# *Update on ReLive, Livatag® international phase III clinical trial in HCC*

# *50% patients randomized*

**Paris (France), Copenhagen (Denmark), July 21, 2015 –** Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, updates on the clinical development status of ReLive , the Livatag®phase III trial in the treatment of hepatocellular carcinoma.

**Livatag®, a new therapeutic approach for hepatocellular carcinoma**

Livatag® is based on the innovative « Transdrug ™ » technology designed to formulate a chemotherapy (doxorubicin) with nanoparticles. This innovative therapeutic approach allows drug resistance to be avoided by short-circuiting the mechanisms of multi-drug resistance developed by tumor cells through the masking of the anticancer agent. Acting as a Trojan horse, the nanoparticle formulation avoids rejection of doxorubicin outside the cell so that it can exert its cytotoxic action. By specifically accumulating in the liver cells and overcoming resistance to doxorubicin, Livatag® represents a potential significant breakthrough in the treatment of hepatocellular carcinoma. This very severe cancer is the 6th most widespread cancer in the world and the 2nd cause of cancer-related death.

**As of July 2015, ReLive clinical phase III trial authorized in 11 countries and 50% of the planned patients have been randomized**

ReLive is an international phase III trial designed to assess Livatag®'s efficacy on survival in 400 patients with advanced hepatocellular carcinoma (HCC) following treatment after failure or intolerance to Sorafenib. In line with Onxeo's strategic expansion plan for ReLive, the company has recently extended the phase III trial to 4 new countries including Lebanon, Egypt, the Kingdom of Saudi Arabia and more recently Turkey. Some of these countries like Egypt have a very high prevalence of hepatitis C virus infection, which is the major risk factor for HCC*. This expansion follows the former ones realized in Europe as well as the USA.

To date, 50% of patients (i.e. about 200 patients) have been randomized, around 65 patients per arm and more than 100 patients have been treated with Livatag® for a total of about 450 infusions.

This recruitment rate is in line with expected timelines of issuing preliminary outcomes of the phase III by H1 2017.

*"Livatag® represents a major and highly promising asset for Onxeo. We are entering the last part of the trial, with enlarged geographic implementation in countries offering a strong recruitment potential. This will therefore enable to speed up the second half of enrollment, allowing us both to meet our expected timelines and expand Livatag® awareness among the hepatologist and oncologist community",* comments Graham Dixon, CSO Head of R&D of Onxeo.

*"Hepatocell carcinoma is an extremely severe disease for which the need of new treating option is critical. Livatag® could represent one of the next available treatments for patients suffering from HCC and failing or intolerant to Sorafenib treatment which would give us a very competitive position in this major market"* , adds Judith Greciet, CEO of Onxeo.

**Next Data Safety Monitoring Board (DSMB) will take place in October 2015 and will be the 7th one.**

The Data Safety and Monitoring Board (DSMB), a panel of independent experts, is in charge of reviewing the safety data of all patients randomized in the trial, and meets every 6 months. Since the study started, it has taken place 6 times, the last being in April 2015, and have concluded each time on the absence of unexpected safety signals that could lead to protocol modification or even study stop. These meeting conclusions are important as they reflect the acceptability of the safety profile and their positive outcomes after 3 years and assessement of a large group of patients reflects the adequate safety profile of the drug so far.

** Mohamed H. Shaker, Heba M. Abdella, Mohamed O. Khalifa; Epidemiological characteristics of HCC in Egypt: a retrospective analysis of 1313 cases; Liver International (2013)*

**About Hepatocellular Carcinoma**

Hepatocellular carcinoma (HCC) or hepatocarcinoma is the most common of the primary liver cancers (85% to 90%). According to Globocan (2012 data), liver cancer is the 6th most common cancer in terms of incidence (782,000 new cases worldwide each year, 5.6% of all new cancer cases) with the 2nd highest mortality rate (746,000 deaths, 9.1% of the total) after lung cancer. The risk factors are well known: infection by hepatitis viruses (B and C), overconsumption of alcohol (another major cause of cirrhosis) and metabolic diseases, especially obesity, a growing cause of cirrhosis and HCC.

**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 2nd line treatment of peripheral T-cell lymphoma
*For more information, visit the website www.onxeo.com*

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