Press Release

Nicox provides clinical and regulatory update for NCX 4251 in blepharitis

- **Pre-IND meeting on NCX 4251 with FDA completed**
- **Phase 2 expected to start Q4 2017**

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Sophia Antipolis, France

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic R&D company, today provided certain regulatory and clinical updates for NCX 4251, its novel ophthalmic suspension of fluticasone propionate nanocrystals being developed for the first time as a topical treatment for acute exacerbation of blepharitis.

Based on feedback from a recent pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA), Nicox is finalizing the design of a first-in-human Phase 2 clinical trial evaluating the efficacy and safety of NCX 4251 versus a vehicle comparator in patients with acute exacerbation of blepharitis. This multi-center, dose-ranging study will be conducted in the U.S. The primary objective of the study is to demonstrate a statistically significant and clinically relevant difference in the proportion of subjects with clinical cure (defined as the absence of lid margin redness, lid debris, and lid discomfort) obtained with each dose of NCX 4251 versus vehicle. An additional objective of the study is to identify the recommended Phase 3 dose of NCX 4251. Subject to IND filing and acceptance, Nicox plans to initiate this Phase 2 clinical trial during the fourth quarter of 2017 and expects the trial to take approximately 1 year to complete.

Dr. Mike Bergamini, EVP and Chief Scientific Officer of Nicox commented *"Blepharitis is a significant unmet medical need in ophthalmology. Despite the high incidence of this uncomfortable condition, there are currently no FDA-approved products specifically designed to treat it, and patients often rely on simple, but frequently ineffective, cleansing techniques. Fluticasone, the active ingredient of NCX 4251, is the most potent steroid in development for ocular use, and we believe that our unique formulation will be able to provide relief to these patients. We are also pleased to be working with Ora, Inc., the world's leading ophthalmic CRO, which has extensive experience in the development of ophthalmic products and proprietary research models that will help us conduct a scientifically robust clinical trial."*

"Looking ahead, we believe that 2017 will be a transformative year for Nicox" **said Michele Garufi, Chairman and Chief Executive Officer of Nicox.** *"In addition to the progress of NCX 4251, we plan to communicate the timetable for entry into Phase 2 with NCX 470 for glaucoma within the first quarter. Of course, the main event of the year remains, as stated previously by Bausch + Lomb, the launch of latanoprostene bunod in the U.S, expected in mid-2017[1]. For AC-170, we remain on track to provide an update on the re-submission timing of the NDA by February."*

About NCX 4251

NCX 4251 is a novel suspension of fluticasone propionate nanocrystals, being developed for the first time as a topical treatment for acute exacerbation of blepharitis. NCX 4251 will be applied via an applicator swab to the eyelid margin.

Fluticasone, which has not previously been approved in a topical formulation for use in ophthalmology, has an affinity for the glucocorticoid receptor which is approximately 10 times greater than dexamethasone[2,3], a corticosteroid used extensively in ophthalmology. Fluticasone propionate 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.

NCX 4251 is protected under technology developed by Aciex Therapeutics, Inc., a company which was acquired by Nicox in 2014 and renamed Nicox Ophthalmics, Inc. This technology can be used to repurpose existing drugs by producing novel, patentable nanocrystalline forms. Approval of a New Drug Application (NDA) for NCX 4251 on or before 1st July 2021 would trigger a milestone payment of up to $10 million in Nicox shares to former shareholders of Aciex Therapeutics, Inc.

Based on the extensive safety data available for fluticasone propionate, the development of NCX 4251 is expected to proceed via a 505(b)(2) regulatory pathway. A successful pre-IND meeting was held with the U.S. FDA in late 2016, clearing the path for an IND filing in 2017.

About blepharitis

Blepharitis is an inflammation of the hair follicles and glands along the edges of the eyelids in which scales and debris are often seen. Blepharitis is one of the most common conditions encountered in clinical practice[4] with 37% and 47% of patients seen by ophthalmologists and optometrists, respectively, presenting with signs of the disease. There is currently no FDA-approved drug product specifically for the treatment of blepharitis. Current standard of care includes lid hygiene products, anti-inflammatories, antibiotics, and combinations of anti-inflammatory and antibiotic agents[5]. Nicox estimates potentially more than 2.5 million blepharitis-related prescriptions written per year in the U.S. alone[6], in addition to the use of non-prescription and non-pharmaceutical treatments.

Notes:

1. Subject to regulatory approval. Bausch + Lomb will need to resubmit the New Drug Application. Once the resubmission is filed, the FDA has 30 days to agree that the submission constitutes a complete response and is expected to complete its review within six months from the date of resubmission
2. Hogger P, Rohdewald P. Binding kinetics of fluticasone propionate to the human glucocorticoid receptor. Steroids 59: 597-602, 19941
3. Johnson M. The anti-inflammatory profile of fluticasone propionate. Allergy 1995; 50 (Suppl 23):11-14
4. Lemp MA, Nichols KK. Ocul Surf. 2009 Apr;7(2 Suppl):S1-S14
5. Jackson WB. Blepharitis: current strategies for diagnosis and management. Can J Ophthalmol. 2008;43:170-9
6. Internal estimate based on IMS data.

About Nicox

Nicox is an international ophthalmic R&D company utilizing innovative science to maintain vision and improve ocular health. By leveraging its proprietary expertise in nitric oxide donation and other technologies, the Company is developing an extensive portfolio of novel therapies that target multiple ophthalmic conditions, including glaucoma. Nicox currently has two products at the pre-approval stage with the U.S. Food and Drug Administration (FDA) and a promising pipeline including next-generation stand-alone nitric-oxide donors, with the potential to treat a range of ophthalmic indications. 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 .

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Contacts

Nicox
Gavin Spencer,
Executive Vice President Corporate Development
T +33 (0)4 97 24 53 00
communications@nicox.com

Investor Relations
Europe
NewCap Julien Perez
Valentine Brouchot
T +33 (0)1 44 71 94 94
nicox@newcap.eu

United States
Argot Partners Melissa Forst
Tel +1 (212) 600-1902
melissa@argotpartners.com

Media Relations
United Kingdom
Jonathan Birt
T +44 7860 361 746
jonathan.birt@ymail.com

France
NewCap
Nicolas Merigeau
T +33 (0)1 44 71 94 98
nicox@newcap.eu

United States
Argot Partners Eliza Schleifstein
T +1 (917) 763-8106
eliza@argotpartners.com

Disclaimer

Nicox S.A.
Drakkar 2
Bât D, 2405 route des Dolines
CS 10313, Sophia Antipolis
06560 Valbonne, France
T: +33 (0)4 97 24 53 00
F: +33 (0)4 97 24 53 99