

Press Release

Nicox Accelerates Topline Results from NCX 470 Mont Blanc Phase 3 Glaucoma Trial to November 2022

- **Phase 3 Mont Blanc clinical trial approaches study completion with screening closed**
- **These Phase 3 results will be a key milestone for the Company**

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Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that it has closed screening for additional patients in its Phase 3 Mont Blanc clinical trial of NCX 470 0.1% in patients with open-angle glaucoma or ocular hypertension. Therefore, the Company now expects to advance the announcement of the Mont Blanc topline results to November this year, as opposed to Q1 2023. NCX 470 0.065% has already demonstrated a statistically significant greater reduction of intraocular pressure compared to latanoprost 0.005% in a Phase 2 trial and is being evaluated in Phase 3 at a higher concentration than was tested in Phase 2.

“Thanks to the efficiency of Nicox’s clinical team and the tremendous effort of our clinical sites we now expect to be able to announce topline results from Mont Blanc ahead of schedule in November of this year. These first Phase 3 results for NCX 470 will be a key milestone for Nicox, defining what we expect to be a best-in-class intraocular pressure lowering profile, and potentially opening up multiple opportunities for this program and the Company.” said **Andreas Segerros, Chief Executive Officer of Nicox**. *“The Phase 2 efficacy results showed up to 1.4 mmHg superior intraocular pressure lowering with NCX 470 compared to latanoprost 0.005%. The Mont Blanc trial is testing a higher concentration of NCX 470, and so could potentially demonstrate even greater efficacy. In addition, the NCX 470 results on retinal cell protection in animal models recently presented at ARVO 2022 also open the way to a further differentiated product profile.”*

NCX 470 Phase 2 results and Phase 3 trial design

In the earlier Dolomites Phase 2 clinical trial, NCX 470 0.065% [demonstrated](#) statistical superior lowering of intraocular pressure of up to 1.4 mmHg compared to latanoprost 0.005% at Day 28. The results of the Dolomites trial were recently [published](#) in the *Journal of Glaucoma*. Mont Blanc is a Phase 3 clinical trial in patients with elevated intraocular pressure due to open-angle glaucoma or ocular hypertension. The Mont Blanc Phase 3 trial had an initial adaptive design period during which NCX 470 0.065% was evaluated together with the higher concentration of NCX 470 0.1%. Following the adaptive design period, the NCX 470 0.1% concentration was chosen to continue in the Mont Blanc Phase 3 trial, and was used to initiate the second Phase 3 clinical trial, Denali. Mont Blanc continued after the adaptive design period as a multi-regional, double-masked, 3-month, parallel group trial evaluating the efficacy and safety of NCX 470 ophthalmic solution 0.1% compared to latanoprost ophthalmic solution, 0.005%. Latanoprost is the most widely prescribed first-line therapy for open-angle glaucoma or ocular hypertension. The primary efficacy evaluation in Mont Blanc is based on time-matched IOP at 8 AM and 4 PM at Week 2, Week 6 and Month 3.

Nicox retains 100% of the rights to NCX 470, notably in U.S., Europe and Japan, other than those licensed to its partner Ocumension Therapeutics in China and elsewhere in the Far East. Nicox intends to continue developing NCX 470 itself in the U.S., and to partner in other key territories, particularly in Japan, as a key market opportunity. The Denali topline results are expected after 2023 and the Company will announce a new date for availability of the results when we have a more firm estimate of the overall timelines of the trial.

About Glaucoma and NCX 470

Glaucoma is a disease of the optic nerve which, if left untreated, can lead to irreversible vision loss. Glaucoma is frequently linked to elevated intraocular pressure (90% of patients) and is often due to blockage in the drainage system located in the front of the eye. Currently, reducing intraocular pressure remains the only way to slow the progression of the disease. About 3 million people in the United States between 40 and 80 years of age are affected by the most common form of glaucoma, open-angle glaucoma.

NCX 470 is a novel, potential best-in-class, nitric oxide (NO)-donating prostaglandin analog eye drop designed to release bimatoprost and NO following instillation into the eye. Bimatoprost, marketed under the brand name LUMIGAN® by AbbVie, Inc., is one of the leading branded products in the class of prostaglandin analogs. Prostaglandin analogs are the most widely used class of drugs for IOP-lowering in patients with open-angle glaucoma or ocular hypertension. NCX 470 is in development to reduce IOP in patients with open-angle glaucoma or ocular hypertension. Nitric oxide brings additional IOP-lowering efficacy by enhancing aqueous humor drainage from the eye via a different mechanism of action than that engaged by prostaglandin analogs.

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 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 ZERVIA® 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

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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 which is available on Nicox's website (www.nicox.com)



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