Press Release

Nicox Announces First Patient in China screened in the ongoing NCX 470 Denali Phase 3 Trial in Glaucoma

- **Denali Phase 3 co-funded equally by Nicox and Ocumension Therapeutics**
- **Phase 3 program supports submission of both U.S. and China NDAs**

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Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that the first patient has been screened in China in the ongoing Denali Phase 3 clinical trial, opening the way for New Drug Application (NDA) submissions in both the United States (U.S.) and China for NCX 470, Nicox's lead clinical product candidate in glaucoma. Denali, which also includes a long-term safety extension, has been recruiting patients in the U.S. since November 2020. Approximately 670 patients are expected to be randomized at approximately 60 clinical sites in the U.S. and China, with approximately 80% of the patients to be recruited in the U.S. and the remaining ~20% of the patients to be recruited in China. This is the first patient to be enrolled in the Chinese part of the trial. Results from Denali are expected by the end of 2023.

The Denali Phase 3 trial evaluates the intraocular pressure (IOP) lowering efficacy of once-daily dosed NCX 470 ophthalmic solution 0.1% compared to latanoprost ophthalmic solution 0.005% in patients with open-angle glaucoma or ocular hypertension. Denali is a multiregional (U.S. and China) clinical trial financed equally by Nicox and Ocumension, Nicox's exclusive licensee for China, Korea and Southeast Asia. The inclusion of Chinese patients in the Denali trial is essential to satisfy the requirements of Chinese regulatory authority, the National Medical Products Administration. The Denali trial was designed to fulfill the regulatory requirements to support NDA submissions of NCX 470 in the U.S. and China.

Gavin Spencer, Chief Business Officer of Nicox commented *"The initiation of the Chinese part of the Denali trial marks an important step forward in the realization of the multiregional clinical strategy that we have adopted through our agreements with Ocumension. By supporting dual regulatory submissions in high-value markets – the U.S. and China – we can bring next-generation intraocular pressure-lowering treatments rapidly and efficiently to patients. Our partnership with Ocumension potentially accelerates the development of multiple programs, not only NCX 470 but also ZERVIATE® and NCX 4251."*

NCX 470 is a novel nitric oxide-donating prostaglandin analog with the potential for greater IOP lowering activity than currently marketed products. In addition to the Denali trial, NCX 470 is also being evaluated in the Mont Blanc Phase 3 clinical trial, with its results expected in Q1 2023.

"NCX 470 is one of the key development assets in our pipeline, allowing us to bring an efficacious, novel therapeutic into the Chinese glaucoma market, which is expected to grow exponentially over the next decade. The approach of Nicox in designing a multi-regional, US-China Phase 3 program has accelerated the development of NCX 470 for us, and we are pleased with the Nicox collaboration on all fronts." added **Victor Liu, Chief Executive Officer of Ocumension Therapeutics.**

Nicox has licensed exclusive rights to Ocumension for NCX 470 in China, Korea and Southeast Asia. Ocumension has paid €18 million to Nicox, and is also funding 50% of the Denali Phase 3 clinical trial costs. Nicox also stands to receive tiered royalties of between 6% and 12% on sales of NCX 470 by Ocumension. Ocumension is a Chinese ophthalmology company that listed on the Hong Kong stock exchange in 2020 (HKEX: OCUMENSION-B (1477), Market Capitalization USD $1.4 billion).

Ocumension also has rights to ZERVIATE® in China and the majority of Southeast Asia, and is currently running a Phase 3 clinical trial intended to support an application for regulatory approval for allergic conjunctivitis in China. Ocumension also has rights in China to Nicox's second clinical product candidate, NCX 4251.

About NCX 470

NCX 470 is a novel, potential best-in-class, nitric oxide (NO)-donating prostaglandin analog monotherapy in development to reduce intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Glaucoma is a group of ocular diseases in which the optic nerve is injured, leading to peripheral and, ultimately, central visual field loss and it can eventually lead to blindness if not treated. It is frequently linked to abnormally high IOP (~90% of patients) due to blockage or malfunction of the eye's aqueous humor drainage system in the front of the eye. In 2020, worldwide sales of treatments targeting glaucoma were over $6.0 billion out of a $24.3 billion worldwide market for ophthalmic drugs.

NCX 470 is designed to release both bimatoprost and NO following instillation into the eye. Bimatoprost, marketed under the brand name LUMIGAN® by Allergan, Inc., is one of the leading products in the class of prostaglandin analogs, the most widely used class of drugs for IOP-lowering in patients with open-angle glaucoma or ocular hypertension.

About Nicox

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 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 ZERVIATE® in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of Southeast 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.

Analyst coverage

Bryan, Garnier & Co	Victor Floc'h	Paris, France
Cantor Fitzgerald	Louise Chen	New York, U.S.
Edison Investment Research	Pooya Hemami	London, UK
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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 2020*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 1, 2021 and in the 2nd 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).

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