

PRESS RELEASE



## NicOx announces EMEA validation of naproxcinod MAA submission

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January 22, 2010. Sophia Antipolis, France. [www.nicox.com](http://www.nicox.com)

**NicOx S.A.** (NYSE Euronext Paris: COX) today announced that the European Medicines Agency (EMA) has validated the Marketing Authorization Application (MAA) for naproxcinod, which was submitted through the centralized procedure in December 2009. NicOx is seeking approval for an indication for the relief of the signs and symptoms of primary osteoarthritis. This follows the acceptance for filing of a New Drug Application (NDA) by the US Food and Drug Administration (FDA) in November 2009.

*"The validation of our European application for naproxcinod is a key milestone that follows the acceptance of the NDA for filing in last November," commented **Philippe Serrano, Vice President Regulatory Affairs at NicOx.** "Both the EMA and the FDA are now reviewing the naproxcinod data and we will be pleased to work together with them throughout this process."*

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.

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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 MAA was validated by the EMA in January 2010. 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 and dermatological disease.

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

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*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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