

Press Release

Nicox Announces Positive Results from the NCX 470 Phase 3 Denali Trial in Glaucoma Patients

- **Achieving the primary endpoint in both Denali and the first NCX 470 Phase 3 trial, Mont Blanc, meets efficacy requirements for approval in the U.S. and China**
- **NCX 470 was also superior to latanoprost in the reduction of intraocular pressure (IOP) from baseline ($p<0.05$) at 3 out of 6 timepoints and numerically greater at 5 out of 6 timepoints**
- **NCX 470 0.1% was safe and well tolerated**
- **New Drug Application (NDA) submission in the U.S. currently expected in H1 2026**

August 21, 2025 – release at 7:30 am CET

Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that once daily dosing of NCX 470 0.1%, a novel nitric oxide (NO)-donating bimatoprost eye drop, met the primary objective of non-inferiority in lowering intraocular pressure (IOP) from baseline compared to the standard of care, latanoprost 0.005%, in the Denali Phase 3 clinical trial involving 696 patients with open-angle glaucoma or ocular hypertension. The IOP-lowering effect from baseline for NCX 470 was 7.9 to 10.0 mmHg vs. 7.1 to 9.8 mmHg for latanoprost (reduction in time-matched IOP at 8 AM and 4 PM across the week 2, week 6 and month 3 visits). In a pre-specified secondary efficacy analysis of time-matched change from baseline IOP, the IOP reductions for NCX 470 0.1% were numerically greater than those for latanoprost at 5 of the 6 timepoints, and statistically significant ($p<0.05$) at 3 of the 6 timepoints, however overall statistical superiority was not achieved. These results are consistent with those of Mont Blanc, the first Phase 3 trial, successfully [completed](#) in 2022, and confirm the efficacy profile required for regulatory submissions in the U.S. and China.

“The Denali trial results validate the robust therapeutic profile of NCX 470 observed in the Mont Blanc trial, replicating the efficacy and safety outcomes. Consistent results across the two large Phase 3 studies strengthen the case for regulatory submissions and support NCX 470’s potential as an important treatment option for glaucoma patients. I look forward to seeing further data presented at future ophthalmology meetings.” said **Don Budenz, Coordinating Investigator of the Denali trial.**

NCX 470 Glaucoma Denali Phase 3 Topline Results Summary

- Non-inferiority was met vs. latanoprost 0.005% in the primary efficacy analysis.
- IOP-lowering effect from baseline was 7.9 to 10.0 mmHg for NCX 470 0.1% vs. 7.1 to 9.8 mmHg for latanoprost 0.005% (reduction in time-matched IOP at 8 AM and 4 PM across the week 2, week 6 and month 3 visits).
- In a pre-specified secondary efficacy analysis of time-matched change from baseline IOP, NCX 470 0.1% was statistically superior ($p<0.05$) to latanoprost 0.005% in intraocular pressure reduction from baseline at 3 of the 6 timepoints, and numerically

greater at 5 out of 6 timepoints but did not reach the overall statistical superiority pre-specified as a secondary efficacy endpoint. The difference in IOP reduction between NCX 470 0.1% and latanoprost 0.005% was up to 0.8 mmHg in favor of NCX 470.

- NCX 470 0.1% was well tolerated; the most common adverse event was conjunctival hyperaemia in 22.0% of the NCX 470 0.1% patients vs. 9.2% of latanoprost 0.005% patients. In the NCX 470 0.1% patients, there were no ocular serious adverse events and no treatment-related non-ocular serious adverse events. 10.1% of patients on NCX 470 0.1% discontinued compared to 6.6% on latanoprost 0.005%, which includes patients out to 12 months. The long-term safety profile is consistent with that seen in the shorter, 3-month, Mont Blanc trial.

“With a second Phase 3 trial demonstrating the necessary efficacy and safety profile for submission of New Drug Applications – NDAs – in both the United States and China, we are now moving forward towards potential recurrent NCX 470 royalty revenue from 2027 onwards. Our established partnerships with Kowa and Ocumension enable us to accelerate NDA preparations, whilst also allowing us to focus on potential future strategies for the company.” said **Gavin Spencer, Chief Executive Officer of Nicox.**

The Company plans to publish further data at upcoming ophthalmology industry events and is also planning a pre-NDA meeting with the FDA, in collaboration with Kowa.

A presentation of the results of the Denali trial is available on our website, www.nicox.com.

Denali Trial Design

Similar to Mont Blanc, Denali is a randomized, multi-regional, double-masked, parallel group trial that evaluated the safety and efficacy of NCX 470 ophthalmic solution, 0.1% compared to latanoprost ophthalmic solution, 0.005% in 696 patients in 90 sites in the U.S. and China. Latanoprost is the most widely prescribed first-line therapy for open-angle glaucoma or ocular hypertension.

The primary efficacy evaluation was based on reduction from baseline in mean time-matched IOP at 6 timepoints: 8 AM and 4 PM at week 2, week 6 and month 3. The Denali trial also included a long term safety extension through to 12 months and was jointly conducted and equally financed with our Chinese partner, Ocumension Therapeutics.

NCX 470 Licensing Deals

Based on these results, Nicox will receive a milestone payment of €5 million from Kowa. Royalties on net sales in the U.S. will start at 8% with royalties also payable in other territories of the July 2025 agreement with Kowa. The total potential milestones payable under the agreement are valued at €127 million and full details can be found in the Press Release [issued](#) on 17 July 2025. Separate milestone payments and royalties are due under the Kowa NCX 470 agreement for Japan.

Ocumension has co-funded the Denali trial and Nicox will receive royalties of 6% to 12% on net sales of NCX 470 in the Chinese, Korean and Southeast Asian markets.

About NCX 470

NCX 470, Nicox's lead clinical product candidate, is a novel NO-donating bimatoprost eye drop being developed for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension. NDA filings are in preparation in the U.S. and China and Phase 3 clinical

development is underway in Japan. The first two Phase 3 trials completed, Mont Blanc and Denali, have been designed to fulfil the regulatory requirements for safety and efficacy Phase 3 trials to support NDA submissions in both the U.S. and in China, and both studies are required for the submissions. A separate Phase 3 clinical program is underway to support Japanese approval. Should NCX 470 be developed for other territories, there may be additional requirements. NCX 470 is exclusively licensed to Ocumension Therapeutics in China, Korea and Southeast Asia and to Kowa in the rest of the world.

About Nicox

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 (bimatoprost grenod), a novel nitric oxide-donating bimatoprost eye drop, for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension, licensed to Ocumension Therapeutics for the Chinese, Korean and Southeast Asian markets and to Kowa in the rest of the world. Nicox also has a preclinical research program on NCX 1728, a nitric oxide-donating phosphodiesterase-5 inhibitor, with Glaukos. Nicox's first product, VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, is available commercially in the U.S. and over 15 other territories. Nicox generates revenue from 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

Analyst coverage

H.C. Wainwright & Co

Yi Chen

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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Risks factors which are likely to have a material effect on Nicox's business are presented in section 3 of the "Rapport Annuel 2024" which is available on Nicox's website (www.nicox.com).

Finally, this press release may be drafted in the French and English languages. If both versions are interpreted differently, the French language version shall prevail.

Nicox S.A.

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