Onxeo announces positive DSMB recommendation for continuation of Livatag® ReLive study in HCC

Paris (France), Copenhagen (Denmark), October 5, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today announced that it has received a unanimous recommendation from the Data Safety Monitoring Board (DSMB), the independent European board of experts that monitors the safety of the Livatag® Phase III trial, "ReLive", to continue the study without modification. This marks the seventh positive DSMB recommendation and further confirms the acceptable safety profile of Livatag.

ReLive is an ongoing international, randomized Phase III trial designed to evaluate the efficacy of Livatag® in patients with advanced hepatocellular carcinoma (HCC) (primary liver cancer) after failure or intolerance to sorafenib. The study, which plans to enroll a total of 400 patients, compares intravenous administration of Livatag® to the best standard of care.

The DSMB meets regularly, twice a year, to review the safety data of the ReLive trial and subsequently issues recommendations on the conduct of the study.

To date, more than 50% of the patients have been randomized in the study. The DSMB has reviewed the safety data from these patients, totaling more than 500 infusions of Livatag® in the trial and for the seventh time since study initiation, has unanimously recommended to continue the study without modification, based on its positive assessment of the safety data of Livatag®.

"This latest positive recommendation from our independent board of experts confirms once again Livatag®'s acceptable safety profile, based on safety data collected on a substantial number of patients. These data certainly strengthen our confidence in the potential of this product, which represents a potential significant breakthrough in the treatment of hepatocellular carcinoma, a very severe cancer with a high unmet medical need," commented 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 sixth most common cancer in terms of incidence (782,000 new cases worldwide each year, 5.6% of all new cancer cases) with the second 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 sixth most widespread cancer in the world and the second 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 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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