Press Release

Nicox receives FDA approval of ZERVIATE[1] (cetirizine ophthalmic solution) 0.24%

- **First approved US NDA for Nicox**
- **First topical ocular formulation of the antihistamine cetirizine**
- **U.S. patent protection until at least 2030**
- **Partnering discussions underway for U.S. commercialization rights**

May 31, 2017 – release at 3:00 pm CET
Sophia Antipolis, France

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic R&D company, today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for ZERVIATE[1] (cetirizine ophthalmic solution 0.24%; formerly AC-170) the first topical ocular formulation of this well-known antihistamine, for the treatment of ocular itching associated with allergic conjunctivitis.

"*Receiving approval from the U.S. FDA for ZERVIATE is a huge milestone for Nicox and partnering discussions are underway for U.S. commercialization rights,*" **commented Michele Garufi, Chairman and Chief Executive Officer of Nicox.** "*We expect to further solidify our position as a leading ophthalmic R&D company with the anticipated FDA decision on Vyzulta[TM2], which is licensed worldwide to Bausch + Lomb, and the expected commencement of Phase 2 clinical trials for both NCX 4251 and NCX 470. This is an exciting time for Nicox, and we look forward to keeping you updated on our progress."*

Following discussion with the AMF, the Company has requested the suspension of trading in Nicox shares today, Wednesday May 31, 2017. Trading is expected to recommence shortly after the issuance of this press release

ZERVIATE CLINICAL TRIALS

The efficacy of ZERVIATE was established in three randomized, double-masked, placebo-controlled, conjunctival antigen challenge (Ora-CAC®[3] model of allergic conjunctivitis) clinical trials in patients with a history of allergic conjunctivitis. Onset and duration were evaluated in two of these trials in which ZERVIATE demonstrated statistically and clinically significantly less ocular itching compared to vehicle at 15 minutes and 8 hours after treatment.

"Today, the approval of ZERVIATE is a testament to our team's expertise and unwavering commitment to bringing new ophthalmic treatment options to patients," **commented Michael Bergamini, Chief Scientific Officer and Executive Vice President of Nicox, adding** "*We'd like to thank the exceptional team that has worked on this project, both internally and externally."*

About ZERVIATE

ZERVIATE, the brand name approved by the U.S. FDA for cetirizine ophthalmic solution, 0.24% (formerly AC-170), is a novel formulation of cetirizine developed for the first time for topical application in the eye. Cetirizine, the active ingredient in Zyrtec®[4], is a second generation antihistamine (H1 receptor antagonist) that binds competitively to histamine receptor sites to reduce swelling, itching and vasodilation. Cetirizine, in approved oral formulations, has a well-characterized systemic efficacy and safety profile with world-wide exposure representing more than 300 million patient-years[5,6,7].

Approval of the ZERVIATE NDA on or before 1st December 2017 triggers a milestone payment in Nicox

shares equivalent to $6.8 million[8]. This payment will be made to the former shareholders of Aciex within 7 business days of the FDA approval date for ZERVIATE and will result in the issuance of new shares representing approximately 2.4% of the share capital.

Important Information about ZERVIATE

INDICATION: ZERVIATE (cetirizine ophthalmic solution) 0.24% is indicated for treatment of ocular itching associated with allergic conjunctivitis.

DOSAGE AND ADMINISTRATION: The recommended dose is one drop in each affected eye twice daily (approximately 8 hours apart).

IMPORTANT SAFETY INFORMATION

The most commonly reported adverse reactions occurred in approximately 1-7% of patients treated with either ZERVIATE or vehicle. These reactions were ocular hyperemia, instillation site pain, and reduction in visual acuity.

About Allergic Conjunctivitis

Allergic conjunctivitis occurs when an allergic reaction causes conjunctivitis. Conjunctivitis is an inflammation of the thin layer of tissue that lines the white surface of the eye and the inner surface of the eyelids. It is a common eye disease, especially in children, and may affect one or both eyes. The signs and symptoms may include eye redness, excessive watering, itchy burning eyes, discharge, blurred vision and increased sensitivity to light. It is estimated that more than 75 million people suffer from allergic conjunctivitis in the U.S.[9] and the prevalence ranges from 20% to 40%[10,11].

Notes:

1. ZERVIATE is the tradename approved for cetirizine ophthalmic solution, 0.24%
2. Vyzulta™ is the provisionally approved tradename for latanoprostene bunod ophthalmic solution, 0.024%
3. Ora-CAC® is a registered trademark of Ora, Inc.
4. Zyrtec® is a trademark of UCB Pharma SA or GlaxoSmithKline
5. ZYRTEC® (Cross-discipline team-leader review)
6. Charlesworth, E.N., et al., Effect of cetirizine on mast cell-mediator release and cellular traffic during the cutaneous late-phase reaction. J Allergy Clin Immunol, 1989. 83: p. 905-12.
7. Levi-Schaffer, F. and R. Eliashar, Mast cell stabilizing properties of antihistamines. J Invest Dermatol, 2009. 129: p. 2549-51
8. The payment of $10 million in Nicox shares to ex-Aciex shareholders will be reduced by $3.2 million related to the costs incurred by Nicox in running the additional clinical safety study on ZERVIATE.(see Document E 14-060 dated of September 30, 2014 available on Nicox' website). ZERVIATE was developed by Aciex Therapeutics, Inc., which became a wholly-owned subsidiary of Nicox in October 2014, and was subsequently renamed Nicox Ophthalmics, Inc.
9. Global Data: Allergic Conjunctivitis Market Analysis, September 2014.
10. Nathan RA, Meltzer EO, et al. Prevalence of allergic rhinitis in the United States. J Allergy Clin Immunol 1997; 99(6)2:S808-S814.
11. Singh K, et al. Epidemiology of ocular and nasal allergy in the United States, 1988-1994. Journal of Allergy and Clinical Immunology; 2010. 126: 778–783

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 an approved NDA product and another product 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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Upcoming financial and business conferences

June 19-22	2017 BIO International Convention	San Diego, US
September 25-27	Cantor Fitzgerald's 3rd Annual Healthcare Conference	New York; US

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