

# **Press Release**

# U.S. Patents for Nicox's Latanoprostene Bunod, Commercialized as VYZULTA<sup>®</sup>, Eligible for Patent Term Extension

April 22, 2021 – release at 7:30 am CET Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that the United States Patent and Trademark Office (USPTO) has determined that three U.S. composition of matter patents covering latanoprostene bunod, commercialized as VYZULTA<sup>®</sup> (latanoprostene bunod ophthalmic solution), 0.024%, are eligible for patent term extension, potentially through to 2030.

The initial patent term of the latanoprostene bunod patents concerned is 2025. Nicox believes that each of these patents could be extended by almost the maximum 5 years allowable. The duration of this patent extension is subject to calculation by the U.S. Food and Drug Administration (FDA) with the final decision of the USPTO regarding the term of the extension expected in two to three years. Nicox would then select one of the three patents for the extension.

**Michele Garufi, Chairman and Chief Executive Officer of Nicox**, said "VYZULTA was launched in the United States in December 2017 by our exclusive global licensee Bausch + Lomb. The extension of the patents covering this product would ensure a long-term revenue source for the company and solid support for future value as we continue the development of our clinical assets NCX 470 in glaucoma and NCX 4251 in blepharitis."

Latanoprostene bunod, the pharmaceutical active ingredient in VYZULTA, was invented and patented by Nicox, and is the first product from the company's proprietary nitric oxide-donating research platform to be approved for commercialization. Under the patent restoration provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the "Hatch-Waxman Act") certain patents for pharmaceutical products in the U.S. may be extended by up to 5 years once product approval from the FDA has been obtained.

VYZULTA is commercialized in the U.S. (since 2017), Canada (2019), Argentina (2020), Mexico (2020) and Hong Kong (2020), and is now approved in 5 other territories (Brazil, Colombia, South Korea, Taiwan and Ukraine). VYZULTA is indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension in the United States and other territories that have the same indication. Bausch + Lomb, which is planning to launch VYZULTA in Taiwan and in South Korea, will continue seeking approvals in territories where the clinical data package, part of the U.S. New Drug Application, can be used for approval by the regulatory authorities.

Under the terms of the exclusive global license agreement with Bausch + Lomb, Nicox receives increasing tiered royalties of 6% to 12% on net global sales of VYZULTA plus up to \$150 million in potential future milestone payments.

### **About Nicox**

Nicox S.A. is an international 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 nitric oxide-donating prostaglandin 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 in the majority of 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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## Forward-Looking Statements

The information contained in this document may be modified without prior notice. This information includes forward-looking statements. Such forward-looking statements are not guarantees of future performance. These statements are based on current expectations or beliefs of the management of Nicox S.A. and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Nicox S.A. and its affiliates, directors, officers, employees, advisers or agents, do not undertake, nor do they have any obligation, to provide updates or to revise any forward-looking statements.

Risks factors which are likely to have a material effect on Nicox's business are presented in the 3<sup>rd</sup> chapter of the '*Document d'enregistrement universel, rapport financier annuel et rapport de gestion 2020*' filed with the French Autorité des Marchés Financiers (AMF) on March 1, 2021 which are available on Nicox's website (<u>www.nicox.com</u>).

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