

PRESS RELEASE



NicOx submits New Drug Application (NDA) for naproxcinod to the US FDA

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NicOx S.A. (NYSE Euronext Paris: COX) today announced that a New Drug Application (NDA) for naproxcinod has been submitted to the United States Food and Drug Administration (FDA), seeking approval for an indication for the relief of the signs and symptoms of osteoarthritis (OA). The NDA file contains data from three large pivotal phase 3 studies, all of which met their co-primary efficacy endpoints. NicOx plans to submit a Marketing Authorization Application (MAA) for naproxcinod to the European Medicines Agency (EMA) in Q4 2009.

Michele Garufi, Chairman and CEO of NicOx, declared: *"The submission of a New Drug Application is a tremendous achievement for any company and represents a particularly important milestone for NicOx. This accomplishment represents another major step in NicOx' planned transformation into a self-sustainable pharmaceutical company, able to make significant contributions to the successful commercialization of naproxcinod. To achieve this key corporate goal, we continue to focus on building NicOx' future commercial operations in the US."*

About naproxcinod

Naproxcinod is NicOx' lead compound and the first in a new class of anti-inflammatory agents known as CINODs (Cyclooxygenase-Inhibiting Nitric Oxide Donators), for which NicOx is seeking approval for an indication for the relief of the signs and symptoms of osteoarthritis.

The phase 3 clinical program for naproxcinod consisted of three large pivotal trials that enrolled more than 2,700 patients with OA of the knee and hip, the 301, 302 and 303 studies. All three studies met their three standard co-primary efficacy endpoints (the WOMAC™ pain subscale, the WOMAC™ function subscale and subject's overall rating of the disease status).

The phase 3 program also specifically assessed naproxcinod's blood pressure profile, through the collection of Office Blood Pressure Measurements (OBPMs) in a rigorous and standardized manner as a pre-specified secondary endpoint. Moreover, NicOx conducted three randomized, controlled clinical pharmacology studies in a total of 548 subjects, which were specifically designed to characterize naproxcinod's 24-hour blood pressure profile using Ambulatory Blood Pressure Monitoring (ABPM).

The safety database for the naproxcinod NDA submission includes over 6,700 patients, of which more than 4,000 were exposed to naproxcinod. NicOx believes that the data from the clinical studies for naproxcinod show that it is effective, safe and well tolerated.

Pascal Pfister, Chief Scientific Officer and Head of Research & Development at NicOx, added: *"To our knowledge, naproxcinod is the first New Chemical Entity anti-inflammatory to be submitted to the FDA for OA since the withdrawal of the COX-2 inhibitors rofecoxib and valdecoxib and we believe it could become an important treatment option for patients with OA. We would like to congratulate our whole Research & Development department on the submission of this high quality NDA, which includes extensive data on naproxcinod's efficacy, safety and tolerability, collected in more than 4,000 patients. We look forward to submitting a Marketing Authorization Application to the European authorities within the end of the year."*

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 osteoarthritis 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.

NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is a product-driven biopharmaceutical company dedicated to the development and future commercialization of investigational drugs for unmet medical needs. NicOx is applying its proprietary nitric oxide-donating technology to develop an internal portfolio of New Chemical Entities (NCEs) in the therapeutic areas of inflammatory and cardio-metabolic disease.

NicOx' lead product is naproxcinod, a proprietary NCE and a first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory agent 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 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.

Beyond naproxcinod, NicOx has a pipeline containing multiple nitric oxide-donating NCEs, which are in development internally and with partners, including Merck & Co., Inc., for the treatment of prevalent and underserved diseases, such as atherosclerosis, hypertension, widespread eye diseases and respiratory conditions.

NicOx S.A. is headquartered in France and is listed on the NYSE 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.

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 Référence 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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