

Press Release

Nicox Announces U.S. FDA Acceptance of Investigational New Drug Application for NCX 4251 Phase 2 Trial in Blepharitis

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Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that the U.S. Food and Drug Administration (FDA) has completed its review of the Company's Investigational New Drug (IND) application for NCX 4251, a novel patented ophthalmic suspension of fluticasone propionate nanocrystals, being developed as the first targeted topical treatment of the eyelid margin for patients with acute exacerbations of blepharitis. The IND was submitted to the U.S. FDA in December 2018 ahead of the target of the first quarter of 2019.

The IND is now in effect and we look forward to announcing the start of the first-in-human, randomized, placebo-controlled, Phase 2 clinical trial for patients with acute exacerbations of blepharitis, which is expected to report top-line results in the second half of 2019.

About NCX 4251

NCX 4251 is a novel patented ophthalmic suspension of fluticasone propionate nanocrystals which is being developed as the first targeted topical treatment of the eyelid margin for patients with acute exacerbations of blepharitis. Blepharitis is a common eye condition characterized by eyelid inflammation. It is being developed for application via a swab at the eyelid margin, applied directly to the site of inflammation thereby minimizing potential penetration of the drug through the cornea which can lead to the damaging side effects, such as IOP increase, found with current topical steroids.

Fluticasone propionate, the active ingredient in NCX 4251, which has not previously been approved in a topical formulation for use in ophthalmology, has an affinity for the glucocorticoid receptor which is approximately ten times greater than dexamethasone, a corticosteroid commonly used 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.

About Blepharitis

Blepharitis is a condition in which the margins of the eyelids become red and swollen and may contain dandruff like matter and occurs in two forms. Anterior blepharitis affects the outside front of the eyelids, where the eyelashes are attached, and is most commonly caused by bacteria, demodex (a tiny mite that lives in or near hair follicles) and scalp dandruff. Posterior blepharitis affects the inner edge of the eyelids, the moist part which makes contact with the tear film of the eye, and is most commonly caused by problems with certain eyelid oil glands, or meibomian glands. Acne, rosacea and scalp dandruff can also cause posterior blepharitis.

Blepharitis often coexists with other related conditions, such as dry eye, with an incidence that is similar to or higher than dry eye in evaluations of symptomatic patients (24% incidence of blepharitis versus 21% incidence of dry eye). It is believed that in patients with both blepharitis and dry eye, an improvement in blepharitis may lead to an improvement of the dry eye disease. Blepharitis is difficult to study and there is little consensus on the prevalence of the disease. Studies show, however, that blepharitis is one of the



most common conditions encountered in clinical practice. Of patients seen by ophthalmologists and optometrists, 37% and 47%, respectively, present with signs of the disease.

There is currently no FDA approved prescription product solely indicated for blepharitis. Treatment options include lid scrubs, topical ophthalmic steroids, topical ophthalmic antibiotics and topical ophthalmic antibiotic/steroid combinations. The annual U.S. revenues for products prescribed for blepharitis among these three categories total more than \$500 million according to IQVIA Health Analytics. Surveys reveal that ophthalmologists consider anti-inflammatory activity to be the most important product attribute when selecting a treatment for blepharitis, which supports the development of NCX 4251.

About Nicox

Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. By leveraging our proprietary expertise in nitric oxide (NO) donation and other technologies, we are developing an extensive portfolio of novel product candidates that target multiple ophthalmic conditions, including glaucoma. Our portfolio includes three programs in development including NCX 470 for intraocular pressure lowering, based on our proprietary NO-donating research platform and NCX 4251, a proprietary formulation of the well-established molecule fluticasone, for acute exacerbations of blepharitis. Our research activities are focused on novel future generation NO-donors including NO-donating phosphodiesterase-5 (PDE5) inhibitors and NO-donating soluble guanylate cyclase (sGC) stimulators (in partnership with Ironwood). In addition, we have two ophthalmology assets that have been approved by the U.S. Food and Drug Administration (FDA); VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%, exclusively licensed worldwide to Bausch + Lomb, a Bausch Health Companies Inc. company, and commercialized in the U.S. by Bausch + Lomb since December 2017, as well as ZERVIA™ (cetirizine ophthalmic solution), 0.24%, exclusively licensed in the U.S. to Eyeavance Pharmaceuticals. 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

Analyst coverage

Bryan, Garnier & Co Hugo Solvet Paris, France



The views expressed by analysts in their coverage of Nicox are those of the author and do not reflect the views of Nicox. Additionally, the information contained in their reports may not be correct or current. Nicox disavows any obligation to correct or to update the information contained in analyst reports.

Upcoming financial and business conferences

February 12	European Midcap Event	Frankfurt, Germany
March 19-20	Oppenheimer's 29th Annual healthcare Conference	New York, U.S.
April 7-9	H.C. Wainwright Global Life Sciences Conference	London, UK
April 16-17	SmallCap Event	Paris, France
June 18-19	European MidCap Event	Paris, France

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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 2017*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 19, 2018, which are available on Nicox's website (www.nicox.com).

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