Onxeo Reports 2015 Full-Year Results and Provides Business Update

2015: Successful year of consolidation and major achievements in all lead programs

- *Progression of Phase III trial of Livatag® in HCC in line with development calendar; positive results of Phase I trial of Beleodaq® and CHOP in 1st-line PTCL*
- *New preclinical development program of lead products in combination with immunotherapy and other cancer agents to identify new indications and increase value of product portfolio*
- *Progressive launch of commercialized products resulting in increase in recurring revenues*
- *Cash position of €33.6 million, confirming visibility until mid-2017*
- *Strengthening of Board of Directors and senior executive team, bringing significant international expertise in-house*

Paris (France), Copenhagen (Denmark), February 26, 2016 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology therapeutics, today announced its 2015 consolidated accounts and provided a review of its 2015 achievements and anticipated milestones for 2016.

Judith Greciet, CEO of Onxeo, commented*: "2015 has been a year of consolidation and progress for our company and our innovative therapeutics, advancing our position as a leading player in orphan oncology and paving the way for greater achievements in the coming months. 2016 will be a key year for Onxeo as we prepare for a first read-out of the Phase III results of Livatag® in hepatocellular carcinoma in 2017, and will report the initial results of our high-potential preclinical research on Beleodaq® and Livatag® in combination with various compounds including immuno-oncology agents. In financial terms, 2015 saw a significant increase in sales revenues from our three commercialized products, which generated €2.7 million in recurring revenues. The increase in R&D expenses over the period reflects the advancement of our clinical programs, and with our commitment to carefully control expenses, we concluded the year with €33.6 million in cash, allowing us to confirm financial visibility until mid-2017."*

Key events of 2015

Livatag®: Progression of "ReLive" Phase III trial and strengthening of IP position

- 65% of the 400 patients randomized, study expanded to 4 additional countries
- Strong safety profile confirmed by two positive Data Safety Monitoring Board (DSMB) conclusions in April and October 2015, as part of a bi-annual review
- Filing of a new patent application based on a specific composition of Livatag® nanoparticles. If issued, patent will extend industrial property and market exclusivity of Livatag® internationally until 2036
  - Next DSMB in April 2016
  - Expected preliminary outcomes of the Phase III to be issued in 2017

Beleodaq®: Positive results of Phase I trial of Beleodaq® in combination with chemotherapy (BelCHOP) in PTCL presented at ASH 2015

- Positive Phase I results and safety profile of Beleodaq® + CHOP combination announced Q4 2015
- Data supporting a Phase III protocol in treatment of PTCL 1st line
- Several clinical and pre-clinical abstracts presented at AACR & ASCO 2015
  - Phase III synopsis under preparation with US partner

Comprehensive preclinical evaluation of Livatag® and Beleodaq® in combination with other oncology agents for high potential development from 2016-2017

- Explore combinations with immuno-oncology agents (such as checkpoint inhibitors), cytotoxic agents and targeted therapies to identify new opportunities and expand product potential, with a primary focus on solid tumors
  - First set of preclinical data to be obtained in 2016
  - Clinical development of most promising combinations planned for next 12-24 months

Validive®: Final results of Phase II trial presented at major scientific meetings

- Positive Phase II data presented at ASCO Annual Meeting, MASCC/ISOO International Symposium on Supportive Care in Cancer and ASTRO Annual Meeting
  - Preparation of Phase III including advices from Regulatory agencies on development plan

New international partnerships for Sitavig® and Loramyc®

- Sitavig®: In July 2015, Onxeo signed a license agreement with specialty pharmaceutical company Bruno Farmaceutici for commercialization in Italy. The partner will launch the product under its current regulatory status (prescription) in 2016
- Loramyc®/Oravig®: In March 2015, Onxeo signed a licensing agreement with Dara BioSciences, now Midatech Pharma U.S., for the commercialization of Oravig® in the U.S. and in Canada. Oravig® was launched in the U.S. in Q4 2015

Governance: Increased R&D expertise and US footprint

- Joseph Zakrzewski appointed Chairman of the Board of Directors. Joseph offers more than 25 years of experience in the global healthcare industry with a strong focus in the United States
- Drs. Jean-Pierre Kinet, of Harvard Medical School, and Jean-Pierre Bizzari, international expert in oncology, joined the Onxeo Board of Directors as Board Observers
- Three senior appointments: Elisabeth Carstensen as Director of Alliance Management, Graham Dixon as CSO/Head of R&D, Audrey Legentil-Duméry as Director of Human Resources

2015 consolidated accounts

The consolidated accounts for 2015 reflect the progressive commercialization of Beleodaq® and Sitavig®, generating increased recurring revenues, as well as the roll-out of our clinical programs resulting in an increased R&D spend. General and administrative expenses have been contained as a result of the smooth integration of the Topotarget teams after the merger and an overall optimized monitoring. The discrepancy in revenues and net loss between 2015 and 2014 is mainly linked to non-recurring revenues received in 2014, i.e. milestone payments from partners, as well as one-time costs due to the merger.

Consolidated accounts (IFRS-compliant) *In thousands Euros*	31/12/2015	31/12/2014
Revenues, out of which	3,481	22,081
Recurring revenues	*2,733*	*1,625*
Non-recurring revenues	*0,749*	*20,455*
Operating expenses, out of which	(25,657)	(22,697)
R&D expenses	*16,350*	*12,978*
G&A and other expenses	*9,307*	*9,719*
Operating profit/loss	(22,365)	(5,554)
Non-current operating profit/loss	(189)	(4,938)
Financial income	602	5
Income tax	2,353	(2,150)
Net profit/loss	(19,409)	(7,699)

According to IFRS, the above 2014 figures do not take into account the activity of Topotarget over the first semester as the merger of this entity into Onxeo was effective on June 30, 2014.

In 2015, recurring revenues increased 68% over 2014 to €2.7 million as a result of the U.S. commercialization of both Beleodaq® by partner Spectrum Pharmaceuticals and Sitavig® by Innocutis/Cipher.

In the absence of any contractual milestone during the period, non-recurring revenues were limited to the revenue recognition of upfront payments received in previous years as per IAS 18. As a reminder, milestone and upfront payments received in 2014 and related to Beleodaq® and Sitavig® were booked as revenues in the consolidated accounts for an amount of $25 million (€20 million). On a proforma basis, these milestones totaled $43 million over 2014.

Operating expenses totaled €25.6 million, of which 64% was related to R&D, mostly reflecting the roll-out and ramp-up of the international ReLive study with Livatag, which is in line with the planned use of our resources. Research tax credits totaled €3.7 million, in France and in Denmark, and have been netted with operating expenses according to IFRS.

The consolidated cash position at the end of December 2015 stood at €33. 8 million, confirming the good situation of the company and the visibility until mid-2017.

The 2015 financial results were subject to a review by the Company's Statutory Auditors and was approved by the Board of Directors on February 26, 2016.

Conference Call

- A conference call dedicated to financial analysts will be held on February 29, 2016 at 6:30PM CET
- Dial-in number: (+33) 1 70 77 09 34
- Replay (available for 90 days after the event): Reference: 299701#
- FR : +33 1 72 00 15 00 / UK : +44(0) 2033679460 / USA : +1 877 64 230 18

SFAF Meeting

Onxeo will comment on major company updates and its financial statements during its SFAF meeting which will be held on March 7, 2016 at 11:00 AM CET at the Intercontinental Paris Avenue Marceau (64, avenue Marceau – 75015 Paris).

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 deep 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 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 about 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 currently in development as first-line treatment for patients with PTCL.

Onxeo is also evaluating its lead product candidates in combination with other cancer agents to expand their value.

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