# Nicox holds successful pre-NDA meeting with FDA on AC-170 clinical package

January 26, 2015.

Sophia Antipolis, France.

**Nicox S.A.** (NYSE Euronext Paris: COX), the international ophthalmic company, today announced that it has held a positive pre-New Drug Application (NDA) meeting with the United States Food and Drug Administration (FDA) regarding AC-170, a topical ocular formulation of cetirizine developed for the treatment of ocular itching associated with allergic conjunctivitis. The purpose of the meeting was to discuss the clinical package for AC-170, and based on the available efficacy and safety data, the Agency recommended submission of the NDA. Nicox will hold an additional pre-NDA meeting regarding the Chemistry, Manufacturing and Controls (CMC) data package, which is expected to take place in the first quarter of 2015. Nicox will update the market in due course on the expected NDA submission date.

AC-170 is a novel formulation of cetirizine being developed for the first time for topical application in the eye. Cetirizine is a second-generation histamine H1-receptor antagonist and a leading antihistamine which has been marketed for more than 25 years. AC-170 has been developed for the treatment of ocular itching associated with allergic conjunctivitis by Aciex Therapeutics, Inc., which became a wholly-owned subsidiary of Nicox in October 2014.

**About Nicox**

Nicox (Bloomberg: COX:FP, Reuters: NCOX.PA) is an emerging international company focused on the ophthalmic market. With a heritage of innovative R&D, business development and commercial expertise, the Nicox team is building a diversified portfolio of ophthalmic products that can help people to enhance their sight. The Company has established direct commercial operations in the main European markets as well as an expanding international network of distributors.

Nicox's R&D pipeline features several near-term therapeutics, including VESNEO (latanoprostene bunod), a novel compound based on Nicox's proprietary nitric oxide (NO)-donating research platform currently in phase 3 with Bausch + Lomb for glaucoma and ocular hypertension, and AC-170 (cetirizine eye drop), which has completed phase 3 for allergic conjunctivitis. The Company is also conducting other research programs based on its NO-donating platform.

Nicox is headquartered in France and is listed on Euronext Paris (Compartment B: Mid Caps). For more information on Nicox or its products please visit www.nicox.com.

**This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated in the forward-looking statements.**

**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 2013" filed with the French Autorité des Marchés Financiers (AMF) on April 2nd, 2014; the "Rapport semestriel financier et d'activité au 30 juin 2014"; the 5th chapter of the "Actualisation du Document de Référence 2013" filed with the AMF on September 30, 2014 (D. 14-0271-A01); and the section B of the 'Document E' registered with the AMF on September 30, 2014 (E.14-060). All these documents are available on Nicox's website (www.nicox.com).**

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