

Press Release

Nicox's Positive End-of-Phase 2 Meeting with the U.S. FDA Sets Stage for NCX 470 Phase 3 Program in Glaucoma

March 5, 2020 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, announced today that it has successfully completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and agreed on the design for the NCX 470 Phase 3 program, as well as nonclinical and CMC plans supporting submission of a New Drug Application (NDA) in the U.S. NCX 470, a novel second generation nitric oxide (NO)-donating bimatoprost analog for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, is Nicox's lead clinical development program.

In the multicenter, Phase 2 clinical trial ("Dolomites") conducted in the U.S., NCX 470 demonstrated both statistical non-inferiority and superiority to latanoprost, the U.S. market leader in prostaglandin analog prescriptions (see [Press Release of October 2, 2019](#)). 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 is the highest reduction seen in a glaucoma clinical trial with an eye drop.

"Our meeting with the U.S. FDA has clarified the path forward for NCX 470 to a future NDA submission. With this input from the FDA, we are on track to initiate the first pivotal clinical trial by the end of Q2 2020," said Dr. Tomas Navratil, PhD, EVP & Head of R&D of the Nicox Group and General Manager of Nicox Ophthalmics, Inc. "We would like to thank the U.S. FDA ophthalmic division for a productive End-of-Phase 2 meeting. We look forward to further demonstrating in our Phase 3 program the potential of NCX 470 as the best-in-class molecule for the lowering of intraocular pressure in glaucoma patients."

The Mont Blanc trial, the first Phase 3 clinical trial of NCX 470, is expected to start by the end of Q2 2020, with top-line results expected in Q3 2021. As disclosed previously, the Mont Blanc trial will be initiated with 0.065% and 0.1% doses of NCX 470, with one dose being selected during the trial through an adaptive design. Additional details of the trial design will be disclosed following the initiation of the trial.

About Nicox

Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. By leveraging our proprietary expertise in nitric oxide (NO) donation and other technologies, we are developing an extensive portfolio of novel product candidates that target multiple ophthalmic conditions, including glaucoma. Our portfolio has three programs in development including NCX 470, a novel, second-generation NO-donating bimatoprost analog, for intraocular pressure lowering, based on our proprietary NO-donating research platform and NCX 4251, a proprietary formulation of the well-established molecule fluticasone, for acute exacerbations of blepharitis. Our research activities are focused on novel future generation NO-donors including NO-donating phosphodiesterase-5 (PDE5) inhibitors and NO-donating soluble guanylate cyclase (sGC) stimulators (in partnership with Cycleron). In addition, we have two ophthalmology assets that have been approved by the U.S. Food and Drug Administration (FDA); VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%, exclusively licensed worldwide to Bausch + Lomb, a Bausch Health Companies Inc. company, and commercialized in the U.S. by Bausch + Lomb since December 2017, as well as ZERVIATE™ (cetirizine ophthalmic solution), 0.24%, exclusively licensed in the U.S. to Eyevance Pharmaceuticals, LLC.

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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Forward-Looking Statements

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Risks factors which are likely to have a material effect on Nicox's business are presented in the 4th chapter of the 'Document de référence, rapport financier annuel et rapport de gestion 2018' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2019 which are available on Nicox's website (www.nicox.com).

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