Press Release

Nicox announces PDUFA date for ZERVIATE[1] NDA

- **PDUFA date set for September 8, 2017**

April 11, 2017
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 set a PDUFA date of September 8, 2017 for its decision on the New Drug Application (NDA) for ZERVIATE (cetirizine ophthalmic solution) 0.24%, Nicox's novel, proprietary, cetirizine eye drop formulation for the treatment of ocular itching associated with allergic conjunctivitis.

Michele Garufi, Chairman and Chief Executive Officer of Nicox, commented: *"The FDA's acknowledgement regarding the completeness of the NDA resubmission for ZERVIATE and the assignment of a PDUFA goal date of September 8, 2017 are important milestones for Nicox. Together with the August 24, 2017 PDUFA goal date for Vyzulta™, licensed to Bausch + Lomb (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.), we now await two approval decisions from FDA during the next 6 months for our lead programs, both of which are expected to be sources of significant recurrent revenue for the Company. For ZERVIATE, we will continue to work closely with the FDA toward an approval decision in September, and advance our partnering discussions for U.S. commercialization rights which are already underway."*

Nicox resubmitted the NDA for ZERVIATE on March 8, 2017, in reply to a Complete Response Letter (CRL) received from the U.S. FDA in October 2016. The FDA's stated reason for the CRL pertained solely to a CGMP inspection at a third party facility producing the active pharmaceutical ingredient (API), cetirizine, and supplying it to the manufacturer of the finished product. The FDA's Current Good Manufacturing Practice (CGMP) concerns surrounding the production site of the active pharmaceutical ingredient (API), cetirizine, have been resolved[2]. The safety and efficacy data submitted by Nicox in the ZERVIATE NDA have not resulted in the FDA requesting any further clinical or non-clinical testing for the approval of the ZERVIATE NDA. Furthermore, the CRL did not include any concerns related to the finished product manufacturing facility.

About ZERVIATE

ZERVIATE, the brand name provisionally approved by the U.S. FDA for cetirizine ophthalmic solution, 0.24% (formerly AC-170), is a novel formulation of cetirizine being developed for the first time for topical application in the eye. Cetirizine, the active ingredient in Zyrtec®[3], is a second generation antihistamine (H1 receptor antagonist) and mast cell stabilizer 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[4,5,6].

Approval of the ZERVIATE NDA on or before 1st December 2017 would trigger a milestone payment in Nicox shares equivalent to $6.8 million[7].

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.[8] and the

prevalence ranges from 20% to 40%[9,10].

Notes:

1. ZERVIATE is the tradename provisionally approved for cetirizine ophthalmic solution, 0.24%
2. The production site has received an establishment inspection report (EIR). An EIR is issued by the FDA when the FDA considers that an inspection is "closed" under 21 CFR 20.64(d)(3).
3. Zyrtec® is a trademark of UCB Pharma SA or GlaxoSmithKline.
4. ZYRTEC® (Cross-discipline team-leader review)
5. 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.
6. Levi-Schaffer, F. and R. Eliashar, Mast cell stabilizing properties of antihistamines. J Invest Dermatol, 2009. 129: p. 2549-51
7. 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
8. Global Data: Allergic Conjunctivitis Market Analysis, September 2014.
9. Nathan RA, Meltzer EO, et al. Prevalence of allergic rhinitis in the United States. J Allergy Clin Immunol 1997; 99(6)2:S808-S814.
10. 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 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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June 19-22	2017 BIO International Convention	San Diego, US

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