Press Release

Nicox Announces Publication of the Adaptive Design Period of the NCX 470 Mont Blanc Phase 3 Trial

- **An adaptive design is a useful clinical trial design tool which allowed identification of the optimal dose of NCX 470 in the Mont Blanc trial, the first Phase 3 trial of NCX 470**
- **Both doses of NCX 470 ophthalmic solution tested, 0.065% and 0.1%, lowered intraocular pressure more than the comparator, latanoprost 0.005% ophthalmic solution**
- **The 0.1% NCX 470 concentration was chosen for the remainder of the Mont Blanc trial and the ongoing Denali trial based on a greater intraocular pressure reduction compared to the 0.065% concentration and a good safety profile**

November 18, 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 design details and results of the adaptive design period of the NCX 470 Mont Blanc Phase 3 trial evaluating the efficacy and safety of NCX 470 in patients with open-angle glaucoma or ocular hypertension have been published online in *Contemporary Clinical Trials*, Volume 147, 2024, 107730 (online pre-publication https://doi.org/10.1016/j.cct.2024.107730). A portion of this data has previously been presented as a poster at the 2023 World Glaucoma Congress.

The dose finding Phase 2 trial (Dolomites) tested NCX 470 at several concentrations and the results suggested that a higher dose than those tested might provide even better efficacy and safety profile. To test this, concentrations of 0.065% and 0.1% were included in an adaptive dose selection period of the Phase 3 Mont Blanc trial, which compared the safety and efficacy of NCX 470 ophthalmic solution vs. latanoprost ophthalmic solution in adult subjects with open-angle glaucoma or ocular hypertension. At the Week 2 timepoint, the least-squares mean difference in diurnal intraocular pressure (IOP) compared to latanoprost were 1.51 mmHg for NCX 470 0.065 % group ($p = 0.0308$) and 1.71 mmHg for NCX 470 0.1 % group ($p = 0.0123$), in favor of NCX 470. The most common side effect was conjunctival/ocular hyperemia, the frequency and severity of which were similar in both NCX 470 dosing groups ($p > 0.05$).

The adaptive dose selection period was used in place of additional dose ranging studies to select the 0.1% concentration of NCX 470 for the completion of the Mont Blanc clinical trial as well as the second Phase 3 trial, Denali.

The results of the Mont Blanc trial were announced in October 2022. The second Phase 3 trial of NCX 470, Denali, is ongoing and topline results are expected in the third quarter of 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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