Press Release

Nicox Presents New Analysis from the NCX 470 Mont Blanc Trial and Provides Development Update

- **More patients on NCX 470 achieve an intraocular pressure (IOP) of less than or equal to 18 mmHg compared to latanoprost**
- **New analysis provides additional data demonstrating differentiation of NCX 470**
- **Development activities on track for U.S. New Drug Application submission targeted in H1 2026**

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Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today provided details of a poster presentation highlighting additional pre-planned analysis from the NCX 470 Mont Blanc Phase 3 clinical trial at the 2025 American Glaucoma Society (AGS) Annual Meeting, one of the key scientific events in vision research, which was held on February 26 to March 2, 2025 in Washington, United States. The Company also provided an update on NCX 470 Development.

"*These data provide another example of where NCX 470 is differentiated from the standard-of-care for intraocular pressure reduction, latanoprost. In this analysis, we demonstrated that more patients achieve intraocular pressure of less than or equal to 18 mmHg on NCX 470 than on latanoprost. In addition, the mean percentage reduction in intraocular pressure was greater in patients on NCX 470 compared to those on latanoprost." said* ***Doug Hubatsch, Chief Scientific Officer of Nicox****. "We also look forward to announcing the results of the Whistler trial, investigating the mechanism of action of NCX 470, shortly, and the second pivotal Phase 3 trial, Denali, in Q3 of this year.*"

Poster Title: Diurnal Intraocular Pressure Control Responder Analysis with NCX 470 Versus Latanoprost in the Phase 3 MONT BLANC Trial

A statistically significant greater proportion of eyes treated with NCX 470 0.1% achieved mean diurnal IOPs of ≤18 mmHg compared to those in the latanoprost 0.005% group in this analysis of the multinational Phase 3 Mont Blanc clinical trial. Additionally, greater mean percent IOP reductions from baseline were seen in the eyes treated with NCX 470 than in eyes treated with latanoprost.

Summary of key differentiating factors seen in *post hoc* analysis of Mont Blanc

- Statistically significant percentage of patients achieve ≤ 18mmHg IOP on NCX 470 compared to latanoprost
- Mean percentage reduction in IOP greater on NCX 470 than on latanoprost
- In eyes with an initial IOP of ≤ 28 mmHg the IOP-lowering effect from baseline was statistically significantly greater for NCX 470 compared to latanoprost at the majority of timepoints measured

- NCX 470 demonstrates a consistent lowering of IOP regardless of the baseline IOP, whereas the reduction in IOP with latanoprost is dependent on the baseline IOP

- A statistically significant greater proportion of patients who received NCX 470 showed an IOP reduction of greater than 10 mmHg from baseline, compared to those on latanoprost

The Mont Blanc trial demonstrated that NCX 470 met the efficacy standard for approval in the United States, non-inferiority to latanoprost, with an IOP reduction of 8.0 to 9.7 mmHg. While NCX 470 failed to meet statistical superiority to latanoprost in a pre-specified secondary efficacy analysis of time-matched change from baseline IOP, NCX 470 was numerically superior to latanoprost at all time points and statistically significant ($p<0.049$) at 4 of 6 timepoints.

The full Mont Blanc data and publications of other analyses are available on Nicox's website in the section Publications.

Update on NCX 470 Development

In addition to the Denali clinical trial, other development activities to support the preparation of a New Drug Application in the U.S. and China, where NCX 470 is partnered with Ocumension Therapeutics, are ongoing. These include supporting clinical and non-clinical trials and pharmaceutical development. Assuming a partnership for the U.S. or obtaining appropriate financing, the Company believes these activities are on track to allow an NDA filing in S1 2026, supporting potential launch in the U.S. in S1 2027.

The last patient in the ongoing **Whistler Phase 3b** clinical trial investigating NCX 470's dual mechanism of action (nitric oxide and prostaglandin analog) in IOP lowering is now expected to complete the study late in the first of 2025, and therefore the results are now expected in mid-second quarter of 2025, compared to the previous estimate of first quarter.

The **Denali Phase 3** clinical trial evaluating NCX 470 in patients with open-angle glaucoma or ocular hypertension remains on track with all patients recruited and topline results are expected in the third quarter 2025.

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. 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 ZERVIATE® 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 2023*" and in section 4 of the "*Rapport semestriel financier et d'activité 2024*" which are 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.

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