



THE ORPHAN ONCOLOGY INNOVATOR

PRESS RELEASE

Onxeo Announces 10th Positive DSMB Recommendation to Continue Livatag[®] ReLive Phase III Trial in HCC

Paris (France), May 23, 2017 – 6.00 pm CEST – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), a clinical-stage biotechnology company specializing in the development of innovative drugs for the treatment of orphan diseases, in particular in oncology, today announced that the company has received the 10th unanimous recommendation from the Data Safety Monitoring Board (DSMB), to continue without modification the Phase III study of Livatag[®], ReLive, in patients still undergoing treatment. The DSMB is an independent European board of experts that monitors the blind tolerability data from the study.

ReLive is an ongoing international, randomized Phase III trial designed to evaluate the efficacy of Livatag[®] in patients with advanced hepatocellular carcinoma (HCC) after failure or intolerance to sorafenib.

The ReLive study protocol involved the recruitment of approximately 400 patients, divided into three arms: two Livatag[®] treatment arms at 20 and 30 mg /m² every 4 weeks intravenously for 6 hours, until progression or intolerance, and a comparative arm of patients receiving the best available treatment chosen by their physicians. All patients under the protocol have been randomized since the end of January 2017.

“As we approach the key milestone of ReLive's preliminary results, we are once again very encouraged by the positive recommendations of the DSMB that confirm Livatag[®]'s acceptable tolerance profile in terms of safety and side effects. Livatag[®] aims to treat a challenging pathology, patients with advanced HCC. This product candidate represents a potential new and innovative therapeutic option for patients suffering from this orphan and resistant cancer, and could become a potentially impactful catalyst for the Company,” commented Judith Greciet, CEO of Onxeo.

As per study protocol, the DSMB examines blind tolerance data from the ReLive trial twice a year. However, the DSMB does not receive any data that may enable an assessment of the efficacy of Livatag[®].

Preliminary efficacy results from ReLive are expected by mid-2017.



About Onxeo

Onxeo is a biotechnology company developing innovative drugs for the treatment of orphan diseases in oncology, driven by high therapeutic demand in one of the fastest growing segments of the pharmaceutical industry.

Onxeo's objective is to become a major international player in the field of rare cancers. Its growth strategy is founded on the development of innovative, effective, and safe drugs based on breakthrough technologies that can make a real difference in the treatment of orphan oncology diseases and considerably improve the quality of life of patients affected by rare or resistant cancers.

Onxeo's comprehensive portfolio features a broad orphan oncology pipeline, with 3 major products in several on-going preclinical and clinical programs, alone or in combination for various cancer indications.

The Company is headquartered in Paris, France with offices in Copenhagen and in New York, and has approximately 60 employees. Onxeo is listed on Euronext in Paris, France and Nasdaq Copenhagen, Denmark (Ticker: ONXEO, ISIN Code: FR0010095596).

Learn more by visiting www.onxeo.com

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