PRESS RELEASE

NicOx announces NCX 6560 meets primary and secondary objectives in first-in-man study

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NicOx S.A. (NYSE Euronext Paris: COX) today announced that a phase 1b, first-in-man study for NCX 6560, versus placebo and Lipitor® (atorvastatin), has met its primary and secondary objectives. The top-line results demonstrated very good safety and tolerability for all the tested doses of NCX 6560, as well as the expected cholesterol lowering profile. NCX 6560 is an innovative nitric oxide (NO)-donating HMG-CoA Reductase Inhibitor, which has the potential to be developed as a new treatment to further reduce the risk of major adverse cardiac events (MACEs) in Coronary Heart Disease (CHD) patients.

"*These positive first-in-man results for NCX 6560 are an important step forward and show a very good safety and tolerability profile, even at high doses,*" declared **James Shepherd MD, Professor of Cardiovascular and Medical Sciences at the University of Glasgow**. *"The numerous roles of nitric oxide deficiency in the development of cardiovascular disorders have been studied extensively in the past decades. NCX 6560 represents a promising drug candidate, as it could target a number of the biochemical and physiological processes which lead to the most common cardiovascular diseases."*

Statins are the most effective drugs for lowering abnormally raised cholesterol, however, there is a clear need for novel treatment options capable of further reducing MACEs and mortality. Evidence suggests that statins have some beneficial effects beyond cholesterol lowering, which are believed to be derived from their propensity to enhance NO biosynthesis. Abnormally low NO release from the vasculature is believed to play an important role in the key processes underlying the most common cardiovascular disorders, such as endothelium dysfunction, atherosclerosis and thrombosis. NCX 6560 is a New Chemical Entity (NCE) that is an NO-donating atorvastatin, which is designed to provide broadened and increased beneficial effects.

Study design and results

The objectives of this three-part double-blind first-in-man study were to assess the safety, tolerability, pharmacokinetics and pharmacodynamic profile of single and repeated escalating doses of NCX 6560. In the first part of the study, 40 healthy male volunteers received a single dose of either NCX 6560 or placebo. In the second part, 48 male volunteers with high levels of low density lipoprotein (LDL) cholesterol received NCX 6560 (repeated escalating doses), atorvastatin (at marketed dose) or placebo once-daily for 14 days.

The study met its primary objectives, as the results demonstrated a very good safety and tolerability profile, with the highest tested dose of NCX 6560 showing a similar safety profile to the marketed dose of atorvastatin. The highest dose of NCX 6560 in this study corresponds to a much larger dose of atorvastatin than those on the market. The secondary objectives were also met, with single and multiple ascending doses showing a favorable pharmacokinetic profile.

The preliminary evaluation of the cholesterol-lowering effect in subjects with high LDL-cholesterol at baseline, the most important exploratory objective, showed strong activity for NCX 6560 with a dose-related LDL-cholesterol decrease. The highest dose tested reached approximately a 60% reduction after only two weeks of treatment.

The third part of the study enrolled the 10 healthy male volunteers who had received the highest tolerated dose of NCX 6560 in the first part of the study. The volunteers stayed in the same treatment arm (NCX 6560 or placebo) but the dose was administered following a high-fat breakfast. Interestingly, no apparent food effect was observed for NCX 6560.

Pascal Pfister, Chief Scientific Officer and Head of Research & Development at NicOx, added: *"These results are a promising advance for our R&D portfolio in the cardiometabolic domain, a key therapeutic area where NO donation offers numerous opportunities to generate drug candidates with potential clinical advantages. The role of NO in preventing pathological processes in the vasculature suggests NCX 6560 could have the potential to reduce the occurrence of serious cardiovascular adverse events, such as stroke and heart attack, in Coronary Heart Disease patients. In light of these results, we are keen to see NCX 6560 advanced into phase 2.*"

This phase 1b, first-in-man study follows promising preclinical results, which suggested NCX 6560 could inhibit multiple steps in the development of cardiovascular disorders. NCX 6560 showed superior anti-platelet and anti-inflammatory activity, as well as an improved endothelial function in a variety of well-established *in vivo* models, compared to atorvastatin. Significant additional clinical studies, as well as regulatory submissions and regulatory approvals, will be required before NCX 6560 could be commercially sold.

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NicOx (Bloomberg: COX:FP, Reuters: NCOX.PA) is a product-driven pharmaceutical 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, cardio-metabolic and ophthalmologic diseases.

NicOx's 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 submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) 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).

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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.

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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