Press Release

Nicox Announces NCX 470 NDA Submission in China by Partner Ocumension

- **Ocumension has submitted the New Drug Application (NDA) to the Chinese National Medical Products Administration (NMPA) for NCX 470 to lower intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension**
- **Same data package as for the recent submission in the U.S.**
- **Ocumension already has an ophthalmology sales force throughout China**
- **Multiple NCX 470 clinical, approval and launch milestone events expected over the next 12 to 18 months**

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Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that its exclusive licensee in China, Ocumension Therapeutics, has submitted the New Drug Application (NDA) for NCX 470 as a treatment to lower intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension to the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA). The NDA includes the Phase 3 program of both the Mont Blanc trial, and the Denali trial, which specifically included Chinese clinical sites, allowing the program to complete the clinical requirements for approval in China, the same data as recently submitted to the U.S. FDA. Ocumension has already successfully obtained approval for a number of ophthalmology products in China.

"Nicox and Ocumension have been successfully collaborating since 2018 when we signed the first of multiple licensing deals between the two companies. Ocumension was a newly-incorporated company at that time and we are pleased to see that the confidence shown by both sides has been borne out with this next step on the way to the commercialisation of NCX 470 in China. Our second NCX 470 Phase 3 clinical trial, Denali, was conducted with a number of Chinese sites, in cooperation with Ocumension, allowing this submission to be made based on the same dossier as used for the United States." said **Gavin Spencer, Chief Executive Officer of Nicox.** *"NDAs for NCX 470 have now been submitted in two major territories, the United States and China, and Phase 3 trials to support a regulatory submission in Japan have been underway since summer 2025. NCX 470 is on the way to multiple approvals and launches over the next 12 to 24 months."*

"The working relationship between the Nicox and Ocumension teams has now been well established over several years, allowing us to proceed swiftly with the Chinese filing for NCX 470 after the documentation was available for the United States. Our established commercial operation in China, which already markets Nicox's ZERVIATE, is well-placed to launch this novel glaucoma treatment shortly after approval. In addition to being a key partner to Nicox, we are also pleased to have been able to support them as a shareholder and look forward to continuing to work together as we bring NCX 470 to the Chinese market." said **Victor Liu, Chief Executive Officer of Ocumension.**

Ocumension has paid Nicox license fees of €18 million for the rights to develop and commercialise NCX 470 in the Chinese, Korean and Southeast Asian markets, contributed 50% of the Denali clinical trial costs and is one of Nicox's principal shareholders. Nicox will receive tiered royalties on sales of NCX 470 made by Ocumension ranging from 6% to 12%. Ocumension already has an ophthalmology sales force in place throughout China and is therefore well-positioned for a rapid launch of NCX 470.

There is no fixed period for approval of a pharmaceutical product in China, however these are frequently granted in 12 to 18 months following submission. The approval of NCX 470 in China is expected after the approval in the US, where Nicox's partner Kowa recently submitted an NDA.

Key Upcoming NCX 470 Milestones

- **NDA approval in the United States:** Expected in summer 2027, based on a standard 12-month review period
- **Phase 3 clinical program in Japan:** initiated summer 2025
- **U.S. Launch:** expected in H2 2027
- **NDA approval in China:** Submission made in August 2026

About NCX 470

NCX 470 is a novel nitric oxide (NO)-donating bimatoprost eye drop that leverages the potent intraocular pressure (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 signalling molecule that plays a key role in the regulation of IOP through activation of soluble guanylate cyclase (sGC). NO brings additional IOP-lowering efficacy by enhancing aqueous humor drainage from the eye via a different mechanism of action to that of PGAs.

NCX 470 has completed two Phase 3 clinical trials designed to fulfil the regulatory requirements for safety and efficacy to support NDA submissions in the U.S. and China, Mont Blanc and Denali. Both trials were positive and met the efficacy endpoints necessary for submission of a New Drug Application in the United States and China.

About Nicox

Nicox SA is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's lead late-stage development program 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 in the rest of the world. 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).

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 2025*" 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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