Press Release

Nicox Announces Recruitment of Last Patient in U.S. in Denali Phase 3 Trial of NCX 470

- **Recruitment continues in China, on track for topline results in H2 2025**
- **NCX 470 demonstrated robust efficacy and safety in topline results from first Phase 3 trial, Mont Blanc**

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Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced the recruitment and randomization of the last patient in the U.S. in its Denali Phase 3 trial of NCX 470.

The Denali trial is evaluating NCX 470 safety and efficacy in patients with open-angle glaucoma or ocular hypertension and topline results continue to be expected in H2 2025, based on this completion of recruitment of patients in the U.S. and continuing good progress of the trial in China, where recruitment of patients is still ongoing. More than 95% of the total target number of patients have been randomized in this trial so far.

"I would like to thank our patients, the clinical sites, our internal team and our investors for their efforts and support in enabling us to reach this important milestone, the completion of U.S. recruitment in the Denali trial. We will remain fully focused on NCX 470 and on continuing recruitment of patients in China to complete Denali as we move towards expected topline results in H2 2025." said **Doug Hubatsch, Chief Scientific Officer of Nicox.**

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 regulatory requirements to support New Drug Application (NDA) submissions of NCX 470 in the U.S. and China. The U.S. NDA for NCX 470 is expected to be submitted in H1 2026.

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 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 generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and 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*" 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.

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