Press Release

Nicox Announces Last Patient Completes the NCX 470 Denali Phase 3 Clinical Trial

- **Results expected mid-August to mid-September 2025**
- **New Drug Application (NDA) submission in the U.S. targeted for H1 2026**

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Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that the last patient has completed the Denali Phase 3 trial, evaluating the efficacy and safety of NCX 470, its lead compound, in patients with open-angle glaucoma or ocular hypertension. With this milestone reached, all patients have now completed their treatment and follow-up visits.

A total of 696 patients were enrolled in the trial and topline results are expected mid-August to mid-September 2025.

"*Reaching the milestone of the last patient last visit in the Denali Phase 3 trial is a great achievement by our clinical sites, our partner Ocumension and the Nicox development team who have continued to drive this trial. I would like to thank everyone who has been involved in the conduct of the Denali trial including our patients, investigators and their staff.*" said **Doug Hubatsch, Chief Scientific Officer of Nicox** "*We look forward to announcing the topline results in the near future, which we expect will further consolidate the profile of NCX 470 and confirm its potential in the glaucoma market. We remain fully focused on completing the clinical development program and preparing for regulatory submissions.*"

NCX 470, Nicox's lead clinical product candidate, is a novel NO-donating bimatoprost eye drop, currently in Phase 3 clinical development for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. The Denali trial is evaluating the 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 already completed Mont Blanc trial, was designed to fulfil the clinical regulatory requirements to support New Drug Application (NDA) submissions of NCX 470 in the U.S. and China. All remaining NDA-enabling pharmacokinetic and non-clinical studies necessary to support the U.S. NDA filing are on track. Subject to securing a U.S. partner, or obtaining the necessary funding, the Company estimates that a NDA for this country NCX 470 could potentially be submitted in H1 2026.

Key Future Milestones

- **Denali Phase 3 clinical trial evaluating NCX 470 in patients with open-angle glaucoma or ocular hypertension:** Topline results are expected mid-August to mid-September 2025

- **NCX 470 Phase 3 clinical efficacy and long-term safety trials in Japan:** Initiation expected in H2 2025

- **NCX 470 NDA filing in the United States:** expected in H1 2026, subject to securing a U.S. partner, or obtaining the necessary funding

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 for Japan. 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.

Contacts

Nicox
Gavin Spencer
Chief Executive Officer
T +33 (0)4 97 24 53 00
communications@nicox.com

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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.
Sundesk Sophia Antipolis, Bâtiment C, Emerald Square, Rue Evariste Galois, 06410 Biot, France
T +33 (0)4 97 24 53 00