Press Release

Nicox's NCX 470 Receives Approval by Chinese Authorities for Local Start of Denali Phase 3 Trial

March 4, 2021 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that its partner, Ocumension Therapeutics, has received approval from China's Center for Drug Evaluation of the National Medical Products Administration to conduct the Chinese part of the ongoing NCX 470 Denali Phase 3 clinical trial for the lowering of intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension.

Nicox's lead clinical product candidate, NCX 470, is a novel nitric oxide (NO)-donating prostaglandin analog licensed exclusively to Ocumension Therapeutics for the Chinese, Korean and South East Asian markets.

Dr. José Boyer, Interim Head of R&D at Nicox, said: *"This approval allows us to initiate Chinese patients in the Denali trial on schedule. This will pave the way for Nicox and Ocumension to submit New Drug Applications in parallel in the U.S. and China, respectively, and potentially bring NCX 470 to these two important markets in similar timeframes."*

The Press Release by Ocumension can be found here.

Denali, the second Phase 3 trial of NCX 470 for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension, was initiated in the U.S. on November 9, 2020. Denali is a 3-month trial evaluating the safety and efficacy of NCX 470 ophthalmic solution, 0.1% versus latanoprost ophthalmic solution, 0.005% and will also include a long-term safety extension. The trial is financed jointly and in equal parts by Nicox and Ocumension and includes clinical sites in both the U.S. and China, with the majority of the patients to be recruited in the U.S. The Denali trial, together with the ongoing Mont Blanc trial, are designed to fulfill the regulatory requirements for Phase 3 safety and efficacy trials to support New Drug Application (NDA) submissions in the U.S. and China. Top-line results are currently expected in Q4 2022.

NCX 470 is also being studied in Mont Blanc, a 3-month trial evaluating the safety and efficacy of NCX 470 ophthalmic solution, 0.1%, against latanoprost ophthalmic solution, 0.005%, for lowering of IOP in patients with open-angle glaucoma or ocular hypertension. Top-line results are currently expected in H1 2022.

About NCX 470

NCX 470 is a novel, potential best-in-class, nitric oxide (NO)-donating prostaglandin analog in development to reduce intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Glaucoma is a group of ocular diseases in which the optic nerve is injured, leading to peripheral and, ultimately, central visual field loss and it can eventually lead to blindness if not treated. It is frequently linked to abnormally high IOP (~90% of patients) due to blockage or malfunction of the eye's aqueous humor drainage system in the front of the eye. In 2019, worldwide sales of treatments targeting glaucoma were over $6.0 billion out of a $21.9 billion worldwide market for ophthalmic drugs.

NCX 470 is designed to release both bimatoprost and NO following instillation into the eye. Bimatoprost, marketed under the brand name LUMIGAN® by Allergan, Inc., is one of the leading products in the class of prostaglandin analogs, the most widely used class of drugs for IOP-lowering in patients with open-angle glaucoma or ocular hypertension.

About Nicox

Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's lead program in clinical development is NCX 470, a novel nitric oxide-donating prostaglandin analog, for lowering intraocular pressure in patients with glaucoma. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for acute exacerbations of blepharitis. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIATE® in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of South East Asian markets.

Nicox is headquartered in Sophia Antipolis, France, is listed on Euronext Paris (Compartment B: Mid Caps; Ticker symbol: COX) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes.

For more information on Nicox, its products or pipeline, please visit: www.nicox.com.

Analyst coverage

Bryan, Garnier & Co	Victor Floc'h	Paris, France
Cantor Fitzgerald	Louise Chen	New York, U.S.
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Kepler Cheuvreux	Damien Choplain	Paris, France

The views expressed by analysts in their coverage of Nicox are those of the author and do not reflect the views of Nicox. Additionally, the information contained in their reports may not be correct or current. Nicox disavows any obligation to correct or to update the information contained in analyst reports.

Contacts

Nicox
Gavin Spencer
Executive Vice President, Chief Business Officer
& Head of Corporate Development
T +33 (0)4 97 24 53 00
communications@nicox.com

Investors & Media
United States & Europe
LifeSci Advisors, LLC
Mary-Ann Chang
T +44 7483 284 853
mchang@lifesciadvisors.com

Media
France
LifeSci Advisors, LLC
Sophie Baumont
M +33 (0)6 27 74 74 49
sophie@lifesciadvisors.com

Forward-Looking Statements

The information contained in this document may be modified without prior notice. This information includes forward-looking statements. Such forward-looking statements are not guarantees of future performance. These statements are based on current expectations or beliefs of the management of Nicox S.A. and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Nicox S.A. and its affiliates, directors, officers, employees, advisers or agents, do not undertake, nor do they have any obligation, to provide updates or to revise any forward-looking statements.

Risks factors which are likely to have a material effect on Nicox's business are presented in the 3rd chapter of the '*Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2020*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 1, 2021 which are available on Nicox's website (www.nicox.com).

Nicox S.A.
Drakkar 2
Bât D, 2405 route des Dolines
CS 10313, Sophia Antipolis
06560 Valbonne, France
T +33 (0)4 97 24 53 00
F +33 (0)4 97 24 53 99