Information on ReLive Trial Design and Role of its Data Safety and Monitoring Board

PARIS - 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, wishes to clarify information regarding the Relive trial design and conduct and, in particular, the role of its Data Safety and Monitoring Board (DSMB).

ReLive is an international, randomized phase III trial aiming at demonstrating the efficacy of Livatag® vs. best standard of care on survival in patients with advanced hepatocellular carcinoma (primary liver cancer) after failure or intolerance to sorafenib.

The DSMB of the ReLive trial is an independent committee of experts dedicated to safety review only, based on the analysis of adverse effects and causes of deaths in a blinded mode[1]. The protocol and the DSMB charter approved by regulators did not include interim analysis or futility analysis for survival.

Therefore, survival, the main criteria for efficacy, has not been analyzed so far and will become available only mid-2017. Therefore, conclusions from previous DSMBs can only point towards a reasonable safety profile with no unexpected adverse safety signal and do not make it possible to speculate on Livatag efficacy profile.

The study was conducted in 11 countries (Europe, USA, Egypt, Turkey and Libanon), starting in France first to enable a close monitoring of safety during the first year and then gradually extended to additional countries.

In January 2017, the Company has announced the completion of enrollment and randomization in the ReLive trial. and confirmed the expected availability of preliminary efficacy results mid-2017.

About Onxeo

Onxeo is a clinical-stage 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 multiple cancer indications.

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

Onxeo's orphan oncology orphan oncology portfolio includes :

- **AsiDNA™**: First-in-class DNA repair inhibitor which has successfully undergone a proof-of-concept **Phase I** trial in metastatic melanoma ; now in preclinical development to treat various solid tumors via systemic administration.
- **Beleodaq®** (belinostat): **FDA-approved** (accelerated approval program) in the US in 2014 as second-line treatment for patients with peripheral T-cell lymphoma (PTCL) ; currently marketed by Onxeo's partner in the US, Spectrum Pharmaceuticals; also in preclinical development in combination with other cancer agents in first-line treatment for patients with PTCL (BelCHOP) and in other solid tumors.
- **Livatag®** (Doxorubicin Transdrug™): Currently being evaluated in a **Phase III** trial (ReLive) in patients with hepatocellular carcinoma (primary liver cancer); also developed in combination with other cancer agents in first-line HCC.

Learn more by visiting www.onxeo.com

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[1] Reviewers do not know the treatment administered to the patient.

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