

## Press Release

---

# Nicox's Partner Ocumension Therapeutics Initiates ZERVIAE Phase 3 Clinical Trial in China

---

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

**Nicox SA** (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today announced that its partner, Ocumension Therapeutics, has initiated a Phase 3 clinical trial in China with ZERVIAE™, the first and only topical ocular formulation of the antihistamine cetirizine, for the treatment of ocular itching associated with allergic conjunctivitis.

**Gavin Spencer, Chief Business Officer at Nicox**, said: *“Our teams worked very closely to obtain the Chinese Investigative New Drug approval for this trial and we are pleased that Ocumension has been able to capitalize on that with a swift initiation of the trial. This Phase 3 trial, in addition to the data package used by the FDA for ZERVIAE in the United States, is expected to be sufficient to support a Chinese New Drug Application. The initiation of this trial keeps Ocumension on track with their launch plans for China.”*

The Phase 3 trial is a randomized, observer-masked, positive control, multi-center parallel clinical trial evaluating the safety and efficacy of ZERVIAE for Chinese patients with allergic conjunctivitis, and is expected to enroll approximately 296 patients at approximately 15 clinical centers.

The Press Release by Ocumension can be found [here](#):

ZERVIAE™ (cetirizine ophthalmic solution), 0.24%, is the first and only topical ocular formulation of the antihistamine cetirizine. ZERVIAE is exclusively licensed to Ocumension Therapeutics for the Chinese and South East Asian markets. Nicox may potentially receive development and sales milestones of up to US\$19 million together with royalties of between 5% and 9% of net sales of ZERVIAE by Ocumension.

ZERVIAE, launched in the United States in March 2020 by Eyevance Pharmaceuticals, Nicox's exclusive U.S. licensee, is also licensed to Samil Pharmaceutical in South Korea and to ITROM Pharmaceutical Group in the Gulf and Arab markets.

### About ZERVIAE

---

ZERVIAE™ (cetirizine ophthalmic solution), 0.24% is a novel formulation of cetirizine developed and approved for the first time for topical application in the eye for the treatment of ocular itching associated with allergic conjunctivitis. Cetirizine, the active ingredient in ZYRTEC®, is a second-generation antihistamine (H1 receptor antagonist) that binds competitively to histamine receptor sites. Cetirizine, in approved oral formulations, has a well-characterized systemic efficacy and safety profile with worldwide exposure resulting from 20 years of oral use. ZERVIAE was developed by Nicox as the first and only formulation of cetirizine for topical application in the eye.

### 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 outside of the white surface of the eye and the inner surface of the eyelids. It 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.

### 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, 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 ZERVIAE™ in allergic conjunctivitis, licensed in multiple geographies, including to

Eyeavance Pharmaceuticals, LLC, in the U.S. and Ocumension Therapeutics in the Chinese and in the majority of South East 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](http://www.nicox.com).

## Analyst coverage

|                      |                 |                |
|----------------------|-----------------|----------------|
| 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. |
| Kepler Cheuvreux     | Damien Choplain | Paris, France  |
| 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.*

## Contacts

### Nicox

Gavin Spencer  
Executive Vice President, Chief Business Officer  
& Head of Corporate Development  
T +33 (0)4 97 24 53 00  
[communications@nicox.com](mailto:communications@nicox.com)

### Investors & Media

United States & Europe  
LifeSci Advisors, LLC  
Mary-Ann Chang  
T +44 7483 284 853  
[mchang@lifesciadvisors.com](mailto:mchang@lifesciadvisors.com)

### Media

France  
LifeSci Advisors, LLC  
Sophie Baumont  
M +33 (0)6 27 74 74 49  
[sophie@lifesciadvisors.com](mailto:sophie@lifesciadvisors.com)

## 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 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)) and as restated in the 4<sup>th</sup> chapter of the half yearly financial report as of June 30, 2020, which is also available on Nicox's website.

### Nicox S.A.

Drakkar 2  
Bât D, 2405 route des Dolines  
CS 10313, Sophia Antipolis  
06560 Valbonne, France  
T +33 (0)4 97 24 53 00  
F +33 (0)4 97 24 53 99