



PRESS RELEASE

## NicOx presents phase 3 quality of life data for naproxcinod at ISPOR

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**NicOx S.A.** (NYSE Euronext Paris: COX) today announced that quality of life (QoL) and utility results from the first phase 3 study for naproxcinod were presented yesterday at the International Society For Pharmacoeconomics and Outcomes Research (ISPOR) Annual International Meeting in Orlando, Florida. Naproxcinod is a novel Cyclooxygenase-Inhibiting Nitric Oxide Donating (CINOD) anti-inflammatory agent, which completed a phase 3 clinical program in 2008 in patients with osteoarthritis (OA).

The poster entitled 'Utility and Quality of Life of Patients with Osteoarthritis and Changes after Treatment with Naproxcinod' included analyses of data collected from the first phase 3 trial (the 301 study). QoL and utility studies are performed to determine the overall impact of investigational drugs on subjects' health and disease burden, as well as to help determine cost-effectiveness compared to other treatment options.

**Pascal Pfister, Chief Scientific Officer and Head of R&D at NicOx**, commented: *"We were very pleased to present quality of life and utility data for naproxcinod for the first time at the ISPOR Annual International Meeting, which is the leading health economics congress. The positive differences seen with the higher dose of naproxcinod, compared to the standard dose of naproxen, may be explained by a different side-effect profile and its neutral blood pressure effect. We look forward to presenting the utility and quality of life data from the full phase 3 program before the end of 2009."*

### Quality of life results

The 301 study enrolled 918 patients with OA of the knee (for details of the study design and co-primary efficacy endpoints see the NicOx press releases of June 13, 2008 and November 12, 2007). The QoL data were collected with the Short Form 36 (SF36®, see NOTE 1) at baseline and after 13 weeks of treatment with naproxcinod 750 mg bid, naproxcinod 375 mg bid, naproxen 500 mg bid or placebo. All SF36® subscales except mental health showed a significant change from baseline in all four treatment groups and were correlated with changes in the WOMAC™ indices ( $p < 0.001$ ). The change in the three active groups was significantly better than placebo for pain and physical function ( $p < 0.05$ ), representing a clinically relevant improvement in terms of physical health.

Although no significant difference was observed between active treatments in the overall population, the higher dose of naproxcinod (750 mg bid) showed a trend for greater changes from baseline than naproxen 500 mg bid ( $p < 0.07$ ). This difference was statistically significant in the important sub-group of hypertensive patients ( $p < 0.01$ ).

### Utility results

The SF36® questionnaires were also analyzed to give utility scores (SF6D®, see NOTE 2). All groups showed a significant improvement in the utility score after 13 weeks of treatment, with a significantly superior improvement for all active compounds compared to placebo ( $p < 0.01$ ). There was no significant difference among the active treatments in the overall population, although the largest utility changes from baseline were observed for naproxcinod 750 mg bid in the sub-groups of patients with hypertension, obesity and diabetes. The utility change from baseline with naproxcinod 750 mg bid was statistically significantly larger than naproxen 500 mg bid in the hypertensive sub-group of patients ( $p < 0.05$ ).

Likewise, in the patients who had the most severe pain at baseline (on the WOMAC™ scale), the higher dose of naproxcinod provided a trend for a larger utility improvement compared to the other treatment groups.

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**NOTE 1:** The Short Form 36 (SF36®) is a widely used 36-question form designed to assess the health-related quality of life of patients according to eight subscales: bodily pain, role physical, physical function and general health (these four subscales can be summarized by the physical summary score) as well as vitality, role emotional, mental health and social function (which can be summarized by the mental summary score).

**NOTE 2:** The SF6D® is a utility score derived from the SF36® form. Utility is defined as the preference patients have for given states of health with a value of 0 for death and 1 for complete health. Utility scores reflect preferences for the whole health and thus integrate the effects of efficacy as well as adverse events.

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**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.

Resources are focused on the development and pre-commercialization activities for naproxinod, a proprietary NCE and a Cyclooxygenase-Inhibiting Nitric Oxide-Donating (CINOD) anti-inflammatory agent for the treatment of the signs and symptoms of osteoarthritis. Naproxinod has completed three pivotal phase 3 studies with positive results and the submission of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) is projected for mid-2009.

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

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 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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