

Press Release

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

October 26, 2020 – release at 7:30 am
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 carry out the Chinese part of the ongoing Mont Blanc trial, the first Phase 3 clinical trial on NCX 470 for the lowering of intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension.

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

Dr. José Boyer, VP and Interim Head of R&D at Nicox, said: *"We are pleased with this second Chinese IND approval in our collaboration with Ocumension. NCX 470 development remains on track, with first results from the Mont Blanc trial expected in Q4 2021. Initiation of Chinese sites in this trial will be essential in preparing the way for Denali, the second Phase 3 trial with NCX 470, which will include a larger number of Chinese patients."*

The Press Release by Ocumension can be found [here](#):

The NCX 470 Mont Blanc Phase 3 clinical trial is a 3-month trial to evaluate the safety and efficacy of NCX 470 ophthalmic solution, 0.1%, versus the current standard of care, latanoprost ophthalmic solution, 0.005%, for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension. The Mont Blanc trial is expected to randomize approximately 670 patients, at around 50 clinical sites in the U.S. and at a small number of clinical sites in China. The Mont Blanc trial was initiated in the U.S. in June 2020 and top-line results are currently expected in Q4 2021.

Nicox and Ocumension will jointly fund the second NCX 470 Phase 3 glaucoma trial, Denali, which is expected to start by end of 2020 and will also evaluate NCX 470 ophthalmic solution, 0.1%, versus latanoprost ophthalmic solution, 0.005%. The Denali trial will include clinical sites in both the U.S. and China, with the large majority of the patients to be recruited in the U.S. The Denali trial was designed to fulfill the regulatory requirements to support New Drug Application (NDA) filings in the U.S. and China.

About NCX 470

NCX 470 is a novel, potential best-in-class, second generation nitric oxide (NO)-donating bimatoprost 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, second-generation nitric oxide-donating bimatoprost

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 Eyeavance 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.
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Oppenheimer & Co	Hartaj Singh	New York, U.S.



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.

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Forward-Looking Statements

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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 2019' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2020 which are available on Nicox's website (www.nicox.com).

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