

## Press Release

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# Nicox's NCX 470 Dolomites Phase 2 Results Published in *Journal of Glaucoma*

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April 11, 2022 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that the results from its Dolomites Phase 2 clinical trial of NCX 470 in patients with open-angle glaucoma or ocular hypertension have been published online by the *Journal of Glaucoma*, the official journal of the World Glaucoma Association. The publication “*A Randomized, Controlled Comparison of NCX 470 (0.021%, 0.042% and 0.065%) and Latanoprost 0.005% in Patients with Open-Angle Glaucoma or Ocular Hypertension: The Dolomites Study*” is available by clicking [here](#). NCX 470 is currently in two Phase 3 clinical trials.

Dolomites was a dose-response Phase 2 clinical trial comparing three concentrations of NCX 470 ophthalmic solution (0.021%, 0.042%, and 0.065%) to latanoprost ophthalmic solution, 0.005% in 433 patients with open-angle glaucoma or ocular hypertension. Aligned with previously reported topline results on Dolomites, NCX 470 0.065% achieved statistical superiority compared to latanoprost 0.005% at all time-matched points measured on day 28, with a peak improvement in intraocular pressure (IOP) lowering of 1.4 mmHg greater than latanoprost. All tested concentrations of NCX 470 were statistically non-inferior to latanoprost and the dose response of NCX 470 showed improved IOP lowering with each incremental concentration. NCX 470 was safe and well-tolerated with no drug-related serious adverse events and no evidence of treatment-related systemic side effects.

*“As presented at the American Glaucoma Society in February 2020 by Dr David Wirta, the Dolomites Phase 2 data demonstrate that NCX 470, a monotherapy with a dual mechanism of action, has the potential to be a new standard of care for reducing intraocular pressure in patients with open-angle glaucoma or ocular hypertension.”* said **Doug Hubatsch, Chief Scientific Officer of Nicox**. *“We are pleased to be able to share the results of this Phase 2 trial in a peer-reviewed publication with the international glaucoma community. We are looking forward to the results of the subsequent Phase 3 trials of NCX 470 – Mont Blanc and Denali – which use a higher dose of NCX 470, based on the results of an initial adaptive design dose-ranging phase of the Mont Blanc trial.”*

NCX 470 is currently enrolling patients in two multi-regional Phase 3 glaucoma clinical trials, Mont Blanc and Denali. The objective of these two trials is to demonstrate statistically superior IOP lowering of once-daily dosed NCX 470 ophthalmic solution 0.1% over latanoprost ophthalmic solution 0.005% (first marketed as Xalatan), the most prescribed prostaglandin analog in the U.S. for patients with open-angle glaucoma or ocular hypertension.

### About NCX 470

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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 2020, worldwide sales of treatments targeting glaucoma were over \$6.0 billion out of a \$24.3 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

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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 open-angle glaucoma or ocular hypertension. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for dry eye disease. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIAE® 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 C: 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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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.*

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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 2020' filed with the French *Autorité des Marchés Financiers* (AMF) on March 1, 2021 and in the 2<sup>nd</sup> chapter of the amendment to the "Document d'Enregistrement Universel, rapport financier annuel et rapport de gestion 2020" filed with the AMF on December 9, 2021 which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).

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