

Press Release

Top Line Results from Glaucoma Dolomites Phase 2 Trial Show Nicox's NCX 470 Meets Primary Endpoint and Demonstrates Statistical Superiority vs Latanoprost

- **NCX 470 met the primary endpoint of non-inferiority and also demonstrated superiority to latanoprost, the U.S. market leader in prostaglandin analog prescriptions, in multiple pre-specified analyses**
- **Intraocular pressure (IOP) lowering effect from baseline of NCX 470 was 7.6 to 9.8 mmHg**
- **All doses of NCX 470 were well tolerated with no drug-related serious adverse events**

October 2, 2019 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced positive topline results from its U.S. multicenter, Dolomites dose-response Phase 2 clinical trial evaluating investigational NCX 470, a novel second-generation nitric oxide (NO)-donating bimatoprost analog, compared to latanoprost ophthalmic solution, 0.005% in 433 patients with open-angle glaucoma or ocular hypertension.

Michele Garufi, Chairman and CEO of Nicox, said “We are very pleased that NCX 470 0.065% demonstrated statistical superiority to latanoprost in a pre-specified secondary efficacy analysis. If these results are confirmed in Phase 3 clinical trials, NCX 470 could potentially become the first non-combination product with statistical superiority to a prostaglandin analog. Moreover, NCX 470 has demonstrated what we believe to be the highest IOP reduction from baseline in a glaucoma clinical trial with up to 9.8 mmHg in time-matched IOP. We are planning an end-of-phase 2 meeting with the FDA early next year to finalize plans to conduct the Phase 3 trials against a prostaglandin analog.”

NCX 470 Dolomites Phase 2 Trial Summary

- Statistical non-inferiority was met vs. latanoprost in the primary efficacy analysis (mean diurnal IOP reduction from baseline at Day 28)
- IOP lowering effect of NCX 470 0.065% from baseline was 7.6 to 9.8 mmHg vs. 6.3 to 8.8 mmHg for latanoprost (reduction in time-matched IOP at 8 AM, 10 AM and 4 PM across all visits)
- Statistical superiority was met with NCX 470 0.065% being up to 1.4 mmHg superior to latanoprost in a pre-specified secondary efficacy analysis of time-matched IOP at 8 AM, 10 AM and 4 PM at Day 28 (p<0.025)
- NCX 470 was well tolerated; the most frequent adverse event was conjunctival hyperemia in 16.8% of the NCX 470 0.065% patients vs. 6.5% of latanoprost patients, with most events rated as mild; and there were no drug-related serious adverse events and no evidence of treatment-related systemic effects

Dr. Donald L. Budenz, MD, Chairman of Ophthalmology at University of North Carolina at Chapel Hill and member of Nicox Glaucoma Clinical Advisory Board, stated: *“Based on the current encouraging results, NCX 470 has the potential to become a key part of the standard of care for the physicians treating patients with open-angle glaucoma or ocular hypertension.”*

“We would like to acknowledge and thank all patients, clinical investigators and their teams for their contributions to the Dolomites study. The current dose response curve of NCX 470 shows improved IOP lowering with each incremental concentration of NCX 470 tested, which creates the potential for additional IOP lowering at higher doses to be evaluated in future trials.” **said Tomas Navratil, PhD, Executive Vice President, Head of Development of Nicox.**

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 2018, worldwide sales of treatments targeting glaucoma were \$5.4 billion representing 27% of the \$19.9 billion worldwide market for ophthalmic drugs. In the U.S., sales of treatments targeting glaucoma totaled \$2.8 billion in 2018 or 32% of the \$8.7 billion U.S. market for ophthalmic drugs. Of the U.S. sales of treatments targeting glaucoma, \$1.4 billion, or approximately 50%, was sales of prostaglandin analogs, of which more than 85% were the branded products, TRAVATAN Z® (travoprost ophthalmic solution), 0.004% and LUMIGAN (bimatoprost ophthalmic solution), 0.01%. 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 prostaglandin 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 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 Cyclerion). 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 ZERVIAE™ (cetirizine ophthalmic solution), 0.24%, exclusively licensed in the U.S. to Eyevence 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.

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Upcoming Conferences

Bryan, Garnier & Co European Healthcare Conference 12-13 November, 2019, Paris
Actionaria 21-22 November, 2019, Paris

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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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