Nicox Strengthens Ophthalmic Portfolio with Immco Diagnostics’ Proprietary Test in the Dry Eye Market

Exclusive North American Agreement with rest of the world option

- Exclusive rights to promote a proprietary laboratory test targeted at early diagnosis of Sjögren’s Syndrome, one of the most prevalent and underdiagnosed of all auto-immune diseases, with dry eye being among the early signs and symptoms
- With more than 20 million patients suffering from dry eye in the US\(^1\), eye care practitioners are poised to play a significant and pivotal role in Sjögren’s Syndrome identification
- 1 in 10 patients with dry eye symptoms may have undiagnosed Sjögren’s Syndrome\(^2\)
- Test was approved in the US in 2013 and available to doctors across North America. Commercial launch by Nicox expected in the second half of this year
- Nicox to receive majority share of revenue

June 19, 2013.

Sophia Antipolis, France.

Nicox S.A. (NYSE Euronext Paris: COX) announced today that it has entered into an exclusive agreement with Immco Diagnostics Inc. (“Immco”), a worldwide leader in autoimmune diagnostic products and services, to promote a proprietary laboratory test targeted at early detection and diagnosis of Sjögren’s Syndrome to eye care professionals in North America. Dry eye is one of the early primary symptoms of the disease and the collaboration will give eye care practitioners and their patients’ increased access to this new state-of-the-art and unique test which supports early diagnosis and potentially more efficient management of this chronic disease.

Under the terms of the agreement, Immco will grant Nicox the exclusive rights to promote the laboratory test 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 a nine month option to negotiate an agreement to promote the test in the rest of the world. During this period, Immco and Nicox are planning to study and evaluate the feasibility and implementation steps for the test in other markets, including Europe.

Sjögren’s Syndrome is among the most common and underdiagnosed autoimmune diseases. Current diagnostic methods are only moderately effective at diagnosing the disease and can be used only once it has progressed to an advanced stage where treatment options are limited.

“This new test will facilitate faster diagnosis and we look forward to working in partnership with our eye care colleagues. Many early stage Sjögren’s Syndrome patients see their Ophthalmologist or Optometrist initially with dry eye signs and symptoms, in some cases years before ever being formally diagnosed at later stage by a Rheumatologist. The eye care community is really on the “front line” of identifying and detecting these patients at an early stage where we can have a more profound impact on the course of the disease”, said Julian L. Ambrus Jr., M.D., Associate Professor of Medicine, Rheumatology, University of Buffalo.

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. Sjögren’s Syndrome frequently progresses into a multisystem disorder involving exocrine glands and other organs, and can lead to a significant increased risk of lymphoma.

Dry eyes are among the most common reasons for patients to visit an eye care professionals’ office today. In the US alone, it is estimated that more than 20 million patients aged 40 years and older have dry eye disease¹. Studies indicate that 10% of these may have early stage, yet to be diagnosed, Sjögren’s Syndrome². At present, many of these patients who develop the advanced disease will not be diagnosed until much later by another medical specialty.

The new laboratory test developed by Immco is a highly sensitive and specific diagnostic test combining three novel proprietary biomarkers (SP-1, CA-6, PSP) and the traditional markers (ANA, Ro, La, RF). This breakthrough test can aid in diagnosing Sjögren’s Syndrome at an earlier stage compared to traditional methods therefore significantly improving management of the disease. The test was approved by the appropriate US regulatory authorities in 2013, and is already available to doctors across North America.

“The convergence of Dry Eye symptoms and undiagnosed, early stage Sjögren’s Syndrome uniquely positions Ophthalmologists and Optometrists to be able to make this diagnosis because these patients are coming into our offices every day. Clinical studies have indicated that about 1 in 10 patients with clinically significant dry eye are positively diagnosed with Sjögren’s Syndrome which may surprise many eye care professionals” said Gary Foulks, M.D., Emeritus Professor of Ophthalmology, University of Louisville School of Medicine.

Nicox has significant experience within the ocular surface disease space and ophthalmic diagnostic markets, and recently built its own commercial organization in the US. The Company intends to expand its existing sales organization to maximize the opportunity with this new test alongside AdenoPlus®, the first and only CLIA-waived point-of-care diagnostic test that aids in the differential diagnosis of acute conjunctivitis, and other point-of-care diagnostic tests.
“Immco is a well-established and innovative organization with a reputation for cutting edge science and high quality products. The addition of this new test into our portfolio synergizes well with our existing point-of-care offering, and will contribute to the momentum we are building in the marketplace with AdenoPlus®”, said Jerry St Peter, Executive Vice President and General Manager of Nicox Inc.

“Nicox is one the few eye care specialists in the world with an already existing marketing and sales infrastructure in the ophthalmic diagnostic space. This expertise makes Nicox an ideal partner to deliver Sjögren’s diagnostic solutions”, said Bill Maggio, President and CEO of Immco Diagnostics.

About the laboratory test

The development of this new diagnostic test is based on the discovery of novel antibodies in Sjögren’s Syndrome by researchers at the University at Buffalo and Immco Diagnostics, Inc.: SP-1 (salivary gland protein-1), CA-6 (carbonic anhydrase-6) and PSP (parotid secretory protein). Traditional tests use ANA, Ro, La and RF antibodies which have significant limitations of sensitivity and/or specificity and are associated with later-stage disease. During studies, these novel antibodies were found in 45% of patients meeting the criteria for Sjögren’s Syndrome who lacked the traditional antibodies for Ro or La. In patients diagnosed with idiopathic xerostomia and xerophthalmia for less than two years, 76% had antibodies to SP-1 and/or CA-6 while only 31% had antibodies to Ro or La.

The new test combines novel and traditional markers supporting an accurate and early diagnosis with high sensitivity and specificity. US eye care practitioners can obtain more information on the test by calling 1.855.MY.NICOX.

About Sjögren’s Syndrome

Sjögren’s Syndrome is a systemic chronic autoimmune disorder of the exocrine glands with associated lymphocytic infiltrates in affected glands. It is one of the most common and underdiagnosed autoimmune disorders affecting more than 4 million Americans. 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.

1 2010 Datamonitor report
2 Prevalence and predictors of Sjögren’s syndrome in a prospective cohort of patients with aqueous-deficient dry eye - Melissa (Shiao Hui) Liew, Min Zhang, Elizabeth Kim, Esen K Akpek Evaluation of Patients with Dry Eye for Presence of Underlying Sjögren’s Syndrome - Esen Karamursel Akpek, MD, Alena Klimava, BS, Jennifer E. Thorne, MD, PhD, Don Martin, MD, Kaevalin Lekhanont, MD, and Ann Ostrovsky, MD
4 Sjögren’s Syndrome Foundation
This communication may contain 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) and on the AMF’s website (www.amf-france.org).