



## PRESS RELEASE

# NicOx and Ferrer enter into option agreement for naproxcinod

**Leading Spanish pharmaceutical group Ferrer Grupo granted option on co-marketing rights for NicOx's naproxcinod in Spain and Germany, and on exclusive marketing rights in Greece and Portugal.**

March 18, 2011. Sophia Antipolis, France. [www.nicox.com](http://www.nicox.com)

**NicOx S.A.** (NYSE Euronext Paris: COX) and **Grupo Ferrer Internacional S.A.**, a subsidiary of Ferrer Grupo, today announced the signature of an option agreement for NicOx's osteoarthritis candidate naproxcinod. Naproxcinod has not been authorized to date for marketing in Europe.

Under the terms of the agreement, Ferrer has been granted an option which it can exercise following the potential approval of naproxcinod in Europe. The option is to take exclusive distribution rights for naproxcinod in Greece and Portugal and co-marketing rights in Spain and Germany. NicOx retains the right to enter into co-marketing agreements with third parties in Spain and Germany. NicOx retains full rights to naproxcinod in all other territories.

This agreement should not be interpreted as giving any indication about the likelihood or timing of any approval for naproxcinod in Europe. Ferrer may decide not to exercise its option even if naproxcinod is approved. Ferrer's option will lapse if European approval is significantly delayed or is subject to additional studies which NicOx does not wish to undertake.

**Michele Garufi, CEO of NicOx**, commented: *"Ferrer and NicOx have been partners for a number of years in the dermatology field, and we are pleased to sign this new agreement. With a strong marketing track record and a significant commercial presence, particularly in Spain, Ferrer would be an excellent partner for naproxcinod and we look forward to working with them through the regulatory process."*

**Jorge Ramentol, CEO of Ferrer**, said: *"Osteoarthritis is a debilitating condition, which affected more than 35 million people in the five major European markets in 2009, including 4.8 million in Spain<sup>(1)</sup>. If approved, we believe naproxcinod could offer a valuable treatment option for osteoarthritis sufferers and we are enthusiastic about working with NicOx."*

Naproxcinod is currently under review by the European Medicines Agency (EMA). A Marketing Authorization Application (MAA) was submitted by NicOx through the centralized procedure in December 2009. The Committee for Medicinal Products for Human Use (CHMP) opinion on whether to approve naproxcinod is expected by mid-2011.

If Ferrer exercises the option under this agreement, NicOx could receive potential regulatory and commercial milestones from Ferrer of up to €7 million. NicOx would supply naproxcinod capsules to Ferrer at an agreed transfer price which would result in a financial return to NicOx equivalent to a royalty. NicOx has agreements for the manufacture and supply of naproxcinod active pharmaceutical ingredient (API), and capsules with DSM and Capsugel, respectively.

NicOx submitted a New Drug Application (NDA) for naproxcinod to the U.S. Food and Drug Administration (FDA) and received a Complete Response Letter in July 2010 stating that the FDA did not approve naproxcinod. NicOx is planning to appeal the FDA decision on naproxcinod under the FDA's Formal Dispute Resolution process.

### About naproxcinod

Naproxcinod is a New Molecular Entity (NME) and a first-in-class CINOD (Cyclooxygenase-Inhibiting Nitric Oxide-Donating) anti-inflammatory candidate developed by NicOx for the relief of the signs and symptoms of osteoarthritis. A large clinical program of 37 studies was conducted for naproxcinod with more than 6,500 patients. The phase 3 program comprised three large pivotal trials which achieved highly statistically significant results on all three co-primary efficacy endpoints. Naproxcinod's safety was also carefully assessed, with more than 4,000 patients exposed to naproxcinod and a safety database exceeding the threshold set by the relevant ICH guidelines. Overall, the general safety profile of naproxcinod appeared to be consistent with that of the non steroidal anti-inflammatory drug (NSAID) class.

## 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 December 2009, OA is estimated to have afflicted over 81 million people in 2009 in the seven major markets (US, Japan, France, Germany, Italy, Spain and the UK). Symptomatic treatments commonly used by OA patients include traditional non-steroidal anti-inflammatory drugs (NSAIDs) and COX-2 inhibitors.

<sup>(1)</sup> *Stakeholder Insight: Osteoarthritis*, Datamonitor, December 2009.

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## About NicOx

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

NicOx's lead investigational compound is naproxcinod, an NME in development for the relief of the signs and symptoms of osteoarthritis. In addition to naproxcinod, NicOx's pipeline includes several nitric oxide-donating NMEs, which are in development internally and with partners, including Merck (known as MSD outside the United States and Canada) and Bausch + Lomb, for the treatment of select cardiovascular indications, eye diseases and dermatological diseases.

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



## About Ferrer

Ferrer is a privately held European R&D-based pharmaco-chemical and medical device company headquartered in Barcelona, Spain. Ferrer operates in over 60 countries with the overall aim of improving people's health and quality of life. Based on its policy of continuous expansion throughout the world, Ferrer commercialises products in more than 90 countries, with direct presence in Southern and Central Europe and in all of Latin America and an extensive commercial experience in Africa, the Middle East and Far East. For more information on Ferrer visit [www.ferrergrupo.com](http://www.ferrergrupo.com).

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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.**

Risks factors which are likely to have a material effect on NicOx's business are presented in the 4<sup>th</sup> chapter of the « *Document de référence, rapport financier annuel et rapport de gestion 2010* » filed with the French Autorité des Marchés Financiers (AMF) on February 25, 2011 and available on NicOx's website ([www.nicox.com](http://www.nicox.com)) and on the AMF's website ([www.amf-france.org](http://www.amf-france.org)).

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