

## Press Release

---

# Nicox Reaches 50% Enrollment Threshold in U.S. Phase 2 Study with NCX 470 Ahead of Schedule

---

January 8, 2019 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced it has reached the 50% patient enrollment threshold of its multicenter, United States (U.S.) Phase 2 clinical study evaluating NCX 470 ahead of schedule. Nicox's lead product candidate, NCX 470, is a novel, second-generation nitric oxide (NO)-donating prostaglandin analog for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. NCX 470 has demonstrated a 2 to 3 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 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 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.

**Tomas Navratil, PhD, Executive Vice President, Head of Development of Nicox, said:** *“We are encouraged by the brisk patient recruitment rate of our NCX 470 Phase 2 study, and we are grateful for the support and the commitment of the patients and clinical sites in the NCX 470 study. We believe that NCX 470 has the potential to become a leading first-line therapy for glaucoma patients due to its IOP lowering superiority versus the market leader as demonstrated in preclinical models.”*

Nicox expects to report top-line data from this Phase 2 study in the second half of 2019.

### 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 includes three programs in development including NCX 470 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 Ironwood). 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 Eyevance Pharmaceuticals.

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](http://www.nicox.com).

## Analyst coverage

---

Bryan, Garnier & Co    Hugo Solvet    Paris, France



*The views expressed by analysts in their coverage of Nicox are those of the author and do not reflect the views of Nicox. Additionally, the information contained in their reports may not be correct or current. Nicox disavows any obligation to correct or to update the information contained in analyst reports.*

## Upcoming financial and business conferences

---

February 12, 2019	European Midcap Event	Frankfurt, Germany
March 19-20, 2019	Oppenheimer's 29th Annual healthcare Conference	New York, U.S.
April 7-9, 2019	H.C. Wainwright Global Life Sciences Conference	London, UK

## Contacts

---

### Nicox

Gavin Spencer,  
Executive Vice President, Chief Business Officer  
T +33 (0)4 97 24 53 00  
[communications@nicox.com](mailto:communications@nicox.com)

### Investors & Media

United States & Europe  
LifeSci Advisors, LLC  
Hans Herklots  
T +41 79 598 71 49  
[hherklots@lifesciadvisors.com](mailto:hherklots@lifesciadvisors.com)

**Media**

France

LifeSci Advisors, LLC

Sophie Baumont

M. +33 (0)6 27 74 74 49

[sophie@lifesciadvisors.com](mailto:sophie@lifesciadvisors.com)

**Disclaimer**

---

The information contained in this document may be modified without prior notice. This information includes forward-looking statements. Such forward-looking statements are not guarantees of future performance. These statements are based on current expectations or beliefs of the management of Nicox S.A. and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Nicox S.A. and its affiliates, directors, officers, employees, advisers or agents, do not undertake, nor do they have any obligation, to provide updates or to revise any forward-looking statements.

Risks factors which are likely to have a material effect on Nicox's business are presented in the 4<sup>th</sup> 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](http://www.nicox.com)).

**Nicox S.A.**

Drakkar 2

Bât D, 2405 route des Dolines

CS 10313, Sophia Antipolis

06560 Valbonne, France

T +33 (0)4 97 24 53 00

F +33 (0)4 97 24 53 99