

## Press Release

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# Nicox to Receive €15 Million and Half of the Cost of the Second NCX 470 Phase 3 Clinical Trial from Ocumension Therapeutics under Amended Agreement

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- **Ocumension will pay Nicox €15M**
- **Ocumension will additionally fund half of the costs of a joint U.S.-Chinese Phase 3 clinical trial on NCX 470, expected to begin in H2 2020, after the start of the Mont Blanc Phase 3 clinical trial**
- **Accelerates the NCX 470 development plans and New Drug Application (NDA) submissions in the U.S. and China**
- **Ocumension rights to NCX 470 are extended to Korea and South East Asian markets**

March 11, 2020 – release at 7:30 am CET  
Sophia Antipolis, France

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that it has amended its December 2018 licence agreement with **Ocumension Therapeutics**, which originally granted Ocumension exclusive rights to develop and commercialize NCX 470 for glaucoma in the Chinese market. Under the amended agreement, Ocumension will immediately pay Nicox €15 million (in place of the milestones in the original agreement), will gain additional rights to NCX 470 for Korea and South East Asia and will pay 50% of the costs of the second glaucoma Phase 3 clinical trial of NCX 470 ('Denali'). The two companies will jointly manage the Denali trial in the U.S. and China.

NCX 470, a novel second generation nitric oxide (NO)-donating bimatoprost analog for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, is Nicox's lead clinical development program. In the multicenter, Phase 2 clinical trial ('Dolomites') conducted in the U.S., NCX 470 demonstrated both statistical non-inferiority and superiority to latanoprost, the U.S. market leader in prostaglandin analog prescriptions.

*"We believe conducting the Denali Phase 3 trial together will allow both companies to more effectively achieve the development goals for NCX 470," said **Gavin Spencer, Chief Business Officer of Nicox**. "Bringing forward the Ocumension milestone payments in this way is a major step in the financing of the U.S. and Chinese NCX 470 programs allowing us to initiate both Phase 3 clinical trials this year and accelerating the NDA submission of NCX 470 in the U.S. and Chinese markets."*

Ocumension is funded by top-tier venture capital investors including 6 Dimensions Capital and other distinguished investors. Ocumension recruited highly qualified management and development teams with significant international experience gained in companies including Santen, Alcon and Novartis. The Ocumension team has conducted ophthalmology clinical studies in China previously and has the personnel and infrastructure in place in China to effectively collaborate with Nicox on the Denali study.

*"Executing one of the key clinical trials for NCX 470 in collaboration with Nicox is the best route for us to achieve approval in the Chinese market and therefore we are very pleased to be further strengthening*

*our relationship with Nicox in this way. We look forward to even deeper collaboration between the teams as we prepare for this trial,” said Ye Liu, Chief Executive Officer of Ocumension.*

As a result of the amendment, Nicox will conduct both of its planned Phase 3 clinical trials, Mont Blanc and Denali, as multi-regional clinical trials in U.S. and China. The two planned Phase 3 trials are required for NDA submission in the U.S. The inclusion of Chinese patients in the Denali trial is designed to support the NCX 470 NDA submission in China without further clinical trials in China. Including the €15 million payment from Ocumension, Nicox now has a cash position of approximately €47 million.

### NCX 470 Phase 3 Clinical Trials Planned

- The first Phase 3 clinical trial on NCX 470 ('Mont Blanc') for lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension is due to start by the end of Q2 2020, with top-line results expected in Q3 2021. The Mont Blanc trial will be managed by Nicox and it will also include a small number of Chinese patients. The Mont Blanc trial will be initiated with 0.065% and 0.1% doses of NCX 470, with one dose being selected during the trial through an adaptive design.
- Nicox and Ocumension will jointly manage, and equally fund, a second glaucoma Phase 3 clinical trial with NCX 470 ('Denali') including clinical sites and patients in both the U.S. and China, with majority of the clinical sites and patients being in the U.S. A sufficient number of patients from China will be included in the Denali trial to support the NCX 470 NDA filing in China.
- The inclusion of the Chinese patients in the NCX 470 Phase 3 program was discussed and agreed on with the U.S. FDA during the recently reported End-of-Phase 2 meeting.

### Amendment Agreement Terms

Under the 2018 agreement, Ocumension received exclusive rights to develop and commercialize NCX 470, at its own cost, in the Chinese market. Nicox received a one-time upfront payment of €3 million from Ocumension. Under the amended agreement, Ocumension will immediately pay Nicox €15 million and, furthermore, will fund 50% of the costs of the joint U.S.-China second Phase 3 clinical trial. No future NCX 470 milestones will be due from Ocumension to Nicox. In the unlikely case that the Joint Trial would not take place, refunds of some or the significant majority of this payment may be made and in certain situations the original milestones of the agreement would again apply.

Under the amendment, Nicox also expanded the grant of exclusive NCX 470 rights to Ocumension to include Korea and the ASEAN group of countries. The tiered royalties of 6% to 12% of the original agreement remain unchanged and will apply to sales in the original and the additional territories.

As also announced today, the territory of the ZERVIAE license agreement between Nicox and Ocumension was expanded to include certain Asian countries.

### About Nicox

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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 has three programs in development including NCX 470, a novel, second-generation NO-donating bimatoprost analog, 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 Cyclicerion). 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 ZERVIAE™ (cetirizine ophthalmic solution), 0.24%, exclusively licensed in the U.S. to Eyevence Pharmaceuticals, LLC.

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.

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For more information on Nicox, its products or pipeline, please visit: [www.nicox.com](http://www.nicox.com).

### About Ocumension Therapeutics

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Ocumension is a China-based company with a mission of being a pioneer in Ophthalmology. It develops and provides prescription medicines that meet the evolving needs of patients, healthcare professionals, and caregivers. With its experienced group, Ocumension's capabilities span from research and development to clinical trial execution to marketing and sales of in-licensed and wholly owned products. Aiming to help more patients, Ocumension is building its portfolio of new medications and technologies through internal research & development and strategic alliances with global partnerships.

### Analyst coverage

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Bryan, Garnier & Co	Victor Floc'h	Paris, France
Cantor Fitzgerald	Louise Chen	New York, U.S.
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Oppenheimer & Co	Hartaj Singh	New York, U.S.



*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.*

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### Forward-Looking Statements

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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 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](http://www.nicox.com)).

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