

## Press Release

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# Results from Mont Blanc Phase 3 Trial of Nicox's NCX 470 in Glaucoma Published in the American Journal of Ophthalmology

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- **First publication of the data from the Mont Blanc Phase 3 trial in a peer-reviewed journal**
- **Authors conclude: "NCX 470 could become an important first-line therapy for IOP reduction in glaucoma."**
- **Topline results from second Phase 3 trial of NCX 470, Denali, expected in H2 2025**

March 20, 2024 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that the results from the Mont Blanc pivotal Phase 3 trial comparing NCX 470 to latanoprost in the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension have been published in the peer-reviewed journal *American Journal of Ophthalmology*. The principal author of the publication is Dr. Robert Fechtner, Professor and Chair of the Department of Ophthalmology at SUNY Upstate Medical University, Syracuse, NY and Chairman of Nicox's U.S. Glaucoma Clinical Advisory Board.

"We are pleased to see the publication of these data in such a recognized and respected journal," said **Doug Hubatsch, Chief Scientific Officer of Nicox**. "The data from the Mont Blanc Phase 3 trial demonstrated the potential of NCX 470 and we look forward to seeing confirmation of this clinical profile in the upcoming results from the ongoing Denali Phase 3 trial, expected in H2 2025. I'd also like to thank all the Mont Blanc study sites for their excellent work on this trial."

The publication entitled "A Randomized, Controlled Comparison of NCX 470, a Nitric Oxide-Donating Bimatoprost, and Latanoprost in Subjects with Open-Angle Glaucoma or Ocular Hypertension: The MONT BLANC Study" was published online in the American Journal of Ophthalmology on March 16, 2024 and is available by clicking [here](#).

The Mont Blanc publication concludes that "*The NO-donating prostaglandin analogue NCX 470 0.1% was well-tolerated and lowered IOP more than latanoprost in subjects with open-angle glaucoma or ocular hypertension at all 6 time points. With a dual mechanism of action that enhances both uveoscleral and trabecular outflow, NCX 470 could become an important first-line therapy for IOP reduction in glaucoma.*"

### About NCX 470

NCX 470, Nicox's lead clinical asset, is a novel nitric oxide-donating bimatoprost eye drop. The Denali Phase 3 clinical trial evaluating NCX 470 for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension, being conducted in the U.S. and China, is on track to generate topline results in H2 2025. 80% of the target number of patients have been randomized in the trial and completion of recruitment of U.S. patients is expected in Q4 2024. Supportive development data required for the preparation of the U.S. New Drug Application (NDA) is expected to be available on or before the completion of the Denali trial. The database from the trial will not be locked until after the last patient has completed their final trial visit in China, which drives the timing of the Denali results.

### About Nicox

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Nicox SA 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 bimatoprost eye drop, for lowering

intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIA® in allergic conjunctivitis, licensed in multiple geographies, including to Harrow, Inc. in the U.S., and Ocumension Therapeutics in the Chinese and in the majority of Southeast Asian markets.

Nicox, headquartered in Sophia Antipolis, France, is listed on Euronext Growth Paris (Ticker symbol: ALCOX) and is part of the CAC Healthcare index.

For more information [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

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 section 2.7 of the "Rapport Annuel 2022" and in section 4 of the "Rapport semestriel financier et d'activité 2023" which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).

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