

## Press Release

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# Nicox's NCX 470 Mont Blanc Phase 3 Glaucoma Trial Reaches 50% Enrollment Milestone

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- **338 patients randomized as of March 22, 2021, out of a target of 670**
- **Currently on track for top-line results in Q2 2022**

March 23, 2021 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that 50% of patients in the Mont Blanc NCX 470 Phase 3 glaucoma clinical trial have now been randomized out of a target of 670, with top-line results currently on track to be announced during Q2 2022.

**Dr. José Boyer, Interim Head of R&D at Nicox**, said: *"We have been successful in maintaining a good recruitment rate in the Mont Blanc trial through careful selection and support of clinical sites, despite the COVID-19 pandemic environment. This milestone of randomizing 50% of the total planned patients in the trial indicates that we are currently on track for top-line results for this first Phase 3 trial in the second quarter of 2022. The Mont Blanc trial is key to demonstrating the safety and efficacy profile of NCX 470 as potentially the first non-fixed-combination to be submitted for approval using a pivotal trial showing a statistically superior reduction of intraocular pressure over the standard of care, latanoprost."*

Nicox's lead clinical product candidate, NCX 470, is a novel nitric oxide (NO)-donating prostaglandin analog licensed exclusively to Ocumension Therapeutics for the Chinese, Korean and Southeast Asian markets. Mont Blanc is a 3-month multi-regional Phase 3 clinical trial evaluating the safety and efficacy of NCX 470 ophthalmic solution, 0.1% versus latanoprost ophthalmic solution, 0.005%, for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. The Mont Blanc trial was initiated in the U.S. in June 2020 with an initial adaptive design portion wherein the highest dose of NCX 470 tested in the Dolomites Phase 2 clinical trial, 0.065%, was evaluated together with a higher 0.1% concentration of NCX 470. The 0.1% dose of NCX 470 was selected in the adaptive stage of the Mont Blanc trial and enabled the second part of the Mont Blanc Phase 3 trial and the start of Denali Phase 3 trial.

Denali, the second multi-regional Phase 3 clinical trial of NCX 470 for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension, was initiated in the U.S. in November 2020, and approval was recently obtained to start recruitment in China. Denali is a 3-month trial evaluating the safety and efficacy of NCX 470 ophthalmic solution, 0.1% versus latanoprost ophthalmic solution, 0.005% that will also include a long-term safety extension. The trial is financed jointly and in equal parts by Nicox and Ocumension and includes clinical sites in both the U.S. and China, with the majority of the patients to be recruited in the U.S. Top-line efficacy results are currently expected in Q4 2022.

The Denali trial, together with the ongoing Mont Blanc trial, are designed to fulfill the regulatory requirements for Phase 3 safety and efficacy trials to support New Drug Application (NDA) submissions in the U.S. and China.

*We continue to closely watch the spread and impact of the COVID-19 pandemic and we will provide an update of any delays.*

### 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 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

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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 ZERVIAE® in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance 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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*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 which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).

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