THE ORPHAN ONCOLOGY INNOVATOR

PRESS RELEASE

Onxeo Grants Exclusive Worldwide License of Validive® developed for the treatment of oral severe mucositis to Monopar Therapeutics

- ***Agreement includes substantial milestone payments up to $108m as well as escalating royalties on future sales***
- ***Monopar Therapeutics will drive and fund all remaining development, regulatory and commercialization activities***

Paris (France), September 13, 2017 – 8:00 am CEST – Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), ("**Onxeo**" or the "**Company**"), a clinical-stage biotechnology company specializing in the development of innovative drugs for the treatment of orphan diseases, in particular in oncology, today announces the Company has granted a global exclusive license of its product Validive® (clonidine mucoadhesive buccal tablet) developed for the treatment of severe oral mucositis induced by radiotherapy or chemotherapy in patients suffering from head and neck cancer to Monopar Therapeutics (Chicago, Illinois, USA), a biopharmaceutical company focused on developing innovative drug combinations to improve clinical outcomes in advanced cancer.

Following the phase II trial, the company had announced that it would not initiate the next clinical steps on its own for this asset but would actively look for an industrial partner to further its development.

Under the agreement, Monopar Therapeutics Inc. receives an exclusive worldwide license to develop, register, commercialize and manufacture Validive®. Monopar Therapeutics will drive and fund all remaining development and regulatory activities, the first of these activities being a phase III registration study.

"Severe oral mucositis occurs in the majority of patients treated with radiotherapy/chemotherapy for head and neck cancer but there is no effective prevention or treatment available to date," said Chandler D. Robinson, MD, MBA, MSc, CEO of Monopar Therapeutics Inc. "We are pleased with this agreement and strongly believe in the potential of Validive® to answer this large unmet need. The acquisition of a phase III-ready asset is fully aligned with our strategy to build a strong and diversified portfolio of oncology products that will improve clinical outcomes in patients with advanced cancer."

Onxeo is entitled to an immediate $1.0m license fee and to future milestone payments that could reach up to $108m subject to the achievement of the agreed upon milestones, including $15.5m related to regulatory milestones, from phase III to registration. Escalating royalties on sales up to a 2-digit percentage are also part of the agreement.

" It was our stated intention after its successful Phase II to partner Validive® prior to initiating any remaining development steps, as it was the best strategy to maximize its value for Onxeo," said Judith Greciet, CEO of Onxeo. *"This licensing transaction with Monopar Therapeutics is fully in line with this strategy and further demonstrates our capacity to execute such value-creating deals. We are pleased that Validive will get the opportunity to one day serve the unmet needs of many patients affected with severe oral mucositis, while, on our end, we are focusing all our energy on our pipeline of unique breakthrough compounds in orphan oncology."*

About Validive® (clonidine mucoadhesive buccal tablet)

Validive® is a therapeutic application of clonidine based on Onxeo's proprietary mucoadhesive tablet technology. This technology significantly increases the mucous and salivary concentrations of the active ingredient it contains, with decreased systemic absorption. As an agonist of the alpha-2 adrenergic receptors, Validive® exhibits anti-inflammatory properties, and was developed for the prevention and treatment of chemo/radiation therapy-induced severe oral mucositis in patients with head and neck cancer. A Phase II, multi-center, double-blind, randomized, placebo-controlled, three-arm study (NCT01385748) in 183 patients in Europe and in the US demonstrated that the therapy significantly reduces incidence of severe mucositis, improves oral mucositis related symptoms and decreases radiotherapy-related adverse events, and exhibits a favorable safety profile and strong adherence to treatment. Validive® was granted orphan drug status in Europe in November 2011 and also received Fast-Track status from the U.S. Food and Drug Administration (FDA) in January 2014. The Company had stated in 2016 its intention to seek a partner for this product.

About Monopar Therapeutics

Monopar Therapeutics Inc. is an emerging biopharmaceutical company focused on developing innovative drug combinations to improve clinical outcomes in advanced cancer. Monopar's lead compound, huATN-658, is a novel monoclonal antibody for the potential treatment of several deadly cancers. huATN-658 targets the urokinase plasminogen activator receptor (uPAR). Cancer Research UK will be conducting huATN-658's early development, including a Phase I clinical trial. Monopar's team is located in San Francisco, CA and Chicago, IL.

Learn more by visiting www.monopartherapeutics.com

About Onxeo

Onxeo is a biotechnology company developing innovative drugs for the treatment of orphan diseases 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 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. Onxeo's orphan oncology pipeline comprises products in several on-going preclinical and clinical programs, alone or in combination for various cancer indications.

- **Livatag®** is a nanoparticle formulation of the chemotherapy doxorubicin, developed using Onxeo's proprietary Transdrug™ technology designed to facilitate the penetration of the drug into the tumor cell and increase the target DNA exposure to the drug, thereby bypassing the mechanisms of multi-drug resistance developed by tumor cells.
- **Beleodaq® (belinostat):** a HDAC inhibitor, conditionally 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; Onxeo is currently developing an oral formulation of belinostat, to facilitate its use in combination and extend its IP protection ; belinostat in combination with other anti-cancer agents is also in ongoing development in other liquid or solid tumors, with the filing a phase 1 expected by the end of 2017.
- **AsiDNA™:** a first-in-class siDNA (signal-interfering DNA) candidate which has successfully undergone a proof-of-concept Phase I trial with a local administration in metastatic melanoma. Recent positive preclinical proof-of-concept results confirmed AsiDNA™ activity via systemic administration in a murine model of triple negative breast cancer (TNBC). The Company now plans to prepare a phase I trial via systemic administration by the end of 2017.

The Company is headquartered in Paris, France with offices in Copenhagen and in New York, and has approximately 60 employees. Onxeo is listed on Euronext in Paris, France and Nasdaq Copenhagen, Denmark (Ticker: ONXEO, ISIN Code: FR0010095596).

Learn more by visiting www.onxeo.com

Upcoming events

September 16, 2017	11th meeting of the International Liver Cancer Association Oral Presentation of ReLive Results	Seoul, South Korea
October 2nd, 2017	French Society of Financial Analysts meeting ReLive Results & Strategic Update	Paris, France
October 4-5, 2017	Large & MidCap Forum	Paris, France
October 19, 2017	Portzamparc Biotech Symposium	Paris, France
October 26, 2017	Q3 results and business update	

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) or on the Company’s website (www.onxeo.com).

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