



## NicOx announces results for TPI 1020 in COPD

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**NicOx S.A.** (NYSE Euronext Paris: COX) today announced the results of a phase 2a study for TPI 1020, conducted in 62 patients with Chronic Obstructive Pulmonary Disease (COPD) by its partner Topigen Pharmaceuticals Inc. TPI 1020 showed good overall safety and tolerability, although its activity profile was not significantly different from budesonide, a conventional corticosteroid commonly used in respiratory disorders. TPI 1020 is a new chemical entity licensed from NicOx for respiratory indications.

The two co-primary objectives of the study were the safety and tolerability of inhaled TPI 1020 in COPD patients and the effect of TPI 1020 on sputum neutrophil counts compared to budesonide. Neutrophils are inflammatory cells which are directly implicated in the pathology of COPD. TPI 1020 showed a numerical reduction in sputum neutrophil counts in the airways between baseline and day 42, as compared to budesonide which increased them, although the difference did not reach statistical significance ( $p=0.095$ ). A similar trend for a reduction in the number of sputum neutrophils has been observed in a previous phase 2a safety study in asthmatic smokers.

The trial met its co-primary safety objective, with 33.3% of patients on TPI 1020 experiencing at least one adverse event, compared to 50.0% on budesonide and 12.5% on placebo. Not a single serious adverse event was observed in the TPI 1020 group, in contrast to the budesonide group.

In light of the efficacy results of this study, Topigen and NicOx have decided to discontinue the development of TPI 1020 in COPD and will explore potential opportunities for this compound in other indications.

**Pascal Pfister MD, Chief Scientific Officer and Head of Research & Development at NicOx**, commented: "*COPD is a complex disease which is very difficult to treat and proof-of-concept studies are highly challenging. Unfortunately, we did not obtain the differentiated activity in this study required to advance TPI 1020 into further development in COPD. Topigen and NicOx are currently exploring other possible therapeutic opportunities for TPI 1020 in the respiratory field.*"

**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 compound in the Cyclooxygenase-Inhibiting Nitric Oxide-Donating (CINOD) class of anti-inflammatory agents for the treatment 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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