Onxeo announces 6th positive DSMB recommendation for Livatag® ReLive study in HCC

Paris (France), Copenhagen (Denmark), April 13, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today announced that the independent European board of experts, the Data Safety Monitoring Board ("DSMB"), which monitors the safety of the Livatag® phase III trial, "ReLive", has once again unanimously recommended to continue the study without modification.

ReLive is an international, randomized phase III trial aiming at demonstrating the efficacy of Livatag® on survival in 400 patients with advanced hepatocellular carcinoma (HCC) (primary liver cancer) after failure of intolerance to Sorafenib.

The DSMB meets every 6 months to review the safety data of the ReLive trial and consequently issues recommendations on the conduct of the study.

More than 40% of the patients have been randomized already in the study and the DSMB reviewed the data for slightly less patients (approximatively 35% of the patients) totaling about 350 infusions of Livatag®.

For the 6th time since study initiation, the group unanimously recommended to continue the study without modification, based on its positive assessment of the safety data of Livatag® .

> *"Our confidence in Livatag®'s safety profile has so far proven to be correct. The positive recommendation from our independent board of experts, the DSMB, based on substantial number of patients and infusions now, truly reinforces this confidence, and we recognize this 6th recommendation as an emphasis of Livatag®'s potential to aid liver cancer patients, a very severe disease for which the medical need is extremely high"*, comments Judith Greciet, CEO of Onxeo.

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 Livatag®(doxorubicin Transdrug™)

Livatag® (Doxorubicin Transdrug™) is a doxorubicin formulation in the form of lyophilized nanoparticles of polyisohexylcyanoacrylate (PIHCA).This new 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 targeting tumor cells in the liver and overcoming resistance to doxorubicin, Livatag® represents a significant breakthrough in the treatment of this cancer. The first indication of

this product is hepatocellular carcinoma; the 6th most widespread cancer in the world and the 2nd cause of cancer-related death.

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 preliminary top-line 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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