Onxeo Reports First-Half 2016 Business Update and Consolidated Financials

- ***Expansion of orphan oncology pipeline through acquisition of DNA Therapeutics and lead compound AsiDNA™***
- ***Important development milestones on existing assets:***
  - ***Livatag® Phase III trial in HCC: 80% of patients randomized***
  - ***First development steps of the new oral formulation of Beleodaq®***
- ***Board reinforced with high-profile pharma business and scientific experts and establishment of US subsidiary in New York City***
- ***€19.6M cash-on-hand as of June 30, 2016***

Paris (France), Copenhagen (Denmark), July 28, 2016 – Onxeo S.A. (Euronext Paris, Nasdaq Copenhagen: ONXEO), a biopharmaceutical company specializing in the development of innovative drugs for the treatment of orphan diseases, in particular in oncology, today reported its consolidated half-year financials as of June 30, 2016 and provided an update on the key operational and clinical milestones reached during the first six months of the year.

"The first half of 2016 was an exciting and productive period for Onxeo, with the acquisition of DNA Therapeutics and its cutting-edge siDNA technology platform and several milestones in our Livatag® and Beleodaq® development programs. We have reinforced our Board of Directors with three high-profile executives who bring key international Pharma, Biotech, and R&D expertise to the company especially in oncology and, additionally, we have reinforced our presence in the US with the establishment of a subsidiary, based in New York City. We believe these steps strengthen our position as an emerging international leader in the orphan oncology space. We will continue to execute on this progress in the second half of 2016 in achieving our targeted operational and clinical development goals." said Judith Greciet, CEO of Onxeo.

Key first-half 2016 operational and corporate highlights

Strengthened product portfolio through the acquisition of DNA Therapeutics and lead compound, AsiDNA™, based on signal-interfering technology

- Second successful acquisition by Onxeo, giving access to first-in-class DNA Repair signal-interfering technology, with potential for broad applications in numerous cancers as a monotherapy or in combination with other anti-cancer agents
- Ambitious development plan aimed at demonstrating the potential of AsiDNA™ through systemic administration with pre-clinical results expected in 2016 and initiation of clinical trials in 2017
- Data presented at the recent EACR meeting in Manchester (UK), highlighted the therapeutic interest of combining AsiDNA and a PARP inhibitor: Synergistic effect demonstrated in a range of breast cancer cell lines and associated with a clear mechanistic rationale
- USPTO Notice of Allowance for key AsiDNA™ patent, extending IP protection in the US until 2031

Livatag®: Continued progression of "ReLive" Phase III trial

- 80% of patients randomized in the study to date
- Eighth positive DSMB recommendation granted for the ReLive Phase III clinical trial, confirming the good safety profile
- Preliminary data expected mid-2017
- Positive data in evaluating the mechanism of action of Livatag®. These data showed a preferential affinity for the liver and an increased exposure in plasma compared to free doxorubicin, together supporting the use of Livatag® in the treatment of patients suffering from advanced hepatocellular carcinoma (HCC)

Beleodaq®: New steps in both product development and commercialization, international expansion

- Successful outcome in the development of an oral formulation with positive bioavailability results from a preclinical pharmacokinetic (PK) study, creating new opportunities for Beleodaq®
- Signature of an exclusive license agreement with Pint Pharma for the commercialization of Beleodaq® in PTCL in South America for a total deal value greater than USD 20 million

Governance

- Nomination of Joseph Zakrzewski as Board member and non-executive chairman, replacing Patrick Langlois, bringing deep experience as an international pharmaceutical top executive
- Nomination as board members of two renowned scientific experts: Dr. Jean-Pierre Bizzari, a worldwide expert in clinical development notably in Oncology, and Dr. Jean-Pierre Kinet, a leading authority in Pharma Research, particularly in the immunology field

Creation of a US subsidiary

- Establishment of Onxeo US in New York City to expand Onxeo's outreach in the scientific and financial community, headed by Philippe Maître, Executive VP & Chief of US Operations

H1 2016 Consolidated Income Statement

Consolidated accounts (IFRS-compliant) *In thousands Euros*	30/06/2016 (6 months)	30/06/2015 (6 months)
Revenues	1,878	1,533
Incl. recurring revenues	*1,824*	*1,219*
Incl. non-recurring revenues	*54*	*314*
Operating expenses	(13,043)	(13,502)
Incl. R&D expenses	*(8,534)*	*(7,832)*
Operating profit/loss	(11,185)	(11,969)
Financial income	(210)	832
Income tax	167	(200)
Net profit/loss	(11,227)	(11,347)

Revenues for the first half of 2016 totaled €1.8 million, compared with €1.5 million in the first half of 2015:

- 49% growth in recurring revenues, representing product sales to commercial partners and royalties on sales by Onxeo's partners. US partners Spectrum Pharmaceuticals (Beleodaq) and Cipher (Sitavig) continue the aggressive marketing of Onxeo's assets in a very competitive environment, with significant barriers to entry
- Decrease in non-recurring revenues, from €0.3 million in 2015 to €0.1 million in 2016; primarily due to the accounting impact of IFRS adjustments related to recognition of upfront payments on certain licensing agreements

Operating expenses remained stable at €13.0 million for H1 2016 compared to €13.5 million in 2015:

- R&D expenses increased nearly 10% from €7.8 million in 2015 to €8.5 million in 2016, driven by manufacturing activities to support the Livatag ReLive Phase III trial, the initiation of the AsiDNA development program, following the DNA Therapeutics acquisition at the end of March, and innovative preclinical experiments with Beleodaq® and Livatag® aimed at evaluating new combinations with various anti-cancer agents
- Maintained tight control over other operating expenses in order to optimize the company's cash burn

The variation of financial income was primarily due to significant positive exchange rate variances booked in 2015.

As of June 30, 2016, consolidated cash position amounts to €19.6 million and provides extended visibility until Q4 2017 compared to previous assumptions.

The complete half-year financial report (regulated information) is available on www.onxeo.com in the sections "Financial information" and "Regulated information" of the "Investors" webpage. The 2016 half-year financial results were subject to a review by the Company's statutory auditors.

About Onxeo

Onxeo is a biopharmaceutical company specializing in the development of innovative drugs for the treatment of orphan diseases, in particular 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 and aggressive cancers.. Onxeo's comprehensive portfolio features a broad orphan oncology pipeline, with four independent programs in various stages of clinical development, including Onxeo's first approved orphan oncology drug, Beleodaq®. 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's orphan oncology products are:

- **Livatag®** (Doxorubicin Transdrug™): Currently being evaluated in a Phase III trial (ReLive) in patients with hepatocellular carcinoma (primary liver cancer); and in combination with other cancer agents in first-line HCC
- **Beleodaq®** (belinostat): FDA-approved in the US 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 US, Spectrum Pharmaceuticals; belinostat in combination with other cancer agents is currently in development in first-line treatment for patients with PTCL (BelCHOP) and in other solid tumors
- **AsiDNA**: The first-in-class siDNA (signal-interfering DNA) which has successfully undergone a proof-of-concept Phase I trial in metastatic melanoma
- **Validive®** (Clonidine Lauriad®): Positive final results from a Phase II trial in head and neck cancer patients with severe oral mucositis

In addition, Onxeo has successfully developed and registered two non-cancer products which are currently being commercialized in the U.S. and Europe.

Learn more by visiting www.onxeo.com.

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