

## Press Release

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# Nicox Reports on Enrollment Progress in Mont Blanc Phase 3 Clinical Trial in Glaucoma

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- **Over forty clinical sites have been initiated in the first month in the NCX 470 Mont Blanc Phase 3 clinical trial**
- **The NCX 470 Mont Blanc Phase 3 trial is on track to support the adaptive dose selection by the end of 2020**
- **The second NCX 470 Phase 3 trial, Denali, is on track to start by the end of 2020**

July 15, 2020 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that over 40 sites have been initiated in the first month of the Phase 3 Mont Blanc trial, evaluating NCX 470 for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. NCX 470 is the company's novel, second-generation nitric oxide (NO)-donating bimatoprost analog.

**Tomas Navratil, PhD, EVP & Head of R&D of the Nicox Group and General Manager of Nicox Ophthalmics, Inc.**, said, *"Based on the promising results from our Phase 2 Dolomites trial, NCX 470 has the potential to offer patients with elevated IOP an improvement over the current standard of care. We expect to complete the adaptive dose selection of the NCX 470 dose by the end of 2020 paving the way for the remainder of the Mont Blanc trial and the start of our second Phase 3 trial, Denali in 2020. We would like to thank the clinical investigators, research coordinators, all other trial personnel, and trial patients from the participating clinical sites for the rapid trial start-up and a strong first month of enrolment while carefully implementing COVID-19 precautions."*

The Mont Blanc trial is a multi-regional, double-masked, 3-month, parallel group, adaptive design trial evaluating the efficacy and safety of NCX 470 ophthalmic solution, 0.065% and 0.1% compared to latanoprost ophthalmic solution, 0.005% in patients with open-angle glaucoma or ocular hypertension. In an adaptive portion of the trial, one NCX 470 dose will be selected to continue in the subsequent head-to-head 3-month safety and efficacy evaluation of NCX 470 vs. latanoprost. The primary efficacy evaluation is based on time-matched IOP at 8 AM and 4 PM at Week 2, Week 6 and Month 3. The trial is expected to randomize approximately 670 patients at approximately 50 clinical sites, primarily in the U.S., and at a small number of clinical sites in China.

Nicox NCX 470 Phase 3 program has received strong support from the U.S. glaucoma community, including the recently hosted a key opinion leader call on NCX 470 featuring a presentation by the current President of the American Glaucoma Society Dr. Donald Budenz, MD, MPH, Chair, Department of Ophthalmology, UNC Chapel Hill School of Medicine. A recording of the call can be found [here](#).

### COVID-19 Situation

Due to potential delays caused by COVID-19, the Company is not currently providing a target date for the Mont Blanc topline results. Although we currently do not anticipate delays to our clinical timelines, we are closely monitoring the situation and will apprise the market if there is any impact on our development timelines.

## About Glaucoma

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Glaucoma is a group of ocular diseases in which the optic nerve is injured, leading to peripheral and, ultimately, central visual field loss. Glaucoma can eventually lead to blindness if not treated and is currently considered to be one of the three leading causes of irreversible blindness worldwide. Glaucoma is frequently linked to abnormally high intraocular pressure (IOP) due to blockage or malfunction of the eye's aqueous humor drainage system in the front of the eye. Current medications are targeted at reducing IOP to slow the progression of the disease. The requirement for multiple medications to lower an individual patient's IOP to their target level highlights the need for more effective treatments.

In 2019, worldwide sales of treatments targeting glaucoma were over \$6.0 billion out of a \$21.9 billion worldwide market for ophthalmic drugs. In the U.S., sales of treatments targeting glaucoma totaled \$3.2 billion in 2019 or 37% of the \$8.8 billion U.S. market for ophthalmic drugs. Of the U.S. sales of treatments targeting glaucoma, \$1.5 billion, or almost 50%, was sales of prostaglandin analogs, of which nearly 90% were branded products, led by Lumigan (bimatoprost ophthalmic solution), 0.01% and Travatan Z (travoprost ophthalmic solution), 0.004%. Currently, we estimate that 3.5% of the worldwide population between 40 and 80 years of age are affected by the most common forms of glaucoma, and we estimate that, in 2018, around 36 million prescriptions were written in the U.S. annually for glaucoma drugs.

## About NCX 470

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NCX 470 is a novel, second generation nitric oxide (NO)-donating bimatoprost analog in development for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. 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

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Nicox S.A. is an 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 ZERVIAE™ in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and Southeast 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](http://www.nicox.com).

## Analyst coverage

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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.
Openheimer & 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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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 3<sup>rd</sup> 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](http://www.nicox.com)).

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