

Press Release

Nicox Initiates Second Phase 3 Trial of NCX 470 in Glaucoma

- **Denali Phase 3 clinical trial to randomize 650+ patients at sites across the U.S. and China**
- **Denali trial will be equally funded by Nicox and Ocumension**
- **Together with the Mont Blanc Phase 3 trial, Denali will support New Drug Application (NDA) submissions in the U.S. and China**

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Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced the initiation of the second Phase 3 clinical trial of NCX 470, ‘Denali’, evaluating NCX 470 for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. The first patients were enrolled in the U.S. on November 9, 2020.

NCX 470, Nicox’s lead clinical product candidate, is a novel second-generation nitric oxide (NO)-donating bimatoprost analog. The Denali trial will be financed jointly and in equal parts by Nicox and Ocumension Therapeutics, Nicox’s exclusive licensee for the Chinese, Korean and South East Asian markets.

Dr. José Boyer, VP and Interim Head of R&D at Nicox, said: *“The Denali trial is the second pivotal trial required for the New Drug Applications of NCX 470 in both the United States and China. With this initiation, our NCX 470 development program is entering the final phase and remains on track. We have assembled a strong and experienced in-house development team in the glaucoma space and have selected an international Clinical Research Organization with a strong presence in both the U.S. and China, to ensure a timely and efficient execution of this multi-regional trial”.*

Denali is a 3-month Phase 3 trial evaluating 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 trial, which will also include a long-term safety extension, is expected to randomize 650+ patients, at approximately 50 clinical sites in the U.S. and China, with a majority to be recruited in the U.S. The Denali trial was designed to fulfill the regulatory requirements to support NDA submissions of NCX 470 in the U.S. and China.

The first Phase 3 trial of NCX 470 is the ongoing Mont Blanc trial which was initiated in the U.S. in June 2020, with top-line results currently expected in Q4 2021. The 3-month Mont Blanc trial, also evaluating the safety and efficacy of NCX 470 ophthalmic solution, 0.1%, versus latanoprost ophthalmic solution, 0.005%, for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension, is expected to randomize approximately 670 patients, at approximately 50 clinical sites in the U.S. and a small number of clinical sites in China. Ocumension recently received approval from China’s Center for Drug Evaluation of the National Medical Products Administration to carry out the Chinese part of Mont Blanc trial.

We continue to closely watch the spread and impact of the COVID-19 pandemic. We do not currently anticipate delays in our clinical timelines but we are monitoring the situation and will provide an update when needed.

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 ZERVIA™ 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.



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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

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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).



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