Press Release

Nicox's Positive FDA Meeting Shows Clear Path for NCX 4251 in Dry Eye

- **Statistically significant and clinically relevant results were obtained for the reduction of dry eye symptoms in patients with moderate to severe dry eye disease in a *post hoc* analysis of the Phase 2b Mississippi clinical trial**
- **A path forward to develop NCX 4251 as a treatment for dry eye disease has been confirmed following a recent meeting with the United States Food and Drug Administration**

February 8, 2022 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that it will be focusing the future development of NCX 4251 on dry eye disease. This decision follows the encouraging *post hoc* results from the Mississippi Phase 2b clinical trial and a subsequent positive meeting with the U.S. Food and Drug Administration (FDA). The results, reported on November 30, 2021, suggest that once-daily dosed NCX 4251, fluticasone propionate ophthalmic suspension 0.1%, is effective in reducing dry eye symptoms in patients who score more highly for a key sign of dry eye disease.

"Based on the Mississippi trial results and following a recent meeting with the United States Food and Drug Administration, we identified a clear route for the development of our NCX 4251 as a treatment for dry eye disease. The post hoc analysis of the Mississippi data shows that NCX 4251 has a statistically significant and clinically relevant effect over placebo on a number of dry eye symptoms, and an effect on a key sign of dry eye which approached statistical significance and that we believe would be statistically significant in a larger trial," said **Doug Hubatsch, EVP and Chief Scientific Officer of Nicox.** *"We are currently designing the next clinical trial with our clinical advisors and expect to initiate it in 2023."*

NCX 4251 profile

- Novel, patented nanocrystal suspension of fluticasone propionate, a steroid with affinity for the glucocorticoid receptor approximately ten times greater than dexamethasone
- Application of fluticasone propionate to the eyelid margins via an applicator minimizes potential steroid exposure through the cornea which can lead to damaging side effects such as intraocular pressure increase found with current topical steroids
- The convenience of once-a-day dosing may improve compliance and patient acceptance

Further pharmaceutical development activities will need to be completed to support the next steps in the clinical development of NCX 4251. The clinical trials are not currently financed, per the recently announced cash runway of Q4 2023.

Dry Eye Disease

Dry eye disease is a common condition that occurs when the quality and/or quantity of tears aren't able to adequately hydrate or lubricate the eyes. This inadequate lubrication can lead to dryness, inflammation, pain, discomfort, irritation, diminished quality of life, and in severe cases, permanent vision impairment. Dry eye disease is estimated to impact around 34 million adults in the U.S. alone. The estimated worldwide market for dry eye disease treatment is over $5 billion.

About NCX 4251 and Dry Eye Disease

NCX 4251, our novel patented ophthalmic suspension of fluticasone propionate nanocrystals, is in development as a topical treatment, applied to the eyelids, for patients with dry eye disease. 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. Fluticasone propionate has not been approved previously for topical ophthalmic use.

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 open-angle glaucoma or ocular hypertension. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for dry eye disease. 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 C: 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	Dylan van Haaften	Paris, France
Edison Investment Research	Pooya Hemami	London, UK
H.C. Wainwright & Co	Yi Chen	New York, U.S.
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Forward-Looking Statements

The information contained in this document may be modified without prior notice. This information includes forward-looking statements. Such forward-looking statements are not guarantees of future performance. These statements are based on current expectations or beliefs of the management of Nicox S.A. and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Nicox S.A. and its affiliates, directors, officers, employees, advisers or agents, do not undertake, nor do they have any obligation, to provide updates or to revise any forward-looking statements.

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 and in the 2nd chapter of the amendment to the "*Document d'Enregistrement Universel, rapport financier annuel et rapport de gestion 2020*" filed with the AMF on December 9, 2021 which are available on Nicox's website (www.nicox.com).

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