Onxeo Announces 9th Positive DSMB Recommendation to Continue Livatag® ReLive Phase III Trial in HCC

Paris (France), Copenhagen (Denmark), November 21, 2016 – Onxeo S.A. (Euronext Paris, Nasdaq Copenhagen: ONXEO), a biopharmaceutical 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 9th unanimous recommendation from the Data Safety Monitoring Board (DSMB), an independent European board of experts that monitors the safety of the Livatag® Phase III trial, "ReLive", to continue the study without modification.

The nine consecutive positive DSMB recommendations reinforce the acceptable safety profile of Livatag®. The ReLive study is an ongoing international, randomized Phase III trial designed to evaluate the efficacy of intravenous (IV) administration of Livatag® in patients with advanced hepatocellular carcinoma (HCC) after failure or intolerance to sorafenib. The study plans to enroll a total of 400 patients across approximately 90 sites. To date, more than 90% of the patients have been randomized in the study. The DSMB reviews the safety data of the treated patients in the study, totaling more than 900 infusions of Livatag®.

"As we are approaching complete randomization in the ReLive study, we are, once again, encouraged by the DSMB's positive recommendation which confirmed the acceptable safety profile of Livatag® as regards to unexpected safety events. Enrolment is well on track and we should reach the 400 patients in the coming weeks, which comforts us in our planning of preliminary data announcement mid-2017. Livatag®'s potential to address the unmet medical need for HCC patients combined with the drug's favorable safety profile is a significant cornerstone in Onxeo's mission to develop innovative medicines for patients, providing patients with new therapeutic options, and a significant catalyst for the company value," said Judith Greciet, CEO of Onxeo.

As per study protocol, the DSMB meets twice a year since study initiation to review the safety data of the ReLive trial and subsequently issues recommendations on the conduct of the study.

About Onxeo

Onxeo is a biopharmaceutical company specializing in the development of innovative drugs for the treatment of orphan diseases, in particular 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 and aggressive cancers. Onxeo's comprehensive portfolio features a broad orphan oncology pipeline, with four independent programs in various stages of clinical development, including Onxeo's first approved orphan oncology drug, Beleodaq®. The

Company is headquartered in Paris, France and has approximately 50 employees. Onxeo is listed on Euronext in Paris, France (Ticker: ONXEO, ISIN Code: FR0010095596) and Nasdaq Copenhagen, Denmark (Ticker: ONXEO).

Onxeo's orphan oncology products are:

- **Livatag®** (Doxorubicin Transdrug™): Currently being evaluated in a Phase III trial (ReLive) in patients with hepatocellular carcinoma (primary liver cancer); and in combination with other cancer agents in first-line HCC
- **Beleodaq®** (belinostat): FDA-approved in the US in 2014 under the agency's accelerated approval program as a second-line treatment for patients with peripheral T-cell lymphoma (PTCL) and currently marketed by Onxeo's partner in the US, Spectrum Pharmaceuticals; belinostat in combination with other cancer agents is currently in development in first-line treatment for patients with PTCL (BelCHOP) and in other solid tumors
- **AsiDNA**: The first-in-class siDNA (signal-interfering DNA) which has successfully undergone a proof-of-concept Phase I trial in metastatic melanoma
- **Validive®** (Clonidine Lauriad®): Positive final results from a Phase II trial in head and neck cancer patients with severe oral mucositis

In addition, Onxeo has successfully developed and registered two non-cancer products, which are currently being commercialized in the U.S. and Europe.

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