

NicOx: additional 24-hour blood pressure results for naproxcinod presented at the European Meeting on Hypertension

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NicOx S.A. (NYSE Euronext Paris: COX) today announced that additional results from the 111 Ambulatory Blood Pressure Monitoring (ABPM) study for naproxcinod were presented on Saturday, June 13, at the European Meeting on Hypertension (annual meeting of the European Society of Hypertension, ESH) in Milan, Italy, by Professor Raymond Townsend MD, from the University of Pennsylvania Hospital, Philadelphia. Naproxcinod is an investigational drug and the first-in-class Cyclooxygenase-Inhibiting Nitric Oxide Donating (CINOD) anti-inflammatory agent, which is in preparation for regulatory submissions in the US and Europe for the relief of the signs and symptoms of osteoarthritis (OA).

The oral presentation, entitled 'A 12-Week, Double-Blind, Randomized, Forced Titration, Parallel-group Study to Assess the Effects of Naproxcinod and Naproxen on Arterial Blood Pressure as Measured by ABPM in Osteoarthritis Patients with Controlled Essential Hypertension', included further important details of the mean 24-hour systolic blood pressure (SBP) changes from baseline, as well as 24-hour SBP curves for all the naproxcinod and naproxen doses.

Raymond Townsend MD, Professor of Medicine and Director of the Hypertension Program at the Hospital of the University of Pennsylvania, Philadelphia, declared: "Treating hypertensive patients who suffer from osteoarthritis-related pain raises important issues, due to the risk of blood pressure destabilization not uncommonly seen with existing treatments, particularly traditional NSAIDs. The 111 study clearly illustrates naproxcinod's favorable blood pressure profile, likely due to its donation of nitric oxide, which has a well known role as a modulator of vascular tone."

In the study, 24-hour blood pressure monitoring was conducted at baseline and at the end of each three-week dose escalation, using an FDA validated, ABPM device. Positive top-line results for the primary ABPM parameter were presented in late 2008 (see the press release of November 4).

The additional results presented on Saturday included the mean changes from baseline at each visit to the treatment centers (i.e. at the end of week 3, 6 and 9). These showed that the naproxcinod-treated patients saw their mean 24-hour SBP decrease from baseline following each dose escalation (i.e. at 3, 6 and 9 weeks). Likewise, an increase from baseline was consistently observed in the naproxen group. The greatest difference between the treatments was observed for the 750 mg bid naproxcinod dose compared to the 500 mg bid naproxen dose.

Furthermore, the presentation also included 24-hour SBP curves, showing that both therapeutic doses of naproxcinod (375 and 750 mg bid) had lower SBP hourly means than the two corresponding doses of naproxen (250 and 500 mg bid) at all time points, confirming naproxcinod's favorable blood pressure profile in the sensitive group of patients with controlled hypertension.

COX-2 selective inhibitors and traditional non-steroidal anti-inflammatory drugs (NSAIDs), such as naproxen, have been shown to destabilize blood pressure control in patients with previously controlled hypertension.

Jacques Djian MD, Cardiologist and Vice-President of Exploratory Development and Translational Medicine at NicOx, commented: "We were very pleased to present these key data at the European Meeting on Hypertension, which is a major worldwide congress attended by renowned hypertension specialists. The scientific exchange was very productive and has strengthened our confidence in naproxcinod's therapeutic potential. We look forward to presenting further analyses from our pharmacological studies for naproxcinod, using the gold standard ABPM technique, at future congresses."

In addition, a poster on naproxcinod preclinical results entitled 'The CINOD Naproxcinod Reduces Blood Pressure and Improves Vascular Relaxation in Spontaneously Hypertensive Rats' (poster number 915) was presented yesterday by NicOx' researchers.

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 naproxcinod, a proprietary NCE and the first-in-class Cyclooxygenase-Inhibiting Nitric Oxide-Donating (CINOD) anti-inflammatory agent for the relief of the signs and symptoms of osteoarthritis. Naproxcinod 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 naproxcinod, 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 and 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 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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