documents are available on Nicox's website (www.nicox.com).

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