Press Release

Nicox Announces Plans for NCX 4251 Phase 2 Trial in Blepharitis

- **Mississippi Phase 2 trial will evaluate once-daily dosed NCX 4251 0.1% against placebo in blepharitis patients**
- **Trial is targeted to start in December 2020 with top-line results expected in Q4 2021**
- **If the primary endpoint is met, the trial could count as one of two pivotal trials required for approval in the U.S.**

October 13, 2020 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that the upcoming Mississippi Phase 2 trial of its second clinical candidate, NCX 4251 0.1%, will be focused on acute exacerbations of blepharitis. If successful in meeting the primary endpoint for blepharitis previously agreed upon with the U.S. Food and Drug Administration (FDA), the trial could represent the first of two pivotal trials needed to support a New Drug Application (NDA) in the U.S. The Mississippi trial is targeted to start in December 2020 with top-line results currently expected in Q4 2021.

NCX 4251, a novel patented ophthalmic suspension of fluticasone propionate nanocrystals, was evaluated in the successful Danube Phase 2 trial completed in late 2019. While not powered for efficacy, in the prospectively defined pooled analysis of once-daily and twice-daily dosing of NCX 4251 0.1%, there was a statistically significant reduction in the composite score of eyelid redness, eyelid debris and eyelid discomfort at day 14. Eyelid redness, eyelid debris and eyelid discomfort are the hallmark signs and symptoms of blepharitis.

"*With a U.S. market for the treatment of acute exacerbations of blepharitis estimated at over $700 million, and no product approved for this indication, we believe that targeting blepharitis first is the best value-creating opportunity for Nicox.*" said **Dr José Boyer, Vice President and Head, Clinical Development at Nicox**. "*Our Danube Phase 2 trial demonstrated a robust efficacy of NCX 4251 in this indication and also showed promising efficacy in reducing signs and symptoms of dry eye disease. Consequently, we will also include signs and symptoms of dry eye disease as secondary efficacy endpoints in the forthcoming Mississippi trial, paving the way for a potential future additional standalone Phase 3 program in dry eye disease.*"

Further details will be disclosed at the time of the start of the trial in December.

We continue to closely watch the spread of COVID-19 and its impact. We do not currently anticipate delays to our clinical timelines but we are monitoring the situation and will provide updates if there is an impact on our development projects and timelines.

NCX 4251 - Danube Phase 2 trial

NCX 4251 completed a U.S. multicenter, dose escalating, first-in-human, 36-patient Danube Phase 2 clinical trial which evaluated its safety and tolerability in patients with acute exacerbations of blepharitis. In the Danube Phase 2 trial, NCX 4251 met the primary objective of selecting the dose for further development. Although the trial was not powered for efficacy, in the prospectively defined pooled analysis of once-daily (QD) and twice-daily (BID) dosing of NCX 4251 0.1%, there was a statistically significant reduction in the composite score of eyelid redness, eyelid debris and eyelid discomfort at the Day 14 study endpoint (n = 20 for NCX 4251 0.1% and n = 16 for placebo with p = 0.047 for study eyes and p = 0.025 for combined study eyes and contralateral eyes). The NCX 4251 0.1% QD treatment was selected to advance into a larger Phase 2 clinical trial. The selected dose of NCX 4251 0.1%, also demonstrated

promising efficacy in reducing signs and symptoms of dry eye disease. There were no serious adverse events, no treatment related systemic adverse events, and no adverse events of IOP elevation, the most common side effect of topical ophthalmic steroids.

Following the Danube trial, a successful Type C meeting was held with the U.S. FDA, with agreement on Phase 2 trial designs for NCX 4251 in both acute exacerbations of blepharitis and the reduction of signs and symptoms of dry eye disease.

About NCX 4251 and Blepharitis

NCX 4251, our novel patented ophthalmic suspension of fluticasone propionate nanocrystals, is being developed as a targeted topical treatment of the eyelid margin for patients with acute exacerbations of blepharitis, a common eye condition characterized by eyelid inflammation. Fluticasone propionate, the active ingredient in NCX 4251, is a well-established corticosteroid which has been marketed for more than 20 years for a number of extra ophthalmic indications, including asthma and allergic rhinitis, and it has an affinity for the glucocorticoid receptor approximately ten times greater than dexamethasone, a corticosteroid commonly used in ophthalmology. 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 developed as a targeted topical treatment of the eyelid margin for patients with acute exacerbations of blepharitis.

Nicox and Ocumension Therapeutics have entered into an exclusive license agreement for the development and commercialization of NCX 4251 for blepharitis in the Chinese market.

About Nicox

Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's lead program in clinical development is NCX 470, a novel, second-generation nitric oxide-donating bimatoprost analog, for lowering intraocular pressure in patients with glaucoma. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for acute exacerbations of blepharitis. Nicox generates revenue from VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch & Lomb, and ZERVIATE™ in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of South East Asian markets.

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	Victor Floc'h	Paris, France
Cantor Fitzgerald	Louise Chen	New York, U.S.
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Oppenheimer & Co	Hartaj Singh	New York, U.S.

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Forward-Looking Statements

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Risks factors which are likely to have a material effect on Nicox's business are presented in the 3rd chapter of the '*Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2019*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2020 which are available on Nicox's website (www.nicox.com).

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