



Onxeo Reports Third Quarter 2015 Business Update

Continued advancement of key company initiatives and strong cash position

Paris (France), Copenhagen (Denmark), November 5, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today published an update on major milestones achieved during the third quarter of 2015 as well as its consolidated revenues for the period ending September 30, 2015.

> Continued advancement of key R&D programs

- **Livatag[®]** (doxorubicin nanoformulation in Phase III trial for treatment of hepatocellular carcinoma):
 - Seventh positive DSMB recommendation to continue Phase III clinical trial
 - New patent application with potential to provide new and extended worldwide protection on the product until 2036
- **Validive[®]**:
 - Presentation of Phase II clinical data at various international conferences
 - Preparation for next phase of development including guidance from European and U.S. regulatory agencies
- **Beleodaq[®]**:
 - BELIEF Phase II results published in the Journal of Clinical Oncology (JCO)
 - Completion of Beleodaq-CHOP Phase I trial, prerequisite for Phase III first line protocol. Results to be presented at American Society of Hematology (ASH) Annual Meeting

> Evolution of governance with planned succession of chairman Patrick Langlois by Joseph Zakrzewski in January 2016

“The third quarter of 2015 saw significant advancements in our three orphan oncology-focused clinical development programs. We maintained good control of our cash burn, while continuing to fund our clinical developments notably our key asset Livatag[®], a short term and very strong value driver for the company. Recurring revenues are progressing and we are working closely with our three U.S. partners - Spectrum Pharmaceuticals, Innocutis/Cipher and Dara BioSciences - to improve market penetration and build sales momentum. Our ability to generate revenues from

registered products combined with a promising R&D pipeline in orphan oncology distinguish Onxeo from other European biotech companies. We believe that this unique value proposition will enable us to continue growing and realize our goal of becoming a leader in the markets we serve”, commented Judith Greciet, CEO of Onxeo.

Q3 Financial information

Total revenues for the third quarter of 2015 amounted to €1.1 million, out of which:

- €0.7 million of recurring revenues corresponding to product supplies to commercial partners and royalties on partners’ sales;
- and €0.4 million of non-recurring revenues, mostly corresponding to the upfront payment (€0.3 million) received from Bruno Pharmaceutici, our new partner for Sitavig® in Italy.

Over the first nine months of the year, total revenues stood at €2.7 million, out of which €2.0 million were recurring revenues versus €0.9 million in 2014. This two-fold increase results from the launch of Beleodaq® and Sitavig® in the U.S. by partners Spectrum Pharmaceuticals and Innocutis/Cipher respectively during the summer of 2014, as well as from the initial supply of Oravig® batches to new U.S. partner Dara BioSciences prior to the launch of the product in October 2015.

Although overall revenues significantly increased compared to last year, Beleodaq® and Sitavig® still face significant competition and high barriers to entry in their respective markets in the U.S. Onxeo’s goal is to foster an active coordination with its partners in order to ensure the best conditions for sales uptake for these products in the important U.S. market.

Over the first 12 months of commercialization in the U.S., Beleodaq® net sales have reached \$10 million and Sitavig® sales have reached \$2.3 million.

As of September 30, 2015, consolidated cash position amounted to €35.8 million. Operating cash burn over the quarter stood at €7.1 million, in line with expectations. Current cash position, taking into account the cashing in of the 2014 R&D tax credit and a new tranche of the Bpifrance grant for Livatag® (total received in October: €2.9 million), is expected to be sufficient to fund the Company until mid 2017, including the ability to fully support ongoing clinical programs.

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 U.S. in 2nd line treatment of peripheral T-cell lymphoma

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

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Contacts :

Nathalie Delair-Trepo
Investor Relations
+ 33 1 45 58 76 00
investors@onxeo.com

Caroline Carmagnol / Florence Portejoie – Alize RP (France)
onxeo@alizerp.com
+33 6 64 18 99 59 / +33 1 44 54 36 64

Kirsten Thomas / Lee Roth – The Ruth Group (U.S.)
kthomas@theruthgroup.com / lroth@theruthgroup.com
+1 508 280 6592 / +1 646 536 7012