Press Release

Nicox's Denali Phase 3 Trial of NCX 470 Fully Enrolled in China Earlier than Expected

- **Confirms topline results expected to be reported Q3 2025**
- **NCX 470 demonstrated robust efficacy and safety in topline results from first Phase 3 trial, Mont Blanc**
- **NCX 470 partnering efforts will focus on routes for bringing the product to market in the U.S.**
- **Results from the NCX 470 Phase 3b Whistler Mechanism of Action trial expected in Q1 2025**

December 2, 2024 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that its Denali Phase 3 trial, evaluating the efficacy and safety of NCX 470 in patients with open-angle glaucoma or ocular hypertension, is now fully enrolled in China and screening has been closed. Completion of recruitment of patients in the U.S. for the trial was announced in July 2024 and therefore the target number of patients to be enrolled in the Denali trial has been met. Topline results are expected in Q3 2025.

"Following completion of the recruitment of the Denali trial in the United States, we have seen an acceleration in the number of Chinese patients randomized in this multi-center international trial, allowing us to close Chinese patient recruitment earlier than expected." said **Doug Hubatsch, Chief Scientific Officer of Nicox.** *"I would like to thank the teams at both Nicox and Ocumension and the clinical staff and patients at our sites, as well as our partner organisations for their dedication through the final stages of the recruitment. We look forward to announcing the topline results in Q3 next year. Whilst we continue the final stages of this trial, we are also completing the additional development steps necessary to support the preparation of New Drug Applications in both the United States and China to ensure that these could be submitted as soon as possible after the receipt of the Denali topline data."*

"NCX 470 continues to generate interest from potential commercialisation partners. With strong collaborations in Japan, China, Korea and Southeast Asia already in place, we are focussing on the route to commercialisation for NCX 470 in the United States, with potential for regional partnerships elsewhere." added **Emmet Purtill, VP Business Development.**

The Denali trial is evaluating the intraocular pressure (IOP) lowering efficacy of once-daily dosed NCX 470 ophthalmic solution 0.1% compared to latanoprost ophthalmic solution 0.005% in patients with open-angle glaucoma or ocular hypertension. It is a multi-country (U.S. and China) clinical trial financed equally by Nicox and Ocumension, Nicox's exclusive licensee for China, Korea and Southeast Asia. The Denali trial,

together with the Mont Blanc trial, was designed to fulfill the clinical regulatory requirements to support New Drug Application (NDA) submissions of NCX 470 in the U.S. and China. The company estimates that a U.S. NDA for NCX 470 could potentially be submitted in H1 2026, subject to the company entering into a partnership for the commercialization of NCX 470 in the U.S. or obtaining appropriate financing.

Topline results from the first Phase 3 trial, Mont Blanc, showed the IOP-lowering effect from baseline was 8.0 to 9.7 mmHg for NCX 470 vs. 7.1 to 9.4 mmHg for latanoprost. Statistical non-inferiority was met vs. latanoprost in the primary efficacy analysis and 4 out of 6 timepoints additionally demonstrated superiority; the trial therefore met the efficacy requirements for approval in the U.S. NCX 470 was well tolerated and discontinuation rates were low. The results of the Mont Blanc trial have been published in the prestigious American Journal of Ophthalmology, and numerous post hoc analyses have been presented. Full details of all presentations and publications can be found at nicox.com/pipeline-markets-and-science/#publications.

About NCX 470

NCX 470 is a novel nitric oxide (NO)-donating bimatoprost eye drop that leverages the potent IOP lowering effects of NO and prostaglandin analogs (PGAs). NCX 470 incorporates Nicox's proprietary NO-donating research platform and bimatoprost in a single molecule. NCX 470 is designed to release bimatoprost and NO into the eye to lower IOP by two different pathways in patients with open-angle glaucoma or ocular hypertension. NO is a well-known small, naturally occurring signaling molecule that plays a key role in the regulation of IOP through activation of soluble guanylate cyclase. NO brings additional IOP-lowering efficacy by enhancing aqueous humor drainage from the eye via a different mechanism of action to that of PGAs. Bimatoprost, marketed under the brand name LUMIGAN® by AbbVie, Inc., is the leading branded PGA. PGAs are the most widely used class of drugs for IOP-lowering in patients with open-angle glaucoma or ocular hypertension.

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.

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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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