

Press Release

Nicox Estimates Potential Annual Global Net Sales for NCX 470 of over \$300 million

- NCX 470 therapeutic profile positively received among U.S. eye care professionals in a market survey conducted with a leading, independent research agency
- Potential annual global net sales for NCX 470 estimated to reach at least \$300 million within 8 years from the date of launches in U.S. and China
- Nicox currently seeking U.S. and Japanese commercial partners for NCX 470

July 10, 2023 – release at 7:30 am CET Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today provided details of a U.S. market survey evaluating the commercial potential of NCX 470, a nitric oxide (NO)-donating bimatoprost, in development for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension and estimated potential global annual net sales for NCX 470.

"We recently conducted a market survey with a leading, independent research agency in the United States which confirmed the interest from ophthalmologists and optometrists in the potential use of NCX 470 as a therapeutic option for patients who do not reach their target intraocular pressure. The research also informed our potential pricing and reimbursement strategies, which we have factored into our assessment of the potential sales." said **Andreas Segeros, CEO of Nicox.** "Based on this data, and insights from our Chinese and Southeast Asian partner, Ocumension Therapeutics, together with estimates of sales in other territories, we believe that annual global net sales of NCX 470 could be over \$300 million within 8 years of the date of launches in the U.S. and China."

About NCX 470

NCX 470, a novel NO-donating bimatoprost eye drop, is currently in Phase 3 clinical development for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension. Results of Mont Blanc, the first of the two Phase 3 clinical trials, were <u>announced</u> in October 2022. The second Phase 3 clinical trial, Denali, is currently ongoing, and the results are expected¹ in 2025. Mont Blanc and Denali have been designed to fulfill 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 protected worldwide by composition of matter patents until 2029, with potential extension of up to 5 years in the U.S. and Europe, and by formulation patents to 2039 in the U.S., EU, Japan and China as well as other territories.

Basis of Estimated Sales Forecast

The primary market research in the U.S. assumed NCX 470 obtained U.S. FDA approval with the safety and efficacy profile seen in the Mont Blanc Phase 3 trial. The research involved ophthalmology key opinion leaders, prescribers and payors in a qualitative phase, followed by 100 glaucoma prescribers in a quantitative internet survey. Taking into account expected genericization of the market, basing the undiscounted price on appropriate branded references, and applying appropriate discounts, the net

¹ This date is based on projections of increased recruitment which take notably into account the lifting of COVID-19 restrictions in China. www.nicox.com



annual sales potential in the U.S. alone was estimated at between \$115 and \$165 million by year 8. Ocumension Therapeutics, our exclusive licensing partner in China and Southeast Asia, has also conducted market evaluation and provided a forecast of NCX 470 sales for their territory. We assume approval in the U.S. and China in a similar timeframe, with the NDA submissions in both territories made after the results of the Denali Phase 3 trial expected in 2025². The global net sales estimate also includes assessments of potential sales outside of the U.S. and China. We are currently looking for U.S. and Japanese commercial partners and would also seek partners in other territories which can use the U.S. approval closer to that time. Our assumptions consider that those partnerships are in place at the appropriate time to maximize the revenue potential. We are not currently assuming revenue from sales in Europe, which could be a potential upside pending discussions with the European Medicines Agency on the appropriate regulatory route to approval.

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, a novel nitric oxide-donating bimatoprost, for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension. The company is also conducting research on NCX 1728, a nitric oxide-donating phosphodiesterase 5 inhibitor, in retinal conditions. NCX 4251, a novel, patented, ophthalmic suspension of fluticasone propionate nanocrystals for topical ocular application for dry eye disease, is being developed by Ocumension Therapeutics in China under an exclusive license agreement and is available for partnering elsewhere. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIATE® in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance Pharmaceuticals, LLC (a wholly owned subsidiary of Santen Pharmaceutical Co., Ltd.), 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 on Nicox, its products or pipeline, please visit: 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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Forward-Looking Statements

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 2.7 of the 'Rapport Annuel 2022' which is available on Nicox's website (<u>www.nicox.com</u>).



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