Press Release

Nicox's Partner Ocumension Therapeutics Receives Priority Review Status for ZERVIATE New Drug Application in China

- **Nicox's partner, Ocumension Therapeutics, announced on April 26, 2023, that they had received Priority Review Status for the New Drug Application for ZERVIATE in China**

- **Accelerates the ZERVIATE® approval and launch, which are expected in China in 2024**

April 28, 2023 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that the New Drug Application (NDA) for approval to commercialize ZERVIATE® (cetirizine ophthalmic solution), 0.24%, submitted in China by its exclusive Chinese partner, Ocumension Therapeutics, has been included in the priority review and approval process of National Medical Products Administration of the People's Republic of China ("NMPA"). This will accelerate the approval process and potentially the launch of ZERVIATE in China.

ZERVIATE 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. Ocumension is forecasting potential annual net sales of ZERVIATE >$100 million within 7 years.

The ZERVIATE NDA in China is supported by the data package licensed by Nicox to Ocumension and an additional Chinese Phase 3 clinical trial of ZERVIATE run by Ocumension. ZERVIATE was compared to emedastine difumarate ophthalmic solution, 0.05%, an antihistamine marketed under the brand name EMADINE®. ZERVIATE 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. ZERVIATE was safe and well-tolerated with no difference in the proportion of patients with adverse events compared to emedastine difumarate.

The priority review and approval process of NMPA is designed to expedite the approval of drugs that address unmet medical needs or have the potential to offer significant improvements over existing treatment options. The inclusion of ZERVIATE in the priority review and approval process of NMPA will accelerate the review and approval process of its new drug application, which is an important step towards commercialization of ZERVIATE.

ZERVIATE 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 ZERVIATE 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 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 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

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.

Contacts

Nicox
Gavin Spencer
Executive Vice President, Chief Business Officer
& Head of Corporate Development
T +33 (0)4 97 24 53 00
communications@nicox.com

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 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)

Nicox S.A.
Drakkar 2
Bât D, 2405 route des Dolines
06560 Valbonne, France
T +33 (0)4 97 24 53 00
F +33 (0)4 97 24 53 99