



## Nicox launches Sjö™ in the US and partners with the Sjögren's Syndrome Foundation

- Nicox launches Sjö™, an advanced diagnostic for early detection of Sjögren's Syndrome, a serious, progressive and underdiagnosed autoimmune disease
- US eye care professionals are uniquely positioned to identify Sjögren's Syndrome as dry eye is a common early symptom

November 12, 2013.

Sophia Antipolis, France.

**Nicox S.A.** (NYSE Euronext Paris: COX) today announces that Sjö™, an advanced diagnostic panel for the early detection of Sjögren's Syndrome, has been launched in the US. Nicox's sales force is now promoting Sjö™ in select US markets to eye care professionals, who are in a unique position to identify Sjögren's Syndrome as dry eye is a significant and early symptom of the condition. Nicox also announces that it has formed a partnership with the Sjögren's Syndrome Foundation to raise awareness of the disease among eye care professionals.

**Jerry St. Peter, Executive Vice President and General Manager of Nicox Inc,** commented, *"The launch of a proprietary, novel test for early detection of Sjögren's Syndrome demonstrates the potential of ophthalmic diagnostics in a wide range of conditions. Sjö™ is the second diagnostic which Nicox has launched in the US and represents another important step towards our goal of becoming a leading provider of ophthalmic diagnostics, drugs and devices. We are pleased to partner with the Sjögren's Syndrome Foundation to increase awareness of this serious and underdiagnosed condition among eye care practitioners across the country."*

### Introducing Sjö™ for the early detection of Sjögren's Syndrome

Sjö™ is an advanced diagnostic panel for the detection of Sjögren's Syndrome, with high sensitivity and specificity. Sjögren's Syndrome is among the most common and underdiagnosed autoimmune diseases

which can lead to significant morbidity, diminished gland performance and atrophy. It is estimated to affect 4 million people in the US, of which 3 million are undiagnosed<sup>1,2</sup>.

Sjö™ is a proprietary laboratory test developed by Immco Diagnostics Inc. which combines traditional markers with three novel, proprietary biomarkers, allowing earlier detection of the disease. It will be promoted to US eye care professionals by Nicox's US sales force under an exclusive North American agreement signed with Immco in June 2013. Sjö™ is the second product launched by Nicox in the US following the launch of AdenoPlus®, a rapid point-of-care diagnostic test that aids in the differential diagnosis of acute conjunctivitis, in October 2012. Over the past year, Nicox has been building its own specialist sales force in selected US markets to support these and other future launches.

### **Early Diagnosis Can Improve Management of Sjögren's Syndrome**

Sjögren's Syndrome causes patients' immune cells to attack moisture-producing glands resulting in dry eye, which is one of the early and hallmark symptoms of the disease. Many Sjögren's patients first see their eye care practitioner with dry eye symptoms which are often mistaken for routine dry eye. It is estimated that more than 20 million patients aged 40 years and older suffer from dry eyes in the US<sup>3</sup>, and as many as 1 in 10 dry eye patients may also have Sjögren's Syndrome<sup>4</sup>.

Eye care practitioners are therefore in a unique position to help identify patients with Sjögren's Syndrome. Currently, there is an average delay of 4.7 years for patients to receive an accurate diagnosis, and patients are often diagnosed in late stages of the disease after gland degradation has taken effect. Earlier detection is important to allow time for proper management and to help avoid further complications.

Sjö™ was approved by US regulatory authorities in 2013 and is available to eye care practitioners across North America (US, Canada, Puerto Rico, Mexico). The simple, in-office test can be easily incorporated into every dry eye screening. US eye care practitioners can obtain more information and order Sjö™ by calling +1.855.MY.NICOX (+1.855.696.4269). Sjö™ is not available in Europe for the time being.

### **Nicox forms partnership with the US Sjögren's Syndrome Foundation**

Nicox has established a partnership with the US Sjögren's Syndrome Foundation to raise awareness of the prevalence, seriousness and significance of Sjögren's Syndrome to eye care specialists. A targeted media campaign over the next few months will aim to educate specialists about the disease and the role they can play in early detection.

*"The Sjögren's Syndrome Foundation is honored to be partnering with Nicox as they unveil their new Sjögren's diagnostic," commented **Steven Taylor, Chief Executive Officer at the Sjögren's Syndrome Foundation.** "This partnership will help educate eye care professionals about the seriousness of Sjögren's and encourage them to identify potential Sjögren's patients, enabling them to receive proper diagnosis and timely medical care to treat this serious autoimmune disease."*

## **Exclusive North American Agreement with Immco Diagnostics Inc.**

The agreement with Immco grants Nicox exclusive rights to promote Sjö™ to eye care practitioners in North America (US, Canada, Puerto Rico, Mexico). Nicox will be responsible for all marketing activities, while Immco will carry out the test in its CLIA-approved laboratory in Buffalo, NY, and be responsible for regulatory activities and reimbursement. Nicox will receive a majority share of revenue generated from eye care practitioners and no upfront or milestones payments will be made by Nicox.

Nicox also has an option to negotiate an agreement to promote the test in the rest of the world. Immco and Nicox are evaluating the feasibility and implementation steps for the test in other markets, including Europe.

## **About Sjögren's Syndrome**

Sjögren's Syndrome is a systemic chronic autoimmune disorder of the exocrine glands with associated lymphocytic infiltrates in affected glands. Involvement of the lacrimal and salivary glands leads to the classic symptoms of dryness of the eyes and mouth.

Ocular signs and symptoms of Sjögren's Syndrome are consistent with the presentation of dry eye syndrome. Patients often complain of ocular irritation with the accompanying symptoms: burning, stinging, itching, foreign body sensation, lid irritation and swelling, photophobia, ocular fatigue, mucoid discharge. As disease progression advances, patients experience significant morbidity, diminished gland performance, and eventual atrophy.

Damage to other body parts (joints, thyroid, kidneys, liver etc.), and increased dental damage (tooth loss, infection) is also common in advanced disease, along with an increased risk of developing lymphoma.

Sjögren's symptoms frequently overlap with or "mimic" those of other diseases including lupus, rheumatoid arthritis, fibromyalgia, chronic fatigue syndrome, and multiple sclerosis. Dryness can also occur for other reasons, such as a side effect of medications such as anti-depressants and high blood pressure medication. There is no single test that will confirm diagnosis. Rheumatologists have primary responsibility for diagnosing and managing Sjögren's and can conduct a series of tests and ask about symptoms. An international group of experts formulated classification criteria for Sjögren's which help doctors arrive at a diagnosis. These criteria consider dryness symptoms, changes in salivary (mouth) and lacrimal (eye) gland function, and systemic (whole body) findings<sup>1</sup>.

## **About the US Sjögren's Syndrome Foundation**

The Sjögren's Syndrome Foundation is a United States non-profit organization focused on increasing research, education and awareness for Sjögren's Syndrome. It was founded in 1983 to help Sjögren's patients cope with their disease, increase awareness, and support research efforts. The United States Sjögren's Syndrome Foundation serves as the lead organization for all other Sjögren's groups, worldwide. For more information, please visit [www.sjogrens.org](http://www.sjogrens.org).

References:

- <sup>1</sup> Sjögren's Syndrome Foundation. 2001. Available at <http://www.sjogrens.org>. Accessed September 5, 2013.
- <sup>2</sup> Kassan SS, Moutsopoulos HM. Clinical manifestations and early diagnosis of Sjögren's Syndrome. *Arch Intern Med.* **2004**;164: 1275-1284.
- <sup>3</sup> 2010 Datamonitor report.
- <sup>4</sup> Liew M, Zhang M, Kim E, et al. Prevalence and predictors of Sjögren's syndrome in a prospective cohort of patients with aqueous-deficient dry eye. *Br J Ophthalmol.* **2012**;96: 1498-1503.



**About Nicox**

Nicox (Bloomberg: COX:FP, Reuters: NCOX.PA) is an emerging international company focused on the ophthalmic market. With a heritage of innovative R&D, business development and commercial expertise, the Nicox team is building a diversified portfolio of therapies and diagnostic tools that can help people to enhance their sight. The Company's commercial portfolio and near-term pipeline already include several innovative diagnostic tests intended for eye care professionals, as well as a range of eye care products. Nicox's key proprietary asset in ophthalmology is latanoprostene bunod, a novel compound based on Nicox's proprietary nitric oxide (NO)-donating R&D platform, currently in Phase 3 clinical development in collaboration with Bausch + Lomb for the potential treatment of glaucoma and ocular hypertension. Further NO-donors are under development, notably through partners.

Nicox is headquartered in France, with research capabilities in Italy, a growing commercial infrastructure in North America and in the major European markets and an expanding international presence through partners. Nicox S.A. is listed on Euronext Paris (Compartment B: Mid Caps). For more information on Nicox or its products please visit [www.nicox.com](http://www.nicox.com).

**This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated in the forward-looking statements.**

**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 2012 » filed with the French Autorité des Marchés Financiers (AMF) on March 22, 2013 and available on Nicox's website ([www.nicox.com](http://www.nicox.com)) and on the AMF's website ([www.amf-france.org](http://www.amf-france.org)).**



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