Onxeo expands collaborations to advance development program of key orphan oncology assets in combination with immuno-oncology agents

- *Following first positive results already obtained in several types of tumors*
- *New partnership with CIMA's Immunology Program and the Liver Unit at Clinica Universidad de Navarra in Spain under the leadership of Prof. B. Sangro*

Paris (France), Copenhagen (Denmark), February 22, 2016 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology therapeutics, today announced that it has entered into a collaboration with Centro de Investigación Médica Aplicada of the University of Navarra in Spain, a leading European research institution dedicated to translational medical research in several areas including Oncology, Hepatology, Cardiovascular Diseases or Neurosciences. Studies through the collaboration will further evaluate the interest of combining Onxeo's two leading orphan oncology compounds, Livatag® and Beleodaq®, with immuno-oncology agents in various tumor types, as a second step of its current preclinical development program.

As part of Onxeo's goal to expand the value of its key assets enlarging their indications, the company has initiated an ambitious research program in November 2015 to assess the combination of Livatag® and Beleodaq® with various compounds including PD-1 and CTLA-4 checkpoint inhibitors. The objective of these studies is to assess the synergistic effects on the activation of the immune response in several types of solid tumors.

"Emerging immuno-oncology agents targeting checkpoint inhibitors are promising new avenues of treatment in oncology; however, many patients do not respond to these therapies, calling for additional therapeutic strategies seeking for synergistic effects. We are enthusiastically pursuing the development of our lead products in combination with these compounds through this new collaboration with Professor Sangro and his research teams. If positive, the outcomes of this plan will lead us to initiate the clinical phase, based on the most promising combinations. By augmenting our development pipeline, we will increase our assets' value with new indications and build high value for our shareholders while enhancing Onxeo's position at the forefront of innovation in orphan oncology," commented Judith Greciet, CEO of Onxeo.

A first set of preliminary combination studies conducted by Synovo GmBH as part of its collaboration with Onxeo has yielded positive results in several cancer models.

Building on these results, the Immunology Program at CIMA and the Liver Unit at Clinica Universidad de Navarra, led by Dr. Pablo Sarobe and Professor Bruno Sangro, recognized experts in the field of liver disease, immunotherapy and hepatocellular carcinoma (HCC), will now conduct definitive preclinical studies testing the efficacy of combinations of Livatag® and Beleodaq® with PD-1 and CTLA-4 checkpoint inhibitors in preclinical models of HCC. These studies are aiming to build more specifically the understanding of the immune mechanism mediating the combinations' anti-tumor activity. First results are expected in the second half of 2016.

These results will add to the scientific body of knowledge generated by the combination studies of Livatag® and Beleodaq® with cytotoxics and targeted therapies in HCC, currently implemented by Onxeo in partnership with the Research Department at Croix-Rousse Hospital and Centre de Recherche en Cancérologie de Lyon, led by Professor Philippe Merle, M.D., Ph.D., principal investigator of the ReLive study.

About Onxeo

Onxeo is a leading developer of orphan oncology drugs. The Company is focused on developing innovative therapeutics for rare cancers, one of the fastest growing markets in the healthcare industry with high, unmet medical needs. Onxeo's comprehensive portfolio features a broad orphan oncology pipeline, with three independent programs in advanced clinical development, including Onxeo's first approved orphan oncology drug, Beleodaq®. In addition, Onxeo has successfully developed and registered two non-cancer products which are currently being commercialized in the U.S. and Europe. Onxeo's vision is to become a global leader and pioneer in oncology, with a focus on orphan or rare cancers, by developing advanced, effective, and safe therapeutics designed to improve the lives of patients. 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 orphan oncology products at the advanced development stage are:

- **Livatag®** (Doxorubicin Transdrug™): Currently being evaluated in a Phase III trial (ReLive) in patients with hepatocellular carcinoma (primary liver cancer);
- **Validive®** (Clonidine Lauriad®): Positive final results from a Phase II trial in head and neck cancer patients with severe oral mucositis;
- **Beleodaq®** (belinostat): FDA-approved in the U.S. 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 U.S., Spectrum Pharmaceuticals; belinostat in combination with CHOP (BelCHOP) is also in development as first-line treatment for patients with PTCL.

For more information, visit the website www.onxeo.com

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("Facteurs de Risque") section of the 2014 Reference Document filed with the AMF on April 14, 2015, which is available on the AMF website (http://www.amf-france.org) or on the company's website (www.onxeo.com).

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