

Press Release

Nicox Selects 0.1% NCX 470 Dose in Adaptive Stage of Mont Blanc Phase 3 Glaucoma Trial

- **The 0.1% dose of NCX 470 was selected in the adaptive stage of the Mont Blanc Phase 3 trial**
- **This dose selection enables the second part of the Mont Blanc Phase 3 trial with a 1:1 head-to-head comparison vs latanoprost**
- **The dose selection also enables the start of Denali, the second NCX 470 Phase 3 trial, before the end of the year**

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Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced the selection of the 0.1% dose of NCX 470 for Phase 3 following the completion of the adaptive portion of the Mont Blanc Phase 3 clinical trial. As is customary for adaptive design trials, in order to maintain the integrity of the trial, no data from the adaptive portion of the trial will be disclosed until the completion of the trial. NCX 470, Nicox's lead clinical product candidate, is a novel second generation nitric oxide (NO)-donating bimatoprost analog. NCX 470 is licensed to Ocumension Therapeutics for the Chinese, Korean and South East Asian markets.

“Selecting the dose for the remaining Phase 3 trials is an important milestone in the development of this high potential, novel molecule, and progress on the overall program continues to meet our expectations. This progress demonstrates excellent performance by our development team and clinical sites in the current environment, allowing us to maintain our targeted timeline and announce top-line results from Mont Blanc by the end of 2021.” said **Dr. José Boyer, Vice President and Head, Clinical Development at Nicox.**

NCX 470 Phase 3 Clinical Program

Mont Blanc is a Phase 3 clinical trial evaluating NCX 470 for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. It was initiated on June 1, 2020, and currently has 48 clinical sites enrolling patients. Following the completion of the adaptive design portion of the trial announced today, Mont Blanc will continue 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%, the most widely prescribed first-line therapy for glaucoma and ocular hypertension, randomized in a 1:1 ratio. 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 Mont Blanc trial is expected to randomize approximately 670 patients, at approximately 50 clinical sites in the U.S. and at a small number of clinical sites in China. At current recruitment rates, top-line results from Mont Blanc are expected in Q4 2021.

Denali, the second Phase 3 glaucoma clinical trial, which will be jointly managed and equally funded by Nicox and our partner Ocumension Therapeutics, is expected to start before the end of this year, and will compare NCX 470 ophthalmic solution, 0.1% to latanoprost ophthalmic solution, 0.005%, randomized in a 1:1 ratio. It will include clinical sites in both the U.S. and China, with the majority of the patients being in the U.S. Ocumension Therapeutics has exclusive rights for the development and commercialization of NCX 470 in the Chinese, Korean and South East Asian markets. The Denali trial was designed to fulfill the regulatory requirements to support NDA filings in the U.S. and China.

We continue to closely watch the spread of COVID-19 and its impact. We do not currently anticipate delays to our clinical timelines but we are monitoring the situation and will provide updates if there is an impact on our development projects and timelines.

NCX 470 Phase 2 Clinical Data

In the Phase 2 Dolomites trial, NCX 470 ophthalmic solution, 0.065%, demonstrated both statistical non-inferiority and superiority to latanoprost ophthalmic solution, 0.005%. 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 for the 0.065% dose of NCX 470 in the Dolomites trial is the highest reduction demonstrated by an eye drop in a glaucoma clinical trial to date.

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 Eyevance 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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