

## Press Release

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# Nicox Initiates Phase 2 Trial of NCX 4251 in Blepharitis

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- Trial to randomize 30 blepharitis patients in clinical sites across the U.S.
  - Top-line results expected in Q4 2019
  - Targets the estimated \$500+ million U.S. blepharitis market
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March 19, 2019 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced the initiation of a Phase 2 clinical trial evaluating NCX 4251, its novel patented ophthalmic suspension of fluticasone propionate nanocrystals, being developed as the first targeted topical treatment of the eyelid margin for patients with acute exacerbations of blepharitis. Nicox expects to report top-line results from this Phase 2 trial in the fourth quarter of 2019.

This Phase 2 multi-center, randomized, double-masked, placebo-controlled, dose-escalation, 14-day trial aims to evaluate the safety and tolerability of NCX 4251 compared to placebo in patients with acute exacerbations of blepharitis. The trial is expected to randomize approximately 30 patients in clinical sites across the U.S. The primary objective of this clinical trial is to select the dose(s) of NCX 4251 to advance into the next stage of development which will be a larger Phase 2b clinical trial.

**Tomas Navratil, PhD, Executive Vice President, Head of Development of Nicox**, said, *“There is no product approved in the United States solely for the treatment of blepharitis. We believe that the combination of a potent corticosteroid in our novel nanocrystal suspension together with application directly to the site of inflammation, where the disease originates, could lead to an efficacious and better tolerated product for the treatment of blepharitis.”*

**Michele Garufi, Chairman and Chief Executive Officer of Nicox**, said, *“Starting this second clinical program for the company, following the initiation of the NCX 470 clinical trial for the reduction of intraocular pressure in August last year, is a great achievement for our development team. With two commercial assets, two mid-stage clinical assets, and two innovative research projects we are continuing to deliver on building a unique, fully-integrated company in the ophthalmology space.”*

This Phase 2 trial was initiated following the U.S. Food and Drug Administration (FDA) acceptance of the Investigational New Drug (IND) application submitted in December 2018, ahead of the previously disclosed target date of the first quarter of 2019.

### About NCX 4251

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NCX 4251 is a novel patented ophthalmic suspension of fluticasone propionate nanocrystals which is being developed as the first targeted topical treatment of the eyelid margin for patients with acute exacerbations of blepharitis. Blepharitis is a common eye condition characterized by eyelid inflammation. It is being developed for application via a swab at the eyelid margin, applied directly to the site of inflammation thereby minimizing potential penetration of the drug through the cornea which can lead to the damaging side effects, such as intraocular pressure (IOP) increase, found with current topical steroids.

Fluticasone propionate, the active ingredient in NCX 4251, which has not previously been approved in a topical formulation for use in ophthalmology, has an affinity for the glucocorticoid receptor which is approximately ten times greater than dexamethasone, a corticosteroid commonly used in ophthalmology. Fluticasone is a glucocorticoid with potent anti-inflammatory properties that has been approved in numerous drug products over the past 20 years for the treatment of various indications including dermatology, rhinitis and asthma.

## Blepharitis – an untapped market

Blepharitis is a condition in which the margins of the eyelids become red and swollen and may contain dandruff like matter. Of patients seen by ophthalmologists and optometrists, 37% and 47%, respectively, present with signs of the disease.

There is currently no U.S. FDA approved prescription product solely indicated for blepharitis. Annual U.S. sales for products prescribed for blepharitis total more than \$500 million according to IQVIA Health Analytics. Surveys reveal that ophthalmologists consider anti-inflammatory activity to be the most important product attribute when selecting a treatment for blepharitis, which supports the rationale for the development of NCX 4251.

## About Nicox

Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. By leveraging our proprietary expertise in nitric oxide (NO) donation and other technologies, we are developing an extensive portfolio of novel product candidates that target multiple ophthalmic conditions, including glaucoma. Our portfolio includes three programs in development including NCX 470 for intraocular pressure lowering, based on our proprietary NO-donating research platform and NCX 4251, a proprietary formulation of the well-established molecule fluticasone, for acute exacerbations of blepharitis. Our research activities are focused on novel future generation NO-donors including NO-donating phosphodiesterase-5 (PDE5) inhibitors and NO-donating soluble guanylate cyclase (sGC) stimulators (in partnership with Ironwood). In addition, we have two ophthalmology assets that have been approved by the U.S. Food and Drug Administration (FDA); VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%, exclusively licensed worldwide to Bausch + Lomb, a Bausch Health Companies Inc. company, and commercialized in the U.S. by Bausch + Lomb since December 2017, as well as ZERVIA™ (cetirizine ophthalmic solution), 0.24%, exclusively licensed in the U.S. to Eyevance Pharmaceuticals, LLC. 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](http://www.nicox.com)

## Analyst coverage

Bryan, Garnier & Co    Hugo Solvet                      Paris, France  
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*The views expressed by analysts in their coverage of Nicox are those of the author and do not reflect the views of Nicox. Additionally, the information contained in their reports may not be correct or current. Nicox disavows any obligation to correct or to update the information contained in analyst reports.*

## Upcoming financial and business conferences

March 19-20	Oppenheimer's 29th Annual healthcare Conference	New York, U.S.
April 7-9	H.C. Wainwright Global Life Sciences Conference	London, UK
April 16-17	SmallCap Event	Paris, France
May 16	European MidCap Event	Copenhagen, Denmark
June 2-6	BIO 2019	Philadelphia, U.S.
June 18-19	European MidCap Event	Paris, France
June 19-20	JMP Securities Healthcare Conference	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 4th chapter of the '*Document de référence, rapport financier annuel et rapport de gestion 2018*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2019 which are available on Nicox's website ([www.nicox.com](http://www.nicox.com)).

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