Press Release

Nicox Completes Enrolment of NCX 4251 Phase 2 Trial with Top-Line Results on Track for Q4 2019

September 27, 2019 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that it has completed enrolment in its multicenter, dose escalating, U.S. Phase 2 clinical trial evaluating the safety and tolerability of NCX 4251 in acute exacerbations of blepharitis. The primary objective of this clinical trial is to select the dose(s) of NCX 4251 to advance into the next stage of development which will be a larger Phase 2b clinical trial. Nicox expects to report topline data in the fourth quarter of this year.

Michele Garufi, Chairman and Chief Executive Officer of Nicox, said, *"As we continue to demonstrate our ability to execute on plan, we expect to report topline results for both the NCX 4251 and NCX 470 Phase 2 clinical trials in Q4 of this year. NCX 4251 is an innovative product candidate, both through the choice of active ingredient and form of application, which targets the unmet need in acute exacerbations of blepharitis. We estimate that the addressable market for this indication in the U.S. alone may be more than $700 million annually, rising to over $1 billion by 2024."*

"As with NCX 470, we have worked with an excellent group of clinical investigators and their teams and we would like to thank them for their contributions to the timely execution of this trial. We look forward to reporting the results before the end of the year." said **Tomas Navratil, PhD, Executive Vice President, Head of Development of Nicox.**

NCX 4251 is a novel patented ophthalmic suspension of fluticasone propionate nanocrystals which Nicox believes is the first product candidate developed as a targeted topical treatment of the eyelid margin for patients with acute exacerbations of blepharitis. Blepharitis is a common eye condition characterized by eyelid inflammation.

About NCX 4251

NCX 4251 is a novel patented ophthalmic suspension of fluticasone propionate nanocrystals which is being developed as a targeted topical treatment of the eyelid margin for patients with acute exacerbations of blepharitis. We believe that this is the first time that fluticasone propionate is being developed for an ophthalmic indication, and that NCX 4251 is the first product candidate in development directly targeted to the eyelid margin as a topical treatment of acute exacerbations of blepharitis. Blepharitis is a common eye condition characterized by eyelid inflammation. NCX 4251 is being developed for application via eyelid applicator to the eyelid margin, applied directly to the site where the disease originates and thereby potentially minimizing penetration of the drug through the cornea which can lead to the damaging side effects such as IOP increase found with current topical steroids.

Fluticasone propionate, the active ingredient in NCX 4251, which we believe has not previously been approved in a topical formulation for use in ophthalmology, has an affinity for the glucocorticoid receptor which is approximately ten times greater than dexamethasone, a corticosteroid commonly used in ophthalmology. Fluticasone is a glucocorticoid with potent anti-inflammatory properties that has been approved in numerous drug products over the past 20 years for the treatment of various indications including dermatology, rhinitis and asthma.

Blepharitis – an untapped market

Blepharitis is a condition in which the margins of the eyelids become red and swollen and may contain dandruff like matter. Of patients seen by ophthalmologists and optometrists, 37% and 47%, respectively, present with signs of the disease.

There is currently no FDA-approved prescription product solely indicated for blepharitis, which limits our ability to estimate prevalence and market size. There are, however, antimicrobial and antibiotic products, such as ointments and eye drops, indicated for the treatment of blepharitis, as well as other conditions. Treatment options also include lid scrubs, topical ophthalmic steroids, topical ophthalmic antibiotics and topical ophthalmic antibiotic/steroid combinations. We estimate that the market for treatment of acute exacerbations of blepharitis in the U.S. alone may be more than $700 million, rising to over $1 billion by 2024.

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 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	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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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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