Press Release

Nicox resubmits AC-170 (ZERVIATE[1]) NDA to the U.S. FDA

- **CGMP issues at the API manufacturer have been resolved**
- **NDA resubmitted on March 8, 2017**
- **ZERVIATE as the brand name provisionally approved by the U.S. FDA for AC-170**

March 9, 2017
Sophia Antipolis, France

Nicox S.A. (Euronext Paris: FR0013018124, COX), the international ophthalmic R&D company, today announced the resubmission of the New Drug Application (NDA) for AC-170, its novel, proprietary, cetirizine eye drop formulation for the treatment of ocular itching associated with allergic conjunctivitis. The brand name provisionally approved by the U.S. Food and Drug Administration (FDA) for AC-170 is ZERVIATE.

Nicox received confirmation that the FDA's Current Good Manufacturing Practice (CGMP) concerns surrounding the production site of the active pharmaceutical ingredient (API), cetirizine, have been resolved[2], and the Company subsequently updated and resubmitted the ZERVIATE (cetirizine ophthalmic solution) 0.24% NDA to the U.S. FDA. Once resubmitted, the FDA has 30 days to acknowledge its receipt, state the classification, and provide the due date for action, with a maximum review period of 6 months if the resubmission is a Class 2 resubmission.

"Resolution of the FDA's concerns surrounding the API manufacturing site is excellent news for Nicox, allowing us to resubmit the NDA for a potential approval before the end of 2017," **said Michele Garufi, Chairman and Chief Executive Officer of Nicox.** *"Our go-to-market strategy for ZERVIATE is to secure a commercialization partner in the U.S., and this opportunity has already generated interest from several parties, with discussions ongoing involving key industry players active in both eye care and general practitioner segments. Together with latanoprostene bunod (VYZULTA[3]), which, subject to FDA approval, our partner Bausch + Lomb expects to launch into the US market in the second half of 2017, this gives Nicox two potential revenue generating assets approved in 2017 to support our growth and the development of our value-creating pipeline."*

In October 2016, Nicox announced the receipt of a Complete Response Letter (CRL) from the U.S. FDA in response to the ZERVIATE NDA. The FDA's stated reason for the CRL pertained solely to a CGMP inspection at a third party facility producing the API, cetirizine, and supplying it to the manufacturer of the finished product. 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. Food and Drug Administration for AC-170, is a novel formulation of cetirizine, the active ingredient in Zyrtec®[4], being developed for the first time for topical application in the eye. Cetirizine 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, as an approved oral drug, 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 would trigger a milestone payment of $10 million in Nicox shares to ex-Aciex shareholders. The amount of the payments due will be reduced by $3.2 million related to the costs incurred by Nicox in running the additional clinical safety study on ZERVIATE.

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.

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 AC-170
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. Vyzulta is the provisionally approved name for latanoprostene bunod ophthalmic solution (0.24%)
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. 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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March 21-22	Oppenheimer 27th Annual Healthcare Conference	New York, US
April 4-5	Needham's 16th Annual Healthcare Conference	New York, US
April 18-19	Small Cap Event	Paris, France
May 3-4	Deutsche Bank 42nd Annual Health Care Conference	Boston, US
May 22-23	BioEquity Europe	Paris, France
May 30	Gilbert Dupont 15th Annual Healthcare Conference	Paris, France
June 19-22	2017 BIO International Convention	San Diego, US

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