

## Press Release

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# Nicox Highlights Successful 2020 Development Progress and Clinical Milestones for 2021

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- **Initiated two Phase 3 trials with NCX 470 in glaucoma and a Phase 2b trial with NCX 4251 in blepharitis in 2020**
- **Partner Ocumension Therapeutics initiated a Phase 3 trial in China with ZERVIAE™ in allergic conjunctivitis in December 2020**
- **Top-line results for NCX 470 Mont Blanc Phase 3 trial and NCX 4251 Mississippi Phase 2b trial both currently due in Q4 2021**

January 5, 2021 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today highlighted the strong progress in its development programs in 2020 and the key clinical milestones expected in 2021.

**Michele Garufi, Chairman and Chief Executive Officer of Nicox**, stated “*We have positioned ourselves as a major player among international ophthalmic R&D companies. We achieved outstanding progress in 2020 with the start of four large clinical trials, covering our three major assets, despite the challenging environment caused by the COVID-19 pandemic. Looking ahead, we expect significant milestones in 2021, above all the results from late-stage clinical trials with our lead assets NCX 470 and NCX 4251. Furthermore, thanks to our unique advantage of having licensing revenue from two products commercialized in the U.S., and partnered in other markets, we anticipate steadily increasing revenue for many years to come to support our growth.*”

### Overview of Our Late-Stage Clinical Pipeline

- **NCX 470**, Nicox’s lead clinical product candidate, a novel nitric oxide (NO)-donating prostaglandin analog, is being evaluated in the **Mont Blanc** and **Denali Phase 3 clinical trials** for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Top-line results are currently expected in Q4 2021 for Mont Blanc and in Q4 2022 for Denali. Together Mont Blanc and Denali trials will support New Drug Application (NDA) submissions in the U.S. and China.
- **NCX 4251**, a novel patented ophthalmic suspension of fluticasone propionate nanocrystals, is being evaluated in the **Mississippi Phase 2b clinical trial** for the treatment of acute exacerbations of blepharitis. Top-line results are currently expected in Q4 2021. If successful in meeting the primary efficacy endpoint previously agreed with the U.S. Food and Drug Administration (FDA), the Mississippi trial could represent the first of two pivotal trials needed to support the submission of an NDA for the treatment of blepharitis in the U.S.
- **ZERVIAE™**, (cetirizine ophthalmic solution), 0.24%, the first and only topical ophthalmic formulation of the antihistamine cetirizine, is being evaluated in a confirmatory Phase 3 clinical trial in China by our partner Ocumension, to support a Chinese New Drug Application. ZERVIAE is already commercialized in the U.S. by our partner Eyevence Pharmaceuticals, which was acquired by Santen Pharmaceutical Co., Ltd of Japan in September 2020 for \$225 million.

*We continue to closely watch the spread and impact of the COVID-19 pandemic. We do not currently anticipate delays in our clinical timelines but we are monitoring the situation and will provide an update when needed.*

[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, second-generation nitric oxide-donating prostaglandin analog, for lowering intraocular pressure in patients with glaucoma. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for acute exacerbations of blepharitis. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, and ZERVIA™ 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 B: 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

Bryan, Garnier & Co	Victor Floc'h	Paris, France
Cantor Fitzgerald	Louise Chen	New York, U.S.
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Kepler Cheuvreux	Damien Choplain	Paris, France
Oppenheimer & Co	Hartaj Singh	New York, U.S.



*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 the 3<sup>rd</sup> chapter of the 'Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2019' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2020 which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)) and as restated in the 4th chapter of the half yearly financial report as of June 30, 2020, which is also available on Nicox's website.

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