



THE ORPHAN ONCOLOGY INNOVATOR

PRESS RELEASE

## ***Onxeo Reports First Instance Decision from the Commercial Court of Paris in the Lawsuit against SpeBio/SpePharm***

**Paris (France), October 17, 2017 – 10 pm CEST** – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO - FRO010095596), (“Onxeo” or the “Company”), a biotechnology company specializing in the development of innovative drugs in oncology, in particular against rare or resistant cancers, today announced the Commercial Court of Paris’ decision in the litigation which started in 2009 between Onxeo on one hand and, on the other hand, SpePharm and SpeBio B.V., a joint-venture subsidiary managed by SpePharm, which was dedicated to the distribution of Loramyc<sup>®1</sup> in Europe.

As a reminder, Onxeo (formerly known as BioAlliance Pharma) considered that SpePharm and SpeBio breached their contractual obligations. The various contractual breaches of these two companies resulted in a delay in the marketing and sales of Loramyc<sup>®</sup>, forcing Onxeo to terminate its partnership with these two companies in 2009<sup>2</sup> and initiate legal proceedings.

In first instance, the Court ordered Onxeo to pay SpeBio B.V. for costs incurred before termination the sum of €8.6 million with capitalized interest at the legal rate as of June 30, 2014 and to pay SpePharm the sum of €50,000 in damages, as well as €250,000 and €15,000 procedural indemnities to SpeBio and SpePharm respectively.

Given the 50% ownership of SpeBio B.V. by Onxeo and the financial liabilities between both companies, the net financial impact to Onxeo will have to be recalculated.

Onxeo vigorously contests the grounds for this decision and intends to explore all avenues of remedies, including the appeal of this decision.

### **About Loramyc<sup>®</sup>**

Loramyc<sup>®</sup> is a mucoadhesive buccal tablet containing miconazole. It was the first product developed by Onxeo (ex-BioAlliance Pharma) and approved in Europe and the USA for the treatment of oropharyngeal candidiasis. The product was sold in July 2017 to Vectans Pharma, a private pharmaceutical company which develops and markets innovative therapeutics in oral pathologies. Onxeo retains the rights to most of the expected milestone payments from existing partners, related to predefined regulatory or commercial performance events expected over the next 3 years. Please refer to the Company’s press release dated July 31, 2017.

### **About Onxeo**

Onxeo is a biotechnology company developing innovative drugs in oncology, in particular orphan cancers, driven by high therapeutic demand in one of the fastest growing segments of the pharmaceutical industry.

Onxeo’s objective is to become a major player in the field of rare or resistant cancers. Its growth strategy is to develop innovative, effective, and safe drugs based on breakthrough technologies that can make a real difference in patients’ lives, by acquiring or in-licensing first-in-class or unique compounds at an early stage and bringing them through translational research and proof of concept clinical development up to value-creating inflexion points.

<sup>1</sup> Loramyc<sup>®</sup> is also known as Oravig<sup>®</sup> in the US and China, and Oravi<sup>®</sup> in Japan.

<sup>2</sup> A summary of the litigation is part of the HY 2017 financial report published on July 28, 2017 (note 8.1.2 of the condensed interim consolidated accounts).



Onxeo's orphan oncology pipeline comprises products in several on-going preclinical and clinical programs, alone or in combination for various cancer indications.

- **AsiDNA™**: a first-in-class siDNA (signal-interfering DNA) candidate which has successfully undergone a proof-of-concept Phase I trial via local administration in metastatic melanoma. Recent positive in-vivo preclinical proof-of-concept results confirmed AsiDNA™ activity via systemic administration in a murine model of triple negative breast cancer (TNBC). The Company now prepares a phase I trial of AsiDNA™ as monotherapy via systemic (intravenous) administration, expected to be submitted to the regulatory authorities by the end of 2017.
- **belinostat**: a HDAC inhibitor, conditionally FDA-approved in the US in 2014 as a 2<sup>nd</sup> line treatment for patients with peripheral T-cell lymphoma (PTCL) and marketed by Onxeo's partner in the US, Spectrum Pharmaceuticals under the commercial name of Beleodaq®; belinostat in combination with other anti-cancer agents is also in ongoing development in 1<sup>st</sup> line treatment for patients with PTCL (BelCHOP) as well as in other liquid or solid tumors. An oral formulation of belinostat should enter the phase I clinical stage early 2019. Oral belinostat would expand the asset patent protection and facilitates its use in combination with other anti-cancer agents.
- **Livatag®** is a nanoparticle formulation of the chemotherapy doxorubicin designed to facilitate the penetration of the drug into the tumor cell and increase the target DNA exposure to the drug. The ReLive phase III study in hepatocellular carcinoma demonstrated a similar effect of Livatag® as single agent, as the one showed by the best-standard-of-care group which allowed any active cancer treatment, alone or in combination. Data are under review to determine the optimal path for this asset going forward.

Furthermore, AsiDNA™ is the first compound generated from platON™, the Company's proprietary chemistry platform of decoy oligonucleotides. PlatON™ will continue to generate new compounds that will broaden Onxeo's pipeline.

Onxeo is headquartered in Paris (France) with offices in Copenhagen and in New York and listed on Euronext in Paris, France and Nasdaq Copenhagen, Denmark (Ticker: ONXEO, ISIN Code: FR0010095596).

For further information, please visit [www.onxeo.com](http://www.onxeo.com).

#### **Forward looking statements**

This communication expressly or implicitly contains certain forward-looking statements concerning Onxeo and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Onxeo to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Onxeo is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise. For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of Onxeo to differ from those contained in the forward-looking statements, please refer to the section 5.5.1.4 "Risk Factors" ("*Facteurs de Risque*") of the 2016 reference document filed with the *Autorité des marchés financiers* on April 24, 2017 under number D.17-0423, which is available on the *Autorité des marchés financiers* website ([www.amf-france.org](http://www.amf-france.org)) or on the Company's website ([www.onxeo.com](http://www.onxeo.com)).

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