Press Release

Nicox's NCX 470 New Drug Application Submitted in the United States by Kowa, with Associated €3 million Milestone Payment

- **NCX 470 New Drug Application (NDA) submitted to the U.S. Food and Drug Administration (FDA) by exclusive licensee Kowa Company, Ltd. (Kowa) for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension**
- **€3 million milestone payment due to Nicox, with a further milestone payment due upon approval**
- **Submission based on positive results from two Phase 3 clinical trials, Mont Blanc and Denali**
- **NCX 470 is exclusively licensed to Ocumension Therapeutics for the Chinese market, South Korea and Southeast Asia and to Kowa for Japan and the rest of the world**

July 1st, 2026 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced the submission of an NDA to the FDA for NCX 470 (also known as K-911), by exclusive U.S. licensee, Kowa, representing an important step toward potential commercialization in the U.S. NCX 470 (bimatoprost grenod), Nicox's lead clinical product candidate, is a novel nitric oxide-donating bimatoprost eye drop for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

"*Submission of the NDA for NCX 470 in the United States represents a major milestone for Nicox and reflects the dedication of our teams, our partners and the support of our clinical trial sites and patients. Based on the strength of the Phase 3 data from the Mont Blanc and Denali trials, NCX 470 has the potential to offer an important new treatment option for patients with glaucoma or ocular hypertension. We look forward to working closely with Kowa and the FDA during the review process.*" said **Doug Hubatsch, Chief Scientific Officer of Nicox.**

"*This collaboration shows the complementarity of the teams, with Nicox bringing in-depth expertise of the molecule and the development program, coupled with a strong external network, combining with Kowa's broad regulatory and commercial capabilities. We look forward to continuing to work together as we prepare for the commercial launch of NCX 470 in the U.S., which is planned to take place shortly after approval of the NDA in mid-2027.*" said **Junichi Kawagoe, Director and Senior Managing Executive Officer of Kowa.**

The NDA submission is supported by positive results from the Mont Blanc and Denali Phase 3 clinical trials, which together were designed to meet regulatory requirements for efficacy and safety in support of approval in the United States and in China. These trials demonstrated that NCX 470 achieved clinically meaningful reductions in IOP with a favorable safety profile.

The NCX 470 NDA is expected to be the subject of a standard 12-month review period, which would lead to approval in mid-2027, and an expected commercial launch in the U.S. before the end of 2027. Launch of NCX 470 will bring a new, sustainable and recurrent revenue stream to the Company.

NCX 470 Strategic Partnerships

NCX 470 is part of Nicox's global partnering strategy:

- In addition to the U.S., **Kowa** holds exclusive rights to develop and commercialize NCX 470 in Japan, where it has significant experience in glaucoma and a strong commercial presence, and in all other countries outside the Chinese market, South Korea and Southeast Asia. Phase 3 clinical trials on NCX 470 were initiated in Japan in the summer of 2025.
- **Ocumension Therapeutics** holds exclusive rights for China, where regulatory submission activities are expected to soon follow this U.S. filing.

These partnerships position NCX 470 for potential commercialization in key global markets. Nicox may receive regulatory and sales milestones and royalties on worldwide sales. All regulatory and commercialization costs are borne by Kowa and Ocumension.

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.

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

Disclaimer

The information contained in this document may be modified without prior notice. This information includes forward-looking statements. Such forward-looking statements are not guarantees of future performance. These statements are based on current expectations or beliefs of the management of Nicox S.A. and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Nicox S.A. and its affiliates, directors, officers, employees, advisers or agents, do not undertake, nor do they have any obligation, to provide updates or to revise any forward-looking statements.

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 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