



NicOx submits naproxcinod MAA to the EMEA

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NicOx S.A. (NYSE Euronext Paris: COX) today announced that a Marketing Authorization Application (MAA) for naproxcinod has been submitted to the European Medicines Agency (EMA) through the centralized procedure, seeking approval for an indication for the relief of the signs and symptoms of osteoarthritis (OA). This follows the submission of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) in September that has recently been accepted for filing.

Naproxcinod is NicOx's lead investigational compound and the first in a new class of anti-inflammatory agents known as CINODs (Cyclooxygenase-Inhibiting Nitric Oxide Donators). The MAA file is supported by data from a large program of 34 clinical trials that involved more than 4,000 subjects treated with naproxcinod. The program evaluated the efficacy of naproxcinod in relieving signs and symptoms of osteoarthritis, as well as its safety, with a particular care given to its effect on blood pressure.

Philippe Serrano, Vice President Regulatory Affairs at NicOx, commented: "As planned, we have ended 2009 with the regulatory submissions for naproxcinod both in Europe, where we have just submitted an MAA through the centralized procedure, as well as the United States, where the FDA has recently accepted our NDA for filing."

Pascal Pfister, Chief Scientific Officer and Head of Research & Development at NicOx, added: "We are proud of all the achievements of our team during these last few years, including the completion of these important milestones on time. We will enter 2010 with confidence and are looking forward to working with the FDA and the EMA during their review of the naproxcinod data."

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is a pharmaceutical company focused on the research, development and future commercialization of drug candidates. NicOx is applying its proprietary nitric oxide-donating R&D platform to develop an internal portfolio of New Chemical Entities (NCEs) for the potential treatment of inflammatory, cardio-metabolic and ophthalmological diseases.

NicOx's lead investigational compound is naproxcinod, an NCE and a first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory drug candidate for the relief of the signs and symptoms of osteoarthritis. NicOx submitted a New Drug Application (NDA) for naproxcinod to the US Food and Drug Administration (FDA) in September 2009 and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in December 2009, following the successful completion of three pivotal phase 3 studies. The NDA for naproxcinod was accepted for filing by the FDA in November 2009 and the FDA has set a target date of July 24 2010, for the completion of its review. The FDA and the EMA will evaluate the data submitted. NicOx does not wish to make any claims in regard to naproxcinod's safety or efficacy prior to its potential approvals.

In addition to naproxcinod, NicOx's pipeline includes several nitric oxide-donating NCEs, which are in development internally and with partners, including Merck & Co., Inc., for the treatment of widespread eye diseases, cardiometabolic diseases, hypertension, respiratory disorders and dermatological disease.

NicOx S.A. is headquartered in France and is listed on Euronext Paris (Compartment B: Mid Caps).



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.

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For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of NicOx S.A. to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Document de Reference and its update filed with the AMF, which are available on the AMF website (<http://www.amf-france.org>) or on NicOx S.A.'s website (<http://www.nicox.com>).

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