



Press Release

Nicox's Partner Fera Pharmaceuticals Files Application for Orphan Drug Designation for Naproxcinod in Sickle-Cell Disease

April 2, 2020 – release at 7:30 am CET Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, and Fera Pharmaceuticals, a privately-held, U.S. specialty pharmaceutical company, announced today that Fera has filed an application with the U.S. Food and Drug Administration (FDA) for an Orphan Drug Designation (ODD) for naproxcinod in sickle-cell disease.

Following results from *in vivo* primary pharmacodynamics studies of naproxcinod in models of sickle-cell disease, Fera has decided to focus its development on the treatment of painful vaso-occlusive crisis in sickle-cell disease. Fera plans to conduct further studies and other development activities in preparation for entering directly into a clinical efficacy trial of naproxcinod in sickle-cell patients, subject to being granted an ODD.

Naproxcinod, a Cyclooxygenase-Inhibiting Nitric Oxide (NO)-Donating (CINOD) naproxen, is a non-steroidal anti-inflammatory product candidate engineered to release NO, originally discovered and developed by Nicox. Nicox and Fera entered into an agreement in December 2015, amended in September 2018, which granted Fera exclusive rights to develop and commercialize naproxcinod for the U.S. market. Nicox is eligible to potentially receive a single \$40 million sales-based milestone if naproxcinod reaches \$1 billion yearly sales (for any indication) in the U.S. as well as royalties of 7% on net sales of naproxcinod in the U.S. Fera is responsible for all clinical development, manufacturing, regulatory and commercialization activities.

Role of nitric oxide in sickle cell disease

Sickle-cell disease is a rare, inherited blood condition where defects in hemoglobin result in red blood cells adopting a "sickle" shape. Rupture of these cells in the bloodstream can lead to inflammation, a reduction in NO and a subsequent endothelial cell wall thickening as well as platelet activation. In this inflamed environment and reduced volume, sickled red blood cells, leukocytes (white blood cells) and activated platelets aggregate to create a "vascular log-jam" (vaso-occlusion), leading to a painful vaso-occlusive crisis.

About naproxcinod

Naproxcinod is a nitric oxide (NO)-donating naproxen combining the cyclooxygenase (COX) inhibitory activity of naproxen with that of NO (COX-inhibiting NO donor, CINOD). While the inhibitory COX component provides the analgesic and anti-inflammatory efficacy, the NO part may play a significant role in maintaining vascular endothelial cell function and integrity, blood pressure homeostasis and microvascular circulation. A broad clinical package already exists for naproxcinod in osteoarthritis, including three phase 3 trials with over 2,700 patients.

About Fera Pharmaceuticals

Fera Pharmaceuticals is a privately held company. The company goal is to realize opportunities via acquisitions, in-licensing, developing and marketing abbreviated new drug applications (ANDAs), new drug applications (NDAs) and 505(b)(2) NDA products. Areas of interest include products that could benefit from lifecycle management with a special focus on niche markets. For more information visit www.ferapharma.com.





About Nicox

Nicox S.A. is an ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's lead program in clinical development is NCX 470, a novel, second-generation nitric oxide-donating bimatoprost analog, for lowering intraocular pressure in patients with glaucoma. The company is also developing NCX 4251, a proprietary formulation of fluticasone, for acute exacerbations of blepharitis. Nicox generates revenue from VYZULTA[®] in glaucoma, licensed exclusively worldwide to Bausch & Lomb, and ZERVIATE™ in allergic conjunctivitis, licensed in multiple geographies, including to Eyevance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and Southeast Asian markets.

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

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Risks factors which are likely to have a material effect on Nicox's business are presented in the 3rd chapter of the 'Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2019 filed with the French Autorité des Marchés Financiers (AMF) on March 6, 2020 which are available on Nicox's website (www.nicox.com).

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