

Press Release

Nicox's NCX 4251 Mississippi Phase 2b Blepharitis Trial Reaches 50% Enrollment

- **102 patients randomized as of April 22, 2021, out of a target of 200**
- **Milestone shows trial remains on track for top-line results in Q4 2021**

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

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that 102 patients in the NCX 4251 Mississippi Phase 2b blepharitis clinical trial have now been randomized out of a target of 200, with top-line results currently on track to be announced during Q4 2021.

Dr. José Boyer, Interim Head of R&D at Nicox, said: *“Achievement of 50% enrollment in this Phase 2b trial of NCX 4251 in blepharitis is a significant milestone and we remain on track for top-line results before the end of this year. This has been achieved, despite the COVID-19 pandemic situation, due to working with one of the leading ophthalmology Contract Research Organizations and experienced clinical investigators in blepharitis trials. Following the encouraging results seen in the earlier Danube Phase 2 trial, we hope to demonstrate the potential for NCX 4251 in blepharitis with this larger trial and design the path forward for the next phase of clinical development of our drug candidate as a novel treatment for this unmet medical need.”*

NCX 4251 is a novel patented ophthalmic suspension of fluticasone propionate nanocrystals. The direct application of NCX 4251 to the eyelids is designed to target the site of the inflammation whilst minimizing the intraocular exposure to the steroid fluticasone and the risk of developing 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. It is expected to randomize 200 patients at clinical sites across the U.S.

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 being developed 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. 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 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 Eyeavance 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

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Edison Investment Research	Pooya Hemami	London, UK
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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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