

Press Release

Additional Future Royalty Revenue Stream for Nicox from 2024 following New Drug Application Submission for ZERVIAE in China

- **Nicox's partner, Ocumension Therapeutics, submits a New Drug Application for ZERVIAE in China**
- **ZERVIAE® approval and launch expected in China in 2024**
- **Additional future royalty revenue stream for Nicox with Ocumension forecasting potential annual net sales of >\$100 million within 7 years**

April 14, 2023 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that its exclusive Chinese partner, Ocumension Therapeutics, has submitted a New Drug Application (NDA) for approval to commercialize ZERVIAE® (cetirizine ophthalmic solution), 0.24%, in China, for ocular itching associated with allergic conjunctivitis. The approval process is expected to take around 12 months, leading to a potential launch of ZERVIAE in China in 2024. Ocumension plans to manufacture ZERVIAE in their new state-of-the-art purpose-built manufacturing facility located in Suzhou, China.

“Ocumension is a strong partner for Nicox, and we are pleased to see the submission of this New Drug Application, following the completion of an additional Chinese Phase 3 trial carried out by Ocumension. Alongside a broad portfolio of ophthalmology assets in development, Ocumension has also built a commercial operation in China, which will be able to add ZERVIAE directly into their detailing activities upon approval.” said **Gavin Spencer, Chief Business Officer of Nicox**. *“The approval and launch of ZERVIAE in 2024 would add another royalty revenue stream to Nicox, on potential annual net sales which Ocumension forecasts will be over \$100 million within 7 years in China. We look forward to Ocumension also expanding the availability of ZERVIAE to the other Southeast Asian markets they have rights to.”*

“Having built our development pipeline, Ocumension is now seeing the fruits of that pipeline as products arrive at commercialization. ZERVIAE is the first of these to come from our valuable collaboration with Nicox, and we look forward to following this with NCX 470 in glaucoma.” said **Liu Ye, Chief Executive Officer of Ocumension Therapeutics**.

ZERVIAE is the first and only eye drop formulation of the antihistamine cetirizine, the active ingredient in ZYRTEC®, and is currently commercialized in the U.S. for ocular itching associated with allergic conjunctivitis. The prescription market for allergic conjunctivitis products in China is expected to grow to almost \$500 million by 2030.

The ZERVIAE NDA in China is supported by the data package licensed by Nicox to Ocumension and an additional Chinese Phase 3 clinical trial of ZERVIAE run by Ocumension. ZERVIAE was compared to emedastine difumarate ophthalmic solution, 0.05%, an antihistamine marketed under the brand name EMADINE®. ZERVIAE was found to be non-inferior to emedastine difumarate in the primary efficacy endpoint of change from baseline in the itching score in the 24 hours prior to the Day 14 visit. ZERVIAE was safe and well-tolerated with no difference in the proportion of patients with adverse events compared to emedastine difumarate.

ZERVIAE is exclusively licensed to Ocumension Therapeutics for development and commercialization in the Chinese and the majority of the Southeast Asian markets. All costs of commercialization are borne by Ocumension and Nicox may potentially receive sales milestones of up to US\$17.2 million together with royalties of between 5% and 9% of net sales of ZERVIAE by Ocumension.

Ocumension's Press Release can be found [here](#).

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 ZERVIAE® in allergic conjunctivitis, licensed in multiple geographies, including to Eyeavance 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 Paris (Compartment C: Mid Caps; Ticker symbol: COX) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes.

For more information on Nicox, its products or pipeline, please visit: www.nicox.com.

Analyst coverage

Bryan, Garnier & Co	Eric Yoo	Paris, France
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Kepler Cheuvreux	Arsene Guekam	Paris, France



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Forward-Looking Statements

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Risks factors which are likely to have a material effect on Nicox's business are presented in the 3rd chapter of the 'Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2021' filed with the French *Autorité des Marchés Financiers* (AMF) on April 29, 2022 whose first amendment has been filed with the AMF on May 19, 2022, in the 2nd chapter of the second amendment filed with the AMF on November 22, 2022 and in the 2nd chapter of the Securities noted filed with the AMF on November 22, 2022 which are available on Nicox's website (www.nicox.com)

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