

Press Release

Nicox's Partner Kowa Initiates NCX 470 Phase 3 Clinical Trial in Japan

- **Exclusive Japanese partner Kowa has initiated a Phase 3 safety clinical trial of NCX 470 for the treatment of ocular hypertension in Japan**
- **Triggers a €2 million milestone payment to Nicox**

August 5, 2025 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that its exclusive Japanese partner, Kowa, has initiated a Phase 3 safety clinical trial of NCX 470 (also known as K-911) in Japan for the treatment of ocular hypertension, triggering a €2 million milestone payment to Nicox. Only one Phase 3 confirmatory clinical trial in Japanese patients, which will start shortly, plus this safety trial, is required for submission for marketing approval of NCX 470 in Japan. Kowa is responsible for financing and managing the trials under the [February 2024](#) license agreement with Nicox.

“Thanks to our continuing collaborative efforts after Kowa received approval to initiate this trial, we are very pleased to announce that the first patient has been enrolled. The Phase 3 trials in Japan are being managed and financed by Kowa, and only one confirmatory Phase 3 trial is expected to be needed to make a submission for marketing approval of NCX 470 in Japan.” said **Doug Hubatsch, EVP Scientific Officer of Nicox.**

The trial announced today is a safety trial and is detailed here: [JRCT Safety Trial NCX 470](#). The 500 patient confirmatory trial is expected to start shortly and is detailed here: [JRCT Confirmatory Trial NCX 470](#).

About NCX 470

NCX 470, Nicox's lead clinical product candidate, is a novel NO-donating bimatoprost eye drop, currently in Phase 3 clinical development programs in the U.S., China and Japan for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Results of Mont Blanc, the first of the Phase 3 clinical trials, have been extensively [published](#) and are available on our website. All patients have completed the second Phase 3 clinical trial, Denali, and topline results are expected mid-August to mid-September 2025. Mont Blanc and Denali have been designed to fulfil the regulatory requirements for safety and efficacy Phase 3 trials to support NDA submissions in both the U.S. and in China. A separate Phase 3 clinical program is underway to support Japanese approval. NCX 470 is exclusively licensed to Ocumension Therapeutics in China, Korea and Southeast Asia and to Kowa in the rest of the world.

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 elsewhere. 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.



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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