Onxeo expands Livatag® international phase III clinical trial "ReLive" to 3 new countries

Paris (France), Copenhagen (Denmark), March 26, 2015 [6:00 pm CET] – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today announced that Livatag® phase III clinical trial "ReLive" is expanded to 3 new countries in the Middle-East and North Africa region (MENA).

The ReLive study is an international phase III trial designed to assess Livatag®'s (Doxorubicin Transdrug™) efficacy on survival in 400 patients with refractory hepatocellular carcinoma in progression following treatment with Sorafenib. The study is already implemented in about 65 clinical centers in 8 countries, in Europe and North America, with more than 40% of the patients having already been randomized. Preliminary data from the "ReLive" study are expected by early 2017.

Relive phase III trial expansion in line with strategic plan

In line with Onxeo's strategic expansion plan for the Livatag® "ReLive" phase III trial, the company is opening up trial centers in three new countries: Lebanon, Egypt, and the Kingdom of Saudi Arabia (KSA). These new countries are in addition to the 8 countries where patients are currently being recruited. The decision to expand the number of countries in the study is based on the reassuring feedback that has been received from the data safety monitoring board (DSMB) and the additional funds that Onxeo has available post the recent successful capital raising. The addition of these 3 new countries is designed to optimize recruitment rate in the study.

MCT : Specialized CRO for MENA region

Onxeo has engaged MCT, a contract research organization (CRO) specialized in running clinical trials in the Middle East and North Africa (MENA region), to implement the trial in the Lebanon, Egypt, and KSA. MCT, which will be driven by Onxeo´s internal clinical development team, will be in charge of all administrative procedures as well as the opening and follow-up of new trial centers. Approximately 10 additional trial centers should be open and the first patient expected to be enrolled as soon as mid- 2015.

Data Safety and Monitoring Board (DSMB)

The next Data Safety and Monitoring Board (DSMB) session, at which the safety data from this Phase III trial are reviewed, is scheduled to take place in the coming weeks. Since the study started, the DSMB has met 5 times and concluded each time that the trial could be pursued with no modification, which reflects a good safety profile of Livatag® so far.

"Livatag® is a key program within Onxeo's orphan oncology portfolio and the opening of the ReLive trial in an additional region is a critical element of our strategy to perform the study in a timely manner and as result creates significant value from this very attractive asset. The launch of the study in new regions such as MENA also helps to raise awareness about Livatag® with clinicians at a broader level, which will be extremely important for ensuring the product's adoption at a later stage", said 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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