



Onxeo First Quarter 2016 Financial information and Business Update

Pipeline reinforced through major development milestones on existing assets and new product acquisition

Paris (France), Copenhagen (Denmark), April 28, 2016 – Onxeo S.A. (Euronext Paris, Nasdaq Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today provided an update on financial results and major milestones achieved during the first quarter of 2016, ending March 31, 2016.

➤ Continued advancement of R&D programs:

- **Livatag[®]** (doxorubicin nanoformulation in Phase III trial for treatment of hepatocellular carcinoma):
 - Eighth positive DSMB recommendation for the ReLive Phase III clinical trial confirms safety profile
 - New data on Livatag[®]'s unique mechanism of action presented at the AACR Annual Meeting in New Orleans, LA, USA
- **Beleodaq[®]**:
 - Preclinical studies assessing the efficacy of Beleodaq[®] Livatag[®] in combination with other oncology agents; initial data expected mid-2016.
- **Validive[®]**:
 - Strategic decision to pursue further development only through partnership, following confirmation by the U.S. Food and Drug Administration of the clinical development plan

➤ Expansion of Onxeo's orphan oncology pipeline through acquisition of DNA Therapeutics and lead compound based on signal-interfering technology:

- **AsiDNA**, first-in-class signal-interfering DNA (siDNA) molecule which accelerates cancer cell death by breaking the cycle of tumor DNA repair:
 - Technology at the forefront of scientific research for cancers with significant unmet medical needs
 - Potential to generate substantial shareholder value through new orphan oncology opportunities
 - €1.7 million cash-free acquisition closed March 25, 2016, concurrent with €1 million investment in Onxeo by former DNA Therapeutics shareholders via private

placement. Additional milestone payments are expected once the product reaches the market.

- Establishment of New York City-based U.S. subsidiary:
 - Direct U.S. presence will enable expansion of the Company's development programs and establishment of closer ties with the scientific and financial communities in this key market
 - Philippe Maitre, pharmaceutical and biotech industry veteran, appointed Executive VP & Chief of U.S. Operations

- Enhancement of the Company's Board of Directors with the election as Chairman of Joseph Zakrezwski, a top personality in the biotech and pharmaceutical industry, and the appointments of international oncology R&D experts Prof. Jean-Pierre Kinet, M.D. and Jean-Pierre Bizzari, M.D.

Judith Greciet, CEO of Onxeo, commented, *"In the first quarter of 2016, we built upon our momentum and reinforced our position as an emerging leader in the development of orphan oncology therapeutics. We advanced the development of our lead asset, Livatag®. We are approaching near-term completion of Phase III recruitment, leading to reporting preliminary results mid-2017. The quarter was also highlighted by our acquisition of DNA Therapeutics and its siDNA technology platform, which we believe has the potential to change the paradigm of cancer care while greatly enhancing our ability to develop innovative therapies for patients in need. The DNA Therapeutics acquisition comes less than two years after the merger between BioAlliance Pharma and Topotarget that created Onxeo, and demonstrates our commitment to maximizing the opportunities to grow in the orphan oncology space. We are building a robust portfolio of commercialized products and highly promising product candidates. Collectively, these assets form a strong foundation upon which to grow the Company"*.

Q1 financial information

Revenues for the first quarter of 2016 totaled €782K, compared with €918K in the first quarter of 2015, impacted by a decrease in non-recurring revenues, from €157K in the first quarter of 2015 to €27K in the first quarter of 2016. This is primarily due to the accounting impact of IFRS relating to recognition of upfront payments on certain licensing agreements.

First quarter 2016 recurring revenues, which relate to product sales to commercial partners and royalties on product sales by Onxeo's partners, were roughly flat compared to Q1 2015 (€755K compared with €761K in the first quarter of 2015). After the period of integration of Innocutis' products and teams by Cipher mid-2015, revenues originating from Sitavig® are back with a positive trend, resulting notably from an increase in price. Spectrum Pharmaceuticals maintained active marketing efforts to drive the growth of Beleodaq® in the highly competitive second-line PTCL market.

As of March 31, 2016, consolidated cash position amounted to €24.4 million, in line with expectations. This figure does not include the €1 million capital increase linked with the acquisition of DNA Therapeutics, which was received subsequent to the end of the first quarter.

"Taking into account the planned reimbursement of the 2015 R&D tax credit of €3.8 million, our current cash position is sufficient to fund development into the second half of 2017, as per our plans, allowing us to deliver on important milestones over that time", concluded Nicolas Fellmann, CFO of Onxeo.

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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 broad 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 which are 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 approximately 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); and in combination with other cancer agents in first-line HCC
- **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 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/IIa 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;

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