Onxeo Reports First Half 2015 Business Update and Consolidated Accounts

- ***Livatag® Phase III trial in HCC: 50% of patients randomized***
- ***Scientific recognition of Validive® and Beleodaq® preclinical and clinical data at ASCO Annual Meeting and MASCC/ISOO International Symposium***
- ***Sound financial position with €42.9 million cash***

Paris (France), Copenhagen (Denmark), July 30, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today reported its consolidated half-year accounts as of June 30, 2015 and provided an update on the key operational and clinical milestones achieved during the first six months of the year.

"The first half year of 2015 has been extremely active for Onxeo. We have continued the Phase III clinical trial of Livatag® to reach 50% of our patient recruitment target while preparing the opening of new countries, in regions with a high prevalence of hepatocellular carcinoma (HCC). In parallel, Onxeo has been particularly active focusing on elevated scientific exchange, with an increased visibility at several key medical congresses devoted to oncology, including two posters presented at the American Society of Clinical Oncology (ASCO) Annual Meeting. The second half of 2015 will also be significant for the company's development. We are preparing to initiate a Validive® Phase III trial in severe oral mucositis (SOM) in patients with head and neck cancer receiving chemoradiation therapy. We also plan to share the Phase I safety results of Beleodaq® in combination with chemotherapy (BelCHOP) in 1st line treatment of peripheral T-cell lymphoma (PTCL), which are expected at the end of the year. This step is required to finalize the preparatory work on the Beleodaq® Phase III study protocol. We strongly believe that our achievements over this first semester contribute to strengthening our unique pipeline and further positioning Onxeo as a leading player in this attractive market," commented Judith Greciet, CEO of Onxeo.

Key events of the first half 2015

Livatag®: Progression of "ReLive" Phase III trial

- 50% of the 400 patients randomized; more than 100 patients treated with Livatag® totaling approximately 450 infusions in the trial to date; this recruitment rate is in line with expected timelines of issuing preliminary outcomes of the Phase III by 1H 2017.

- Trial expansion into 4 new countries, Lebanon, Egypt, the Kingdom of Saudi Arabia and Turkey, to boost patient recruitment; study now authorized in a total of 11 countries.
  Positive assessment of the 6th Data Safety Monitoring Board (DSMB) in April confirmed Livatag®'s excellent safety profile. The next DSMB is planned for October.

Validive®: Phase III preparation following positive Phase II trial

- Final Phase II data presented at 2015 ASCO Annual Meeting and 2015 MASCC/ISOO International Symposium on Supportive Care in Cancer.
- Positive efficacy and safety profiles confirmed in prevention of severe oral mucositis in patients with head and neck cancer.
- Phase III trial to be initiated in 1H 2016.

Beleodaq®: Phase I safety data of Beleodaq® combination with chemotherapy (BelCHOP) expected by year-end 2015

- Pivotal Phase II BELIEF (PXD101-CLN-19) trial data published in June in the *Journal of Clinical Oncology*, showing positive results as monotherapy, including complete and durable responses, in treating rare cancer PTCL in 2nd line.
- Phase I results and safety profile of Beleodaq® + CHOP combination expected 4Q 2015, which will allow for the finalization of the Phase III protocol in treatment of PTCL in 1st line.
- Preclinical and clinical results from three studies supporting the potential of Beleodaq® in multiple orphan oncology indications, including results from its Phase I/II trial of Beleodaq® in combination with standard chemotherapy in patients with soft tissue sarcomas (STS), were presented at the 2015 ASCO Annual Meeting.

New International partnerships on Sitavig® and Loramyc®

Sitavig®

In July 2015, Onxeo signed a license agreement for Sitavig® (acyclovir Lauriad®) with specialty pharmaceutical company Bruno Farmaceutici for commercialization in Italy. Sitavig® is approved for the treatment of recurrent labial herpes in Europe and in the U.S. As a partner, Bruno Farmaceutici will launch Labiriad® (name of Sitavig® in Italy) under its current regulatory status (prescription) and manage the regulatory procedure to obtain an over-the-counter (OTC) designation, allowing pharmacists to deliver Sitavig® to patients directly.

Loramyc®/Oravig®

In March 2015, Onxeo signed a licensing agreement with Dara BioSciences, a company specializing in oncology support care, giving exclusive rights to commercialize Oravig® in the U.S. and in Canada. Oravig® is planned for launch by the Dara BioSciences commercial team in the U.S. in 4Q 2015, and Onxeo will receive sales-related milestones. Dara BioSciences should be acquired by UK-based Midatech, which will strengthen its financial resources and broader organizational capabilities.

Collaborative program

Fluriad™

The Fluriad™ program initiated in 2011 was aiming at establishing proof of concept for the use of the Lauriad® mucoadhesive tablet for vaccination purpose. This collaborative program was supported by a "Fond Unique Interministériel" ("FUI") grant.

Onxeo will not pursue the program further considering that the Fluriad™ program is not in line with Onxeo's core strategy in the orphan oncology space. However, the company has entered into discussions with certain of the consortium partners on an agreement allowing them to continue the program development, against compensation to Onxeo in event of success.

1H 2015 consolidated accounts

Consolidated accounts (IFRS-compliant) *In thousands Euros*	30/06/2015 (6 months)	30/06/2014 (6 months)	30/06/2014 pro forma
Revenues	1,533	653	13,872
Incl. recurring revenues	*1,219*	*268*	*268*
Incl. non recurring revenues	*314*	*384*	*13,604*
Operating expenses	(13,502)	(9,188)	(11,475)
Incl. R&D expenses	*(7,832)*	*(5,662)*	*(7,188)*
Operating profit/loss	(11,969)	(8,535)	2,397
Non-recurring charges linked to the merger	0	(4,397)	(9,270)
Financial income	832	24	73
Income tax	(200)	0	(873)
Net profit/loss	(11,347)	(12,951)	(7,659)

According to IFRS, the above 2014 figures do not take into account the activity of Topotarget as the merger of this entity into BioAlliance Pharma, creating Onxeo, was effective on June 30, 2014. In order to ensure full comparability between 2015 and 2014, a pro forma P&L account is presented as if the merger had taken place on January 1, 2014. It takes into account all revenues and expenses of Topotarget over 1H 2014 that were not included in the consolidated 1H results in application of IFRS.

Recurring revenues increased significantly compared to 2014 as a result of the U.S. commercialization of Beleodaq® by partner Spectrum Pharmaceuticals and Sitavig® by Innocutis/Cipher in 3Q 2014.

In the absence of any contractual milestone during the period, non-recurring revenues are limited to the revenue recognition of upfront payments received in previous years as per IAS 18 (as a reminder, a

$10m milestone relating to FDA approval for filing of Beleodaq® had been received from Spectrum Pharmaceuticals in 1H 2014 and was booked as revenues in the pro forma accounts).

Operating expenses were impacted by an increase in R&D expenses essentially as a result of the deployment of Livatag® international Phase III and its industrialization program, which is in line with the planned use of proceeds announced during the Company's most recent capital increase. While remaining under a tight control, other operating expenses have increased, as a result of the new dimension of the company and of new activities in support of the company growth strategy.

Financial income increased significantly compared to 2014 due to positive exchange rate differences.

Consolidated cash position at the end of June totaled 42.9 million Euros, compared to 49.5 million Euros end of March, confirming the healthy situation of the company and the good long term visibility.

The full half-year financial report (regulated information) is available on www.onxeo.com in the sections "Financial information" and "Regulated information" of the page "Investors". The 2015 half-year financial results were subject to a review by the Company's Statutory Auditors.

Onxeo will comment on major current issues and its semester financial statements during its SFAF meeting which will be held on September 16, 2015 at 11:30am at the Intercontinental Paris Avenue Marceau (64, avenue Marceau – 75015 Paris) and during the audio/web conference the same day at 5:30 pm:

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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 treatmentof peripheral T-cell lymphoma
For more information, visit the website www.onxeo.com

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