

Press Release

Nicox Initiates Phase 2 Study of NCX 470 in Open-Angle Glaucoma and Ocular Hypertension

- Study to randomize 420 patients in clinical sites across the U.S.
 - Top-line results expected H2 2019
 - Targets \$5 billion worldwide glaucoma market¹
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Sophia Antipolis, France / Research Triangle Park, NC, United States

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced the initiation of a Phase 2 clinical study evaluating NCX 470, its novel, second-generation nitric oxide (NO)-donating prostaglandin analog, for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension by enrolling 10 patients today. NCX 470 is a new chemical entity which uses bimatoprost, a prostaglandin analog, as a scaffold for attaching an NO-donating moiety in order to achieve a dual mechanism of action. NCX 470 has demonstrated a 2 to 3 mmHg greater IOP reduction than bimatoprost alone, 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 United States (U.S.). Nicox expects to report top-line data from this Phase 2 study in the second half of 2019.

This Phase 2 multi-center, double-masked, 28-day, parallel group, dose ranging study aims to evaluate the efficacy and safety of NCX 470 compared to latanoprost 0.005% in adult patients with elevated IOP due to open-angle glaucoma or ocular hypertension. The study is expected to randomize 420 patients in clinical sites across the U.S. The primary endpoint of the study is the mean reduction in diurnal IOP after 4 weeks of treatment, while the overall objective is to identify the appropriate dose of NCX 470 to be advanced into Phase 3 studies.

Tomas Navratil, PhD, Vice President, Head of Development of Nicox, said, “*The Nicox team has the privilege of working with top U.S. investigators in the field of glaucoma, and is prepared to execute on this exciting clinical study that will provide a head-to-head comparison with latanoprost 0.005%, the most widely used IOP-lowering drug by glaucoma patients.*”

Michele Garufi, Chairman and Chief Executive Officer of Nicox, said, “*Based on our preclinical data, we believe that NCX 470 may provide a clinically meaningful improvement over the current standard of care, and become a first-line therapy for these patients. The development of NCX 470 is testimony to the power of our efforts fueled by the seamless collaboration between our U.S. and European R&D teams, and follows on the back of the FDA approval of our first generation NO-donating compound VYZULTA, commercialized in the U.S. since last December by our partner Bausch + Lomb.*”

This Phase 2 study was initiated following the submission of an Investigational New Drug (IND) application in June 2018, ahead of the previously disclosed target date in the third quarter of 2018. The submitted IND has now successfully completed the 30-day review period by the U.S. Food and Drug Administration (FDA). Nicox’s NO-donating research platform has been validated through positive Phase 3 results, and

subsequent U.S. FDA approval and commercialization of VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024% by partner Bausch + Lomb.

Reference

1. IQVIA Health Analytics 2017 reported sales

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 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 totaled \$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 and Lumigan. 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 reduction 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, with two out-licensed commercial-stage products, developing innovative solutions to help maintain vision and improve ocular health. By leveraging its proprietary expertise in nitric oxide donation and other technologies, the Company is developing an extensive portfolio of novel product candidates that target multiple ophthalmic conditions, including glaucoma. Nicox currently has two products with approved U.S. New Drug Applications, VYZULTA™ (latanoprostene bunod ophthalmic solution), 0.024%, licensed worldwide to Bausch + Lomb, and ZERVIA™ (cetirizine ophthalmic solution), 0.24%, licensed in the U.S. to Eyeveance. In addition, our promising pipeline includes clinical stage assets based both on our proprietary NO-donating research platform and on the repurposing of existing molecules as well as future generation stand-alone NO donors and exploratory novel NO-donating compounds with the potential to offer novel approaches to treat a range of ophthalmic conditions. 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
Invest Securities	Martial Descoutures	Paris, France
Gilbert Dupont	Jamina El-Bougrini	Paris, France



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Upcoming financial and business conferences

September 25-26	Oppenheimer Fall Summit	New York, USA
October 1-3	Cantor Global Healthcare Conference	New York, USA
November 22-23	Bryan, Garnier 6 th Annual Healthcare Conference	Paris, France

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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 2017*' filed with the French Autorité des Marchés Financiers (AMF) on March 19, 2018, which is available on Nicox's website (www.nicox.com).

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