

PRESS RELEASE



## NicOx announces FDA accepts naproxcinod NDA for filing

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November 18, 2009. Sophia Antipolis, France. [www.nicox.com](http://www.nicox.com)

**NicOx S.A.** (Euronext Paris: COX) today announced that it has received a filing communication from the U.S. Food and Drug Administration (FDA) stating that the New Drug Application (NDA) for naproxcinod is accepted for filing. NicOx submitted the NDA on September 24<sup>th</sup>, seeking approval for the relief of the signs and symptoms of osteoarthritis.

Based on the Prescription Drug User Fee Act (PDUFA), the FDA will complete its review 10 months after submission and has set an action date of July 24, 2010.

**Philippe Serrano, Vice President Regulatory Affairs at NicOx, declared:** *"We are very pleased to receive this filing communication from the FDA and it is thanks to a collective effort by our entire R&D Department, which has provided a high-quality application. We believe that when approved, naproxcinod could represent a valuable new treatment option for osteoarthritis patients."*

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 naproxcinod NDA file is supported by data from a large program of 34 clinical trials that involved more than 4,000 subjects. The program evaluated the efficacy of naproxcinod in relieving signs and symptoms of osteoarthritis, as well as its safety. During its safety evaluation, particular care was given to its effect on blood pressure. NicOx plans to submit a Marketing Authorization Application (MAA) for naproxcinod to the European Medicines Agency (EMA) by the end of 2009.

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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, following the successful completion of three pivotal phase 3 studies. The FDA stated the application was sufficiently complete to permit a substantive review and that the application is considered filed 60 days after reception of the dossier in accordance with 21 CFR 314.101(a). The FDA 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 approval. The submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) is planned for Q4 2009.

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 the Euronext Paris Stock Exchange (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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