

Press Release

Nicox Announces Results from the NCX 4251 Phase 2b Mississippi Blepharitis Trial

September 23, 2021 – release at 7:30 am CET Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced the results from its Mississippi Phase 2b clinical trial evaluating once-daily dosed NCX 4251, fluticasone propionate ophthalmic suspension 0.1%, against placebo in patients with acute exacerbations of blepharitis. The primary outcome measure was the proportion of patients achieving complete cure in all three hallmark signs and symptoms of blepharitis, eyelid redness, eyelid debris and eyelid discomfort, at Day 15, with two secondary outcome measures on signs and symptoms of dry eye.

The trial did not meet the primary or secondary efficacy endpoints. However, a signal of NCX 4251's potential efficacy was seen in the trial with NCX 4251 0.1% showing a numerical improvement over placebo in the primary outcome measure of complete cure in eyelid redness, eyelid debris and eyelid discomfort at Day 15. NCX 4251 also showed a statistically significant difference against placebo in the exploratory endpoint of change from baseline in the composite score of the same key signs and symptoms at Day 8 (p=0.03), Day 11 (p=0.01) and Day 15 (p=0.01). Data analysis is continuing in order to decide on the key signs and symptoms of focus for future development. NCX 4251 was found to be safe and well-tolerated over 14 days' treatment, with no serious adverse events, and all of the adverse events for the NCX 4251 treatment arm were mild. There were no discontinuations in the study due to an adverse event.

Michele Garufi, Chairman and Chief Executive Officer of Nicox, said "We are pleased to see that there is a signal of efficacy in the composite score of the signs and symptoms of blepharitis. We will continue to analyze the significant amount of data from the trial with the goal of discussing the future development plan in a meeting with the United States Food and Drug Administration early next year. We would like to thank all the patients, clinical sites and clinical investigators who participated in the Mississippi trial."

Blepharitis is a common eye condition characterized by eyelid inflammation. Mississippi was a Phase 2b clinical trial, which recruited 224 patients at multiple clinical centers in the U.S., evaluating once-daily dosed NCX 4251, fluticasone propionate ophthalmic suspension 0.1%, versus placebo in patients with acute exacerbations of blepharitis. The next steps and timelines in the development of NCX 4251 will be announced following a meeting with the U.S. Food and Drug Administration, expected to take place at the beginning of 2022.

About NCX 4251 and Blepharitis

NCX 4251, our novel patented ophthalmic suspension of fluticasone propionate nanocrystals, is in development as a targeted topical treatment of the eyelids 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 non-ophthalmic indications, including asthma and allergic rhinitis. Fluticasone propionate 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 eyelids 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 nitric oxide-donating prostaglandin 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.

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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 2020' filed with the French Autorité des Marchés Financiers (AMF) on March 1, 2021 which are available on Nicox's website (www.nicox.com).

Nicox S.A.

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