Press Release

Nicox Announces April 2027 PDUFA Date for NCX 470 in Glaucoma

- **FDA sets Prescription Drug User Fee Act (PDUFA) review response date by 30 April 2027**
- **Two NDAs filed in major markets, with commercial partners in place for expected launches from H2 2027 onwards**
- **Milestone payment due on U.S. NDA approval plus royalties on sales**
- **NCX 470 Phase 3 program ongoing in Japan in support of approval**
- **Q&A available on Nicox's website**

August 27, 2026 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for NCX 470 (bimatoprost grenod; also known as K-911 in Kowa's publications) for filing and set 30 April 2027 as the Prescription Drug User Fee Act (PDUFA) date[1] for a response on review of the dossier. FDA acceptance confirms that the application is sufficiently complete for formal review and represents an important regulatory milestone toward potential approval. The NCX 470 NDA in the U.S. was submitted by Nicox's exclusive U.S. licensee, Kowa, on June 30, 2026, and a milestone payment will be due upon approval. NCX 470 is a nitric oxide-donating bimatoprost eye drop for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

"The FDA's acceptance of the NCX 470 NDA for filing is the next key step towards the approval of NCX 470 in the U.S., which would lead to a commercial launch in the second half of 2027. NCX 470 NDAs are now filed in two key markets, the U.S. and China. Subject to regulatory approval, we have clear paths to commercialisation with our partners, Kowa and Ocumension, respectively. Both partners have established commercial organisations in place to support launch of NCX 470 swiftly after approval is granted. U.S. NDA approval triggers a milestone payment for Nicox, and royalties on sales would generate a new recurrent revenue stream," said **Gavin Spencer, Chief Executive Officer of Nicox.**

The NDA submission was based on 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 China. These trials demonstrated that NCX 470 achieved clinically meaningful reductions in IOP of up to 10mmHg with a favourable safety profile.

Key Upcoming NCX 470 Milestones

[1] A PDUFA date is the target date by which the U.S. Food and Drug Administration (FDA) aims to complete its review and issue a decision on a New Drug Application (NDA) under the Prescription Drug User Fee Act (PDUFA).

- **Phase 3 clinical program in Japan:** ongoing
- **U.S. FDA Decision:** PDUFA date 30 April 2027
- **U.S. Launch:** targeted in H2 2027, subject to FDA approval
- **NDA approval in China:** NDA submitted August 2026

For further information on our commercialization partners in the U.S. and China, visit the websites of Kowa Pharmaceuticals America and Ocumension Therapeutics.

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, Mont Blanc and Denali, designed to fulfil the regulatory requirements for safety and efficacy to support NDA submissions in the U.S. and China. Both trials were positive and met the efficacy endpoints necessary for submission of a New Drug Application in the United States and China. NDAs for NCX 470 have been submitted in the U.S. and China. NCX 470 is an investigational product and has not yet been approved by the FDA.

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.

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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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