

Press Release

Nicox Initiates First Phase 3 Trial of NCX 470 in Glaucoma

- **Mont Blanc clinical trial to randomize 600+ patients at sites primarily across the U.S.**
- **Adaptive dose selection in Mont Blanc allows the start of the second Phase 3 trial, Denali**
- **NCX 470 will compete in the >\$6 billion worldwide glaucoma market¹**

June 2, 2020 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced the initiation of the first Phase 3 clinical trial, named Mont Blanc, evaluating NCX 470 for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, by enrolling the first 12 patients yesterday. NCX 470 is the company's novel, second-generation nitric oxide (NO)-donating bimatoprost analog.

The Mont Blanc trial is a multi-regional, double-masked, 3-month, parallel group, adaptive design trial evaluating the efficacy and safety of NCX 470 ophthalmic solution, 0.065% and 0.1% compared to latanoprost ophthalmic solution, 0.005% in patients with open-angle glaucoma or ocular hypertension. In an adaptive portion of the trial, one NCX 470 dose will be selected to continue in the subsequent head-to-head 3-month safety and efficacy evaluation of NCX 470 vs. latanoprost. The primary efficacy evaluation is based on time-matched IOP at 8 AM and 4 PM at Week 2, Week 6 and Month 3. The trial is expected to randomize 600+ patients, primarily at clinical sites in the U.S. and at a small number of clinical sites in China.

Michele Garufi, Chairman and Chief Executive Officer of Nicox, said, *“The initiation of the Mont Blanc trial is a pivotal step forward for Nicox. The Dolomites Phase 2 trial has already shown that we have an excellent product candidate in our hands by demonstrating that NCX 470 0.065% is statistically superior vs. latanoprost in IOP lowering. NCX 470 is Nicox’s lead product candidate and value driver, with the potential to be an improvement over the current standard of care for patients with elevated IOP.”*

Tomas Navratil, PhD, EVP & Head of R&D of the Nicox Group and General Manager of Nicox Ophthalmics, Inc., said, *“We have assembled a group of top glaucoma clinical investigators who are enthusiastic to participate in the Mont Blanc trial, based on the promising NCX 470 results from our Phase 2 Dolomites trial. The adaptive design of the Mont Blanc trial will allow us to select the optimal NCX 470 dose for the remainder of the trial and, shortly thereafter, to start our second Phase 3 trial, Denali. Both of these pivotal trials benefit from agreement by the U.S. Food and Drug Administration to conduct the primary efficacy analysis based on time-matched IOPs at 8 AM and 4 PM, rather than the traditional 8 AM, 10 AM and 4 PM measurements, due to Nicox’s use of latanoprost as the active comparator in both the Mont Blanc and Denali trials.”*

In the Phase 2 Dolomites trial, NCX 470 demonstrated both statistical non-inferiority and superiority to latanoprost, the U.S. standard of care for patients with open-angle glaucoma and ocular hypertension, and the market leader in prostaglandin analog prescriptions. We believe the 7.6 to 9.8 mmHg IOP reduction from baseline at 8 AM, 10 AM and 4 PM across the Week 1, 2 and 4 Visits in the Dolomites trial is the highest reduction demonstrated by an eye drop in a glaucoma clinical trial.

COVID-19 Situation

Due to potential delays caused by COVID-19, the Company is not currently providing a target date for the Mont Blanc topline results. Although we currently do not anticipate delays to our clinical timelines, we are closely monitoring the situation and will apprise the market if there is any impact on our development timelines.

Notes:

1. IQVIA Analytics Link 2019

About Glaucoma

Glaucoma is a group of ocular diseases in which the optic nerve is injured, leading to peripheral and, ultimately, central visual field loss. Glaucoma can eventually lead to blindness if not treated and is currently considered to be one of the three leading causes of irreversible blindness worldwide. Glaucoma is frequently linked to abnormally high intraocular pressure (IOP) due to blockage or malfunction of the eye's aqueous humor drainage system in the front of the eye. Current medications are targeted at reducing IOP to slow the progression of the disease. The requirement for multiple medications to lower an individual patient's IOP to their target level highlights the need for more effective treatments.

In 2019, worldwide sales of treatments targeting glaucoma were over \$6.0 billion out of a \$21.9 billion worldwide market for ophthalmic drugs. In the U.S., sales of treatments targeting glaucoma totaled \$3.2 billion in 2019 or 37% of the \$8.8 billion U.S. market for ophthalmic drugs. Of the U.S. sales of treatments targeting glaucoma, \$1.5 billion, or almost 50%, was sales of prostaglandin analogs, of which nearly 90% were branded products, led by Lumigan (bimatoprost ophthalmic solution), 0.01% and Travatan Z (travoprost ophthalmic solution), 0.004%. Currently, we estimate that 3.5% of the worldwide population between 40 and 80 years of age are affected by the most common forms of glaucoma, and we estimate that, in 2018, around 36 million prescriptions were written in the U.S. annually for glaucoma drugs.

About NCX 470

NCX 470 is a novel, second generation nitric oxide (NO)-donating bimatoprost analog in development for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. 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 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 bimatoprost 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 Eyevence Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and 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.
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Oppenheimer & Co	Hartaj Singh	New York, U.S.



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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 2019*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2020 which are available on Nicox's website (www.nicox.com).

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