



Quarterly Information as of March 31, 2015

➤ Significant advancements of company programs

- ***Livatag®: Opening of new centres and active recruitment in the ReLive trial***
- ***Validive®: Presentation of positive preliminary results of the Phase II trial at ASCO***
- ***Beleodaq®: new steps in the product development***

➤ Strengthened internal organization

➤ Strong visibility in terms of cash

Paris (France), Copenhagen (Denmark), April 15, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today publishes the major key milestones achieved during the first quarter of 2015 and the last few weeks.

“Over the first quarter, Onxeo’s teams have continued to dedicate their efforts to build our key orphan oncology pipeline. New centers are being opened in the MENA region to optimize the patient recruitment capacities in our phase III trial with Livatag®. Positive results of our phase II trial with Validive® are strong enough to support the initiation of a phase III, as recommended by our expert board, and will soon be presented at ASCO, the largest worldwide congress in the oncology field. Lastly Beleodaq® development in PTCL is moving forward to position the product in first line treatment of rare cancer PTCL. With these three products, Onxeo capitalizes on major assets with unique features and with combined sales potential over €1 billion”, comments Judith Greciet, CEO of Onxeo.

Livatag®

More than 40% of the planned 400 patients have been recruited as of March 31, 2015, within the “ReLive” phase III trial. This trial evaluates Livatag® in the treatment of primary liver cancer (hepatocellular carcinoma), for which there is a dire need and a growing demand for innovative

treatments. Recruitment will be accelerated with new clinical sites in Egypt, Saudi Arabia and Lebanon that will be opened in the following weeks and that will complement existing sites in Europe and the US. The company plans to announce preliminary results early 2017.

The study safety data are reviewed every semester by a board of independent experts (DSMB). The 6th DSMB has taken place mid-April with positive outcome on Livatag® safety based on the review of a substantial number of treated patients and infusions (- about 35% of patients and 350 infusions).

Validive®

Following positive phase II results of Validive® announced October 2014 , in the prevention of oral severe mucositis in patients treated for H&N cancer and upon recommendation of its international key expert board, the company is preparing the phase III to be initiated by the end of 2015. The phase II data will be presented at ASCO (*American Society of Clinical Oncology*) annual conference end of May in Chicago. This conference is a true tribune and presenting at such forum enlarges product awareness from the medical community.

Beleodaq®

Beleodaq® (belinostat) is registered in the US for the 2nd line treatment of a rare hematologic cancer, the peripheral T-cell lymphoma (PTCL), and commercialized in this territory by Spectrum Pharmaceuticals. The ambition for Beleodaq® is to position the product in 1st line treatment, an extension of the current indication, based on a phase III trial combining Beleodaq® with the current 1st line treatment CHOP (combination of four chemotherapies). This phase III trial is to start H1 2016, in collaboration with Spectrum Pharmaceuticals. As a preliminary step, both companies are currently performing a phase I trial to assess the safety of the drugs combination. Outcome of this phase I trial should be available in H2 2015.

Beyond PTCL, belinostat's profile, supported by clinical data, advocates for its development in new promising orphan oncology indications. The company is currently reviewing potential indications in order to define the optimal development plan for belinostat.

Internal organization

Onxeo, established as a French-based company with a branch in Denmark, now operates as one sole company with a strongly experienced and skilled international teams. The recent addition of new members in the executive committee, including new CSO and head of R&D Graham Dixon, already fuels the organization.

Financials

The consolidated turnover for the first quarter 2015 has increased significantly compared to same period in 2014, with revenues from licensed products multiplied by four as a result of the commercialization of Beleodaq® by US partner Spectrum Pharmaceuticals (launch in the US took place in July 2014).

<i>Consolidated revenues – IFRS – in thousands Euros</i>	Q1 2015	Q1 2014
Recurring revenues from out-licensing agreements	761	158
Non-recurring revenues from out-licensing agreements	157	205
TOTAL	918	363

Non recurring revenues are limited and correspond to the recognition of a portion of upfront payments received in previous years upon signature of license agreements concerning Loramyc® et Sitavig®.

From a dynamic standpoint, royalties generated by partners' sales reach €0.6 million, a stable figure compared to Q4 2014 (+2.6%), despite severe winter weather conditions in the US that have strongly hampered the sales force promotional activity.

Strongly increased over 2014 through significant milestones payments from Spectrum and the year-end fund raising, the consolidated cash position stood at € 49.4 million as of March 31, 2015. This gives Onxeo a visibility of about two years and the ability to efficiently support its 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 preliminary top-line results

Beleodaq® (belinostat): registered in the US in peripheral T-cell lymphoma

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

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