



## NicOx announces FDA Advisory Committee to discuss naproxcinod on May 12

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March 8, 2010. Sophia Antipolis, France. [www.nicox.com](http://www.nicox.com)

**NicOx S.A.** (NYSE Euronext Paris: COX) today announces that on Wednesday, May 12, 2010, the US Food and Drug Administration (FDA) plans to hold a meeting of the Arthritis Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss the New Drug Application (NDA) for naproxcinod.

NicOx submitted an NDA for naproxcinod to the FDA in September 2009, seeking approval for an indication for the relief of the signs and symptoms of osteoarthritis (OA). Based on the Prescription Drug User Fee Act (PDUFA), the FDA aims to complete its review 10 months after submission and has set an action date of July 24, 2010.

*"We believe naproxcinod could become an important treatment option for patients with osteoarthritis and the planned advisory committee meeting represents a very important milestone for NicOx,"* stated **Michele Garufi, Chairman and CEO of NicOx**. *"We look forward to discussing the efficacy and safety data for naproxcinod with the members of the Arthritis Drugs and the Drug Safety and Risk Management Advisory Committees."*

The Arthritis Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee are independent panels of experts, which provide advice and recommendations to the FDA during public meetings. FDA regulations indicate that although the FDA will consider the recommendation of the panel, the final decision regarding the approval of an investigational drug product is made by the FDA. The meeting will take place at the Hilton Washington DC/Silver Spring (8727 Colesville Road, Silver Spring, Maryland, USA). Information can be found on the Office of the Federal Register website ([www.federalregister.gov](http://www.federalregister.gov)) and the US Government Printing Office Access website ([www.gpoaccess.gov/fr/index.html](http://www.gpoaccess.gov/fr/index.html)).

Naproxcinod is the first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory drug-candidate developed for the relief of the signs and symptoms of OA, which is currently under review by regulatory authorities. NicOx submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in December 2009.

### About osteoarthritis

Osteoarthritis (OA), the most common type of arthritis, is a widespread degenerative disease which affects the joints and causes moderate to severe chronic pain. OA mainly occurs in the weight-bearing joints of the hips and knees and is associated with the breakdown of cartilage, a material which covers the ends of bones in normal joints. OA is most commonly seen in older people, especially women, and its exact cause is unknown, although heredity factors, previous joint damage and obesity appear to play a role. According to a Datamonitor estimate published in 2006, approximately 33 million people suffer from OA in the United States and approximately 39 million people in the five key European markets (United Kingdom, Germany, Italy, France and Spain). Symptomatic treatments commonly used by OA patients include traditional non-steroidal anti-inflammatory drugs (NSAIDs) and COX-2 inhibitors.

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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 Molecular Entities (NME) for the potential treatment of inflammatory, cardio-metabolic and ophthalmological diseases.

NicOx's lead investigational compound is naproxcinod, an NME and a first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory drug candidate developed for the relief of the signs and symptoms of OA, which is currently under review by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). 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 NMEs, which are in development internally and with partners, including Merck & Co., Inc. and Bausch + Lomb, for the treatment of hypertension, cardiometabolic diseases, widespread eye diseases 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.*

*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 filed with the AMF, which is 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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