



Onxeo consolidates its industrial property with a US patent protecting Validive® until 2029

Paris (France), Copenhagen (Denmark), June 18, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today announced the allowance by the US Patent and Trademark Office (USPTO) of a patent covering its product Validive® until September 2029. Validive® is based on Onxeo’s mucoadhesive technology Lauriad® and has obtained positive Phase II results last year in the prevention of severe oral mucositis in patients treated for head and neck cancer. This allowed US patent claims a new use of clonidine, the active principle of Validive®, in the treatment of oral mucositis. Moreover, this treatment with clonidine formulated in Onxeo’s mucoadhesive technology Lauriad® is also covered by the patent.

After significant countries in Asia, this allowance from the USPTO strengthens significantly the patent protection of Validive® and its value. Oral mucositis is a radio/chemotherapy related condition occurring very frequently in patients undergoing head and neck cancer treatment. With no curative or preventive treatment currently, oral mucositis represents a serious unmet medical need for the patients. The incidence of head and neck cancer in the US is estimated to expand from 55,000 cases in 2015 to 68,000 in 2029, an attractive market of about \$ 350-400 million.

“The new US patent protection is a key strength reinforcing the product’s potential, while also reflecting and acknowledging the innovation represented by Validive®, a product formulated with our Lauriad® mucoadhesive technology”, comments Judith Greciet, CEO of Onxeo.

About oral mucositis

Oral mucositis is a particularly invalidating pathology induced by radio/chemotherapy treatments and very frequent in patients with head and neck cancer. It may induce intense oral pain and eating disability requiring enteral or parenteral nutritional support. Thirty per cent of patients need to be hospitalized as a result and symptoms can force patients to stop treatment for an undefined period thus reducing treatment efficacy. Oral mucositis has currently no validated curative or preventive treatment.

About Validive®

Validive® (clonidine Lauriad®) is developed for the treatment of severe oral mucositis induced by radiotherapy or chemotherapy in patients suffering from head and neck cancer. This is a new therapeutic application of clonidine based on the mucoadhesive technology Lauriad®. Clonidine stimulates the alpha-2 adrenergic receptors traditionally used to treat high blood pressure. It stimulates these receptors in the brain. This leads to a decrease in peripheral resistance and thus a lowering of blood pressure, as well as a reduction in heart rate and renal vascular resistance. However, clonidine also acts as an agonist of the alpha-2 adrenergic receptors on leucocytes and macrophages, thereby decreasing the expression of the pro-inflammatory genes and the release of cytokines

IL6, IL1 β and TNF α . This effect leads to a reduction in the pro-inflammatory mechanisms. It also acts on the anti-inflammatory mechanisms by increasing the release of TGF β .

The final positive results of the Phase 2 clinical trial, comparing the efficacy and safety of Validive[®] versus placebo in the prevention of radio-chemotherapy induced severe oral mucositis in head and neck cancer patients, were presented in session poster at the 2015 annual ASCO meeting. They found that severe oral mucositis developed in fewer patients receiving Validive[®] than in patients receiving placebo, 45.3% and 60.0% respectively (p = 0.064). Furthermore, patients receiving Validive[®] who developed severe oral mucositis did so at a higher median radiation dose (60.0 Gy) compared to patients receiving placebo (48.0 Gy) (HR = 0.754; p = 0.211), indicating that Validive[®] prevents the onset of severe oral mucositis over a wider radiation dose range.

About Onxeo

Onxeo has the vision to become a global leader and pioneer in oncology, with a focus on orphan or rare cancers, through developing innovative therapeutic alternatives designed to “make the difference”. The Onxeo team is determined to develop innovative medicines that provide patients with hope and significantly improve their lives.

Key orphan oncology products at the advanced development stage are:

Livatag[®] (doxorubicin Transdrug[™]): Phase III in hepatocellular carcinoma
Validive[®] (clonidine Lauriad[®]): Phase II in severe oral mucositis: Positive final results
Beleodaq[®] (belinostat): registered in the US in peripheral T-cell lymphoma
For more information, visit the website www.onxeo.com

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