

Press Release

Nicox Announces Last Patient Completed NCX 4251 Mississippi Phase 2b Blepharitis Trial

July 2nd, 2021 – release at 7:30 am CET Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, announced that the last patient in the NCX 4251 Mississippi Phase 2b blepharitis clinical trial has now completed the two-week treatment phase as well as the required two-week follow up period. Top-line results are expected to be announced in September 2021.

"The Phase 2b Mississippi trial is designed to further explore the NCX 4251 product profile following the encouraging results of the Phase 2 Danube trial," said **Dr. José Boyer, Interim Head of R&D at Nicox**, "The Mississippi trial includes a number of clinical endpoints related to signs and symptoms of blepharitis and dry eye disease. We will therefore generate a significant amount of data which will be used to guide the future development of NCX 4251. We will announce the next steps in the development of NCX 4251 following an End-of-Phase 2 meeting with the FDA."

NCX 4251 is a novel patented ophthalmic suspension of fluticasone propionate nanocrystals. The direct administration of NCX 4251 to the eyelids is designed to target the site of the inflammation whilst minimizing the intraocular exposure to the steroid fluticasone, thereby reducing the risk of adverse effects such as increased intraocular pressure and cataract.

Mississippi is a Phase 2b clinical trial of NCX 4251, evaluating once-daily dosed NCX 4251 0.1% versus placebo in patients with acute exacerbations of blepharitis, and has recruited over 200 patients. The primary outcome measure is the proportion of patients achieving at Day 15 complete cure in eyelid redness, eyelid debris and eyelid discomfort, the hallmark signs and symptoms of blepharitis.

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: <u>www.nicox.com.</u>



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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 (<u>www.nicox.com</u>).

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