Onxeo initiates comprehensive strategy to extend value of key orphan oncology assets

- *Currently exploring combinations for synergistic effect to identify new indications for Livatag® and Beleodaq®*
- *Signed two collaborations with Lyon's University Hospital and Synovo's immuno-oncology specialists*

Paris (France), Copenhagen (Denmark), November 18, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, announced the initiation of a comprehensive strategy to explore further potential indications for Livatag® and Beleodaq® to enhance the value of each therapy. As part of this plan, the Company has signed two collaborations, one with the Croix-Rousse Hospital, Hepato-Oncology Team and the Centre de Recherche en Cancérologie, Inserm U1052, in Lyon, France and a second with the specialized contract research organization (CRO) Synovo GmbH based in Tubingen, Germany. Both collaborations will complement Onxeo's in-house research efforts already initiated.

This first step of Onxeo's strategic plan aims to explore the efficacy of Livatag® (doxorubicin Transdrug™) and Beleodaq® (belinostat), in novel combination therapies with classical cytotoxics, targeted therapies and the new generation of immuno-oncology agents, to identify potential new indications for the two Onxeo products.

Livatag® is currently being evaluated in the ReLive study, a global Phase 3 trial for the treatment of advanced hepatocellular carcinoma (HCC), the primary form of liver cancer, for patients failing sorafenib therapy. The objective of Onxeo's strategy is to next assess the synergistic effect of Livatag® in combination with other drugs, including sorafenib, the current standard of care in first-line HCC.

As a pan-histone deactylase (HDAC) inhibitor, belinostat's mechanism of action affects many cellular processes crucial in the development of cancer. This makes it an ideal combination partner in a range of cancers, notably solid tumors.

The collaboration 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., the principal investigator of the ReLive study and an internationally-recognized expert in HCC, will explore the potential synergies of the two Onxeo products with currently-approved products and those in development for HCC. Following *in-vitro* testing, promising synergistic combinations will be tested in *in-vivo* models (animal models).

In addition, Onxeo has initiated a collaboration with Synovo, which specializes in immuno-oncology testing, to explore the potential of belinostat and Livatag® in a range of cancers in association with emerging immune-oncology agents, such as promising PD-1 and CTLA-4 checkpoint inhibitors currently in development.

A first set of preclinical data will be obtained in early 2016 and will be used to inform decisions for future steps and clinical options to further develop these two products. Clinical development of selected indications could then be initiated over the next one to two years.

Prof. Merle, M.D., Ph.D., principal investigator of the ReLive Phase 3 study of Livatag®, commented: *"Current treatment options are limited for systemic therapy of HCC, with only one product approved to date, sorafenib, and unfortunately more than half of patients lose response to treatment within six months. Other targeted therapies tested as second-line therapies after sorafenib failure or in combination to sorafenib, did not show any significant impact on the outcome of patients. There is a significant need for new therapeutic options in HCC. The Phase 3 trial of Livatag® is currently ongoing, and its safety profile by IV infusion has been confirmed by several DSMB decisions. We expect Livatag® to show strong efficacy to improve the outcome of patients as a potential new efficient tool for the treatment of HCC, alone or in combination with other approaches."*

Judith Greciet, CEO of Onxeo, commented, *"We are thrilled to be launching these new preclinical programs with two leading research organizations in the field of oncology. The decision to explore new avenues of treatment with Beleodaq® and Livatag® was based on extensive research and high-quality preclinical and clinical data generated by our in-house research team. We believe there is strong potential for our products in combination with emerging therapies, which will create value for our company and our shareholders, and further position Onxeo as a clear leader in orphan oncology research and development."*

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 sixth most widespread cancer in the world and the second cause of cancer-related death.

About belinostat (Beleodaq®)

Belinostat is a novel pan-histone deacetylase (HDAC) inhibitor that has anti-cancer activity associated with the inhibition of cell proliferation, the induction of apoptosis (programmed cell death), the inhibition of angiogenesis and the induction of cellular differentiation.

Belinostat is designated as an orphan drug in Europe and the United States. In July 2014, belinostat (Beleodaq®) was granted accelerated approval in the U.S. by the Food and Drug Administration (FDA) for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) in second-line treatment after failure of standard chemotherapy. Approval was based on results from the pivotal Phase 2 BELIEF study (O'Connor et al, JCO, 2015) of belinostat in relapsed or refractory PTCL, which demonstrated durable clinical benefit (objective response rate of 25.8%) and good tolerability. The initiation of a Phase III trial in collaboration with Onxeo's U.S. partner, Spectrum Pharmaceuticals, Inc. is planned in 2016 to expand the indication from second to first-line treatment of PTCL.

Beyond PTCL, belinostat's clinical profile supports further development in new and promising orphan oncology indications. Onxeo is currently reviewing potential indications in order to define the optimal development plan for belinostat.

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 final results
Beleodaq® (belinostat): Registered in the US in 2nd-line treatment of peripheral T-cell lymphoma
For more information, visit the website www.onxeo.com

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