

Press Release

Nicox's Completes Pre-Defined Enrollment of NCX 4251 Mississippi Phase 2b Blepharitis Trial

- **Over 200 patients randomized**
- **Top-line results expected in September 2021**

June 1st, 2021 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, announced that as of today, more than 200 patients, the pre-defined target, have been randomized in the NCX 4251 Mississippi Phase 2b blepharitis clinical trial. Top-line results are expected to be announced during September 2021.

“Blepharitis is a highly prevalent eye condition with frequent exacerbation of signs and symptoms suffered by millions of patients, and there remains a significant unmet need for an effective treatment,” said Dr. José Boyer, Interim Head of R&D at Nicox, “The successful completion of the Mississippi trial enrollment on time in the current pandemic environment is testament to the strength and dedication of our clinical team, investigators and the Clinical Research Organization managing the trial. We look forward to announcing the results, which will drive the preparation of the next steps in the development of this novel asset, in a few months’ time.”

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.

The primary outcome measure is the proportion of patients achieving complete cure in eyelid redness, eyelid debris and eyelid discomfort, the hallmark signs and symptoms of blepharitis, at Day 15. Should NCX 4251 meet this primary efficacy endpoint for blepharitis, the Mississippi trial could represent the first of two pivotal trials needed to support an NDA in the U.S. for the treatment of acute exacerbations of blepharitis.

We continue to closely watch the spread and impact of the COVID-19 pandemic and we will provide an update of any delays.

[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 ZERVIAE® in allergic conjunctivitis, licensed in multiple geographies, including to Eye Vance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of Southeast 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.
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
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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).

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