

Press Release

Nicox Announces Completion of Enrollment in NCX 470 Phase 2 Clinical Study with Top-Line Results on Track for Early 4Q 2019

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Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that it has completed enrollment of patients in its multicenter, United States (U.S.) Phase 2 clinical study evaluating NCX 470, a novel second generation nitric oxide (NO)-donating bimatoprost analog, being tested in patients with open-angle glaucoma or ocular hypertension for its ability to lower intraocular pressure (IOP). This study is a head-to-head comparison of once-daily administration of three different doses of NCX 470 versus latanoprost, which is the most widely prescribed first-line therapy for glaucoma and ocular hypertension.

Michele Garufi, Chairman and CEO of Nicox, stated: *“We look forward to announcing the top-line results of this first efficacy Phase 2 study of NCX 470, which we believe has the potential to be a new best-in-class treatment for the reduction of intraocular pressure in glaucoma patients in the U.S. and worldwide. The timely execution of this study demonstrates that we are continuing to deliver on our strategy across our entire portfolio of product candidates in development.”*

“We would like to thank all patients, clinical investigators, research coordinators, and all personnel from the participating clinical sites for their invaluable contributions to this study. As next steps, we expect the last patient to exit the study by the end of August, with the study on track for the topline efficacy results early in Q4 this year,” **said Tomas Navratil, PhD, Executive Vice President, Head of Development of Nicox.**

Nicox’s lead product candidate, NCX 470, is a novel, second-generation NO-donating prostaglandin analog for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension. NCX 470 has demonstrated up to 3.5 mmHg greater IOP reduction than bimatoprost in head-to-head comparisons in preclinical models. Bimatoprost, marketed under the brand LUMIGAN®, is the current market leader by sales value among glaucoma therapies in the U.S.

The Phase 2, multicenter, double-masked, 28-day, parallel group, dose response study aims to evaluate the efficacy and safety of NCX 470 ophthalmic solution compared to latanoprost ophthalmic solution, 0.005% in patients with elevated IOP due to open-angle glaucoma or ocular hypertension. The primary endpoint of the study is the mean reduction in diurnal IOP after 28 days of treatment, while the overall objective is to identify the appropriate dose of NCX 470 to be advanced into Phase 3 clinical studies. Top-line data of the study are expected early in Q4 of this year.

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 2017, worldwide sales of treatments targeting glaucoma were \$5.0 billion representing 27% of the \$18.6 billion worldwide market for ophthalmic drugs. In the U.S., sales of treatments targeting glaucoma totalled \$2.6 billion in 2017 or 32% of the \$8.1 billion U.S. market for ophthalmic drugs. Of the U.S. sales of treatments targeting glaucoma, \$1.3 billion, or approximately 50%, was sales of prostaglandin analogs, of which more than 90% 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 2017, 36.1 million prescriptions were written in the U.S. annually for glaucoma drugs.

About NCX 470

NCX 470 is a new chemical entity formulated as an ophthalmic solution of this novel, second generation nitric oxide (NO)-donating prostaglandin analog in development for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma and 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. Nicox believes that NCX 470 has the potential for greater IOP lowering activity than either bimatoprost or Bausch + Lomb's VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%, given bimatoprost's efficacy profile and the NO-mediated activity.

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 prostaglandin 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 ZERVIA™ (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	Hugo Solvet	Paris, France
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 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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