

PRESS RELEASE

NicOx presents NCX 6560 phase 1b results at AHA

November 18, 2010. Sophia Antipolis, France. www.nicox.com

NicOx S.A. (NYSE Euronext Paris: COX) today announced that Dr. Jacques Djian, Vice President of Exploratory Development and Translational Medicine at NicOx, recently presented results from the phase 1b first-in-man study for NCX 6560 in an oral session of the American Heart Association (AHA) 2010 Scientific Sessions being held in Chicago, Illinois. NCX 6560 is an innovative nitric oxide (NO)-donating New Molecular Entity (NME) targeting patients with Acute Coronary Syndrome (ACS). The abstract of Dr. Djian's presentation has also been published in a supplement of *Circulation*¹ and is available on the journal's website (http://circ.ahajournals.org).

The oral presentation of Dr. Djian included further details of the phase 1b study results disclosed in November 2009 (see NicOx press release dated November 13, 2009). In this two-week study, NCX 6560, an NO-donating atorvastatin, appeared safe and well tolerated. A dose-related LDL-cholesterol decrease was observed, with the highest tested dose of NCX 6560 (144 mg) reaching a 57% reduction after two weeks of treatment. No significant increase in liver enzymes was observed, even at the highest dose, which was not different from atorvastatin 40 mg. Interestingly, NCX 6560 48 mg had the same lipid-lowering effects as atorvastatin 40 mg despite a lower exposure to atorvastatin and its active metabolites.

NO donation from NCX 6560 is expected to enhance the pleiotropic effects of statins outside of lipid lowering. Preclinical studies have shown that NCX 6560 demonstrated superior anti-thrombotic and anti-inflammatory properties, and greater effects on endothelial function than an equivalent dose of atorvastatin. Preclinical results suggesting promising anti-inflammatory and anti-atherogenic effects were also presented during the AHA 2010 Scientific Sessions². NicOx is currently seeking partners to advance the clinical development of NCX 6560.

- ¹ Djian JP, Maucci R, Guilmin L, Ferreira T, Pfister P, Abstract 14267: NCX 6560, a Novel Nitric Oxide Donating Atorvastatin With a Promising Safety and Efficacy Profile: A Randomised, Double Blind Placebo and Active Control Study, *Circulation* 2010, 122, A14267.
- ² Momi S, Falcinelli E, Alberti FP, Monopoli A, Miglietta D, Ongini E, Gresele P, Abstract 15758: Anti-Inflammatory and Anti-Atherogenic Activities of NCX 6560, a Nitric Oxide (NO)-Donating Statin, in Hypercholesterolemic Mice, *Circulation* 2010, 122: A15758.

Risks factors which are likely to have a material effect on NicOx's business are presented in the 4th chapter of the *« Document de référence, rapport financier annuel et rapport de gestion 2009 »* filed with the French *Autorité des Marchés Financiers* (AMF) on March 5, 2010 and available on NicOx's website (<u>www.nicox.com</u>) and on the AMF's website (<u>www.amf-france.org</u>).

The Company notably draws the investors' attention to the following risk factors:

- Risques liés à la dépendance de la Société à l'égard du naproxcinod (Risks related to the Company's dependence on the success of its lead product naproxcinod)
- Risques commerciaux et développements cliniques (Clinical developments and commercial risk)

- Risques liés aux contraintes réglementaires et à la lenteur des procédures d'approbation (Risks linked to regulatory constraints and slow approval procedures)
- Manque de capacités dans les domaines de la vente et du marketing (Lack of sales and marketing capabilities)
- Incertitude relative aux prix des médicaments et aux régimes de remboursement, ainsi qu'en matière de réforme des régimes d'assurance maladie (Uncertainty on drug pricing and reimbursement policies and on the reforms of the health insurance systems)

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, cardiometabolic 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

NicOx S.A.,

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osteoarthritis (OA). In July 2010, the Food and Drug Administration (FDA) provided a Complete Response Letter to the New Drug Application (NDA) for naproxcinod stating that it does not approve the naproxcinod application. The naproxcinod Marketing Authorization Application (MAA) submitted by NicOx in December 2009 is currently under review by the European Medicines Agency (EMA).

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).



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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