

# **Press Release**

# Nicox Announces up to €3 million in Milestone Payments from Kowa in 2025 as NCX 470 Prepares to Enter Phase 3 Clinical Trials in Japan

- Exclusive Japanese partner Kowa has received regulatory approval to initiate Phase 3 clinical trials on NCX 470 for the treatment of ocular hypertension in Japan
- Milestone payments from Kowa totaling €3 million expected to be received by Nicox in 2025
- Extends Nicox's cash runway until the end of 2025

# May 27, 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 for NCX 470, Kowa, has received Clinical Trial Notification (equivalent of a U.S. Investigational New Drug, IND) approval to initiate Phase 3 clinical trials on NCX 470 for the treatment of ocular hypertension in Japan, triggering a €1 million milestone payment to Nicox. The clinical trials are expected to be initiated in H2 2025, which would trigger a second milestone payment of €2 million.

"This important achievement, which enables the initiation of phase 3 clinical development of NCX 470 for Japanese patients, demonstrates the effective collaboration established between the Kowa and Nicox teams and represents a significant advance by Kowa in the delivery of their accelerated development plan. As a result, we expect to receive a total of €3 million in development milestones from Kowa in 2025, extending our cash runway until at least the end of 2025." said **Gavin Spencer, Chief Executive Officer of Nicox.** "We congratulate our Japanese partner on the swift progress and look forward to continuing to work with them to bring NCX 470 to the Japanese market."

# **Cash Runway**

Based on the current cash position, estimated revenue and anticipated milestone payments (including the Kowa milestones mentioned above) Nicox now estimates that it is financed until the end of 2025. If any of the assumptions around estimated income or costs change, this may impact the cash runway of the Company.

# **Key Future Milestones**

- Denali Phase 3 clinical trial evaluating NCX 470 in patients with open-angle glaucoma or ocular hypertension: Topline results are expected in the third quarter of 2025
- NCX 470 Phase 3 clinical trial in Japan: Initiation expected in H2 2025



## Kowa NCX 470 License

Nicox licensed the rights to develop and commercialize NCX 470 in Japan to Kowa in February 2024. Nicox may receive a further €7 million in development and regulatory milestones, up to €17.5 million in sales milestones and tiered royalties from 7% to 12% on net sales of NCX 470 in Japan. Kowa is responsible for all development, regulatory and commercialization costs for NCX 470 in Japan.

### 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 for the lowering of IOP in patients with openangle glaucoma or ocular hypertension. Results of Mont Blanc, the first of the two Phase 3 clinical trials, have been extensively published and are available on our website. The second Phase 3 clinical trial, Denali, is currently ongoing. The last American patient in Denali has completed their final visit, with Chinese patients completing theirs, and the results are expected in Q3 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, where NCX 470 is exclusively licensed to Ocumension Therapeutics. NCX 470 is also licensed exclusively to Kowa for Japan.

#### **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. 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

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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 2024*" which is available on Nicox's website (<u>www.nicox.com</u>).

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.

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