

## Press Release

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# Nicox's Partner Ocumension Obtains Positive Phase 3 Clinical Trial Results for ZERVIAE® in China

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- **ZERVIAE® (cetirizine ophthalmic solution), 0.24% was non-inferior to comparator emedastine difumarate ophthalmic solution, 0.05%**
- **Allergic conjunctivitis market in China worth almost \$0.5 billion by 2030**

March 1<sup>st</sup>, 2022 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced positive results in a Chinese Phase 3 clinical trial of ZERVIAE® (cetirizine ophthalmic solution), 0.24%, run by its Chinese partner, Ocumension Therapeutics. 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. This clinical trial is required for Ocumension to be able to submit a New Drug Application (NDA) for approval to commercialize ZERVIAE in China.

*“The successful completion of this clinical trial is an important step towards commercialization of ZERVIAE in China and we congratulate our partner, Ocumension, on its swift execution. Ocumension is able to use Nicox’s data previously generated on ZERVIAE in the United States, supplemented with this clinical trial, to support their application for approval of ZERVIAE”* said **Gavin Spencer, Chief Business Officer of Nicox**. *“We look forward to seeing ZERVIAE on the market in China, as well as the territories in the Far East where Ocumension has licensed the rights, and we continue to collaborate with our other partners to obtain approval for ZERVIAE in multiple geographies.”*

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 \$0.5 billion by 2030.

### Clinical Trial Design

This was a randomized, observer-masked, Phase 3 clinical trial to evaluate the safety and efficacy of ZERVIAE (cetirizine ophthalmic solution), 0.24% dosed twice daily compared to emedastine difumarate ophthalmic solution, 0.05% dosed twice daily in Chinese patients with allergic conjunctivitis. The treatment period was 14 days and the primary efficacy endpoint was a non-inferiority analysis of the change from baseline in the itching score within the 24 hours prior to the Day 14 visit. A total of 296 patients were randomized across multiple clinical sites in China.

### ZERVIAE Partnerships

ZERVIAE is exclusively licensed to Ocumension Therapeutics for development and commercialization in the Chinese and the majority of the Southeast Asian markets. 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. ZERVIAE is commercialized in the U.S. by our exclusive U.S. partner Eyevance Pharmaceuticals, a wholly-owned subsidiary of Santen Pharmaceutical Co., Ltd of Japan, and is also exclusively licensed to Samil Pharmaceutical in South Korea, to ITROM Pharmaceutical Group in certain Gulf and Arab markets, and to Laboratorios Grin in Mexico.

## About Nicox

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Nicox S.A. 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 prostaglandin analog, for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for dry eye disease. 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, in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of South East Asian markets.

Nicox is 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](http://www.nicox.com).

## Analyst coverage

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Bryan, Garnier & Co	Dylan van Haaften	Paris, France
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Kepler Cheuvreux	Damien Choplain	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.*

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## Forward-Looking Statements

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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 3<sup>rd</sup> chapter of the 'Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2020' filed with the French *Autorité des Marchés Financiers* (AMF) on March 1, 2021 and in the 2<sup>nd</sup> chapter of the amendment to the "Document d'Enregistrement Universel, rapport financier annuel et rapport de gestion 2020" filed with the AMF on December 9, 2021 which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).

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