

## Press Release

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# Nicox's NCX 470 Demonstrates Significant Intraocular Pressure Lowering in Dolomites Phase 2 Glaucoma Trial

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- **Results Demonstrating Superior Efficacy to Current Standard of Care Presented at World Glaucoma E-Congress 2021**
- **Phase 3 on track with first trial results expected in Q2 2022**

July 1<sup>st</sup>, 2021 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, presented results from the Dolomites Phase 2 clinical trial showing that NCX 470, a novel nitric oxide (NO)-donating prostaglandin analog (PGA), produced significantly greater intraocular pressure (IOP) lowering effects in glaucoma patients compared with the current standard of care, latanoprost.

In Dolomites, a dose-response Phase 2 clinical trial evaluating three concentrations of NCX 470 compared to latanoprost ophthalmic solution, 0.005% in 433 patients with open-angle glaucoma or ocular hypertension, NCX 470 0.065% achieved superiority compared to latanoprost 0.005% at all time points on day 28 with up to 1.4 mmHg superior IOP lowering. All tested concentrations of NCX 470 were 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. The presentation of the results by Dr. David Wirta, one of the clinical investigators in the trial, is available during the World Glaucoma Congress 2021 (June 30 to July 3 2021). The Dolomites trial was completed in late 2019 and the results are detailed [here](#).

*“The Phase 2 Dolomites trial demonstrated that NCX 470 has the potential to be a new standard of care for reducing intraocular pressure in patients with open-angle glaucoma or ocular hypertension. These impressive data showed superior efficacy against latanoprost, the most prescribed prostaglandin analog for patients with open-angle glaucoma or ocular hypertension, and importantly, also suggested that greater efficacy may be possible at concentrations higher than those used in this dose-ranging trial,”* said **Dr. Wirta, Medical Director, Eye Research Foundation, Newport Beach, CA, USA** and one of the clinical investigators in the Dolomites trial, *“NCX 470 was well-tolerated, and the highest dose used in the trial suggests that a higher dose (0.1%) currently being evaluated in Phase 3 has the potential for greater IOP lowering without significant additional risk.”*

NCX 470 is currently in two multi-regional Phase 3 glaucoma clinical trials, Mont Blanc and Denali. The objective with these two trials is to demonstrate statistically superior efficacy of once-daily dosed NCX 470 ophthalmic solution 0.1% over latanoprost ophthalmic solution 0.005% (first marketed as Xalatan), the most prescribed PGA in the U.S., for the lowering of IOP. Results from the first Phase 3 trial, Mont Blanc, are currently expected in Q2 2022. Results from the second Phase 3 trial, Denali, are now expected in 2023, previously announced as Q4 2022.

## 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 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](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. |
| 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

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### Nicox

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

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

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

## 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 which are available on Nicox's website ([www.nicox.com](http://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