

Onxeo Announces Identification of Predictive Biomarkers for AsiDNA™, its First-in-Class DNA Damage Response Inhibitor

- ***Biomarkers correlated to tumoral sensitivity to AsiDNA™, supporting personalized medicine approaches***
- ***A selection tool to screen patients in future clinical development of AsiDNA™ based on these predictive biomarkers of response***

Paris (France), January 3, 2019 – 6.00 pm CET - Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), (“Onxeo” or “the Company”), a clinical-stage biotechnology company specializing in the development of innovative drugs in oncology, in particular against rare or resistant cancers, today announces the identification of predictive biomarkers for AsiDNA™, its first-in-class non-targeted DNA Damage Response (DDR) inhibitor, which enables personalized medicine approaches.

Judith Greciet, Chief Executive Officer of Onxeo, said: *“The development of AsiDNA™ is undergoing a strong momentum both in terms of preclinical and clinical activities. Identifying predictive biomarkers is an important step forward that will assist in the design of the next phases of the clinical development of AsiDNA™. Indeed, these biomarkers will make possible an upstream selection of the patients with a better sensitivity to treatment with AsiDNA™, which will maximize the likelihood of success for upcoming clinical studies as well as enable a personalized medicine approach for these patients over time. We now have a robust and state-of-the-art set of preclinical and clinical data for this particularly promising drug candidate in the field of DDR. The identified biomarkers are important components in the design of future studies and will be included as soon as the next phase 1b/2 combination study that we expect to initiate in the coming weeks, thanks to the favorable intermediate results of activity and tolerance in the ongoing DRIIV-1 study. Each of these advances in our developments significantly enhances the value of AsiDNA™ and our R&D assets.”*

Preclinical studies identified predictive biomarkers for patient selection in upcoming studies of AsiDNA™

Extensive tests investigated AsiDNA™ sensitivity signature using bioinformatics analysis from transcriptomic experiments, validated this signature in vitro on multiple cell lines and then analyzed the genes presenting an expression profile highly correlated with sensitivity to AsiDNA™.

These studies showed that sensitivity to AsiDNA™ is correlated with the level of DNA repair gene expression in the tumor and identified several tumor genes for which the level of expression is the most correlated to AsiDNA™ sensitivity. A low level of these genes expression in a patient’s tumor greatly increases the likelihood that the patient will respond to treatment with AsiDNA™. As a result, analysis of these genes will be used to select the patients with the highest sensitivity to treatment and thus the greater probability of response in upcoming trials.

Use of such predictive biomarkers is part of the best practices in clinical trial design and in treatment (personalized medicine) today. During clinical development, their use greatly reduces risks and maximizes the chances of success. In clinical practice, prior assessment via predictive biomarkers allows for personalized care that optimizes the patient’s chances by selecting the most appropriate treatment for a given patient.



About Onxeo

Onxeo (Euronext Paris, NASDAQ Copenhagen: ONXEO) is a French biotechnology company developing innovative oncology drugs based on DNA-targeting and epigenetics, two of the most sought-after mechanisms of action in cancer treatment today. The Company is focused on bringing early-stage first-in-class or disruptive compounds (proprietary, acquired or in-licensed) from translational research to clinical proof-of-concept, a value-creating inflection point appealing to potential partners.

Onxeo is developing **AsiDNA™**, a first-in-class and highly differentiated tumor DNA Damage Response inhibitor, based on an original decoy and agonist mechanism that acts upstream of multiple DDR pathways. Translational studies have demonstrated unique properties of AsiDNA™, including an increasing sensitivity of tumor cells to AsiDNA™ after repeated treatment with AsiDNA™ and the ability to stop and even reverse the resistance of tumor cells to PARP inhibitors, regardless the genetic mutation status. AsiDNA™ has also shown strong synergy with other tumor DNA damaging agents such as chemotherapies or PARP inhibitors. The ongoing Phase I study DRIIV-1 (DNA Repair Inhibitor-administered IntraVenously) evaluates AsiDNA™ by systemic administration (IV) in solid tumors and has recently produced favorable tolerability and activity results.

AsiDNA™ is the first compound generated from **platON™**, the Company's proprietary chemistry platform of decoy oligonucleotides. PlatON™ will continue to generate innovative compounds targeting tumor DNA-binding functions and broaden Onxeo's pipeline.

Onxeo's R&D pipeline also includes **belinostat**, an HDAC inhibitor (epigenetics). Belinostat is already conditionally FDA-approved in the US as a 2nd line treatment for patients with peripheral T cell lymphoma and marketed in the US by Onxeo's partner, Spectrum Pharmaceuticals, under the name Beleodaq® (belinostat IV form).

For further information, please visit 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 5.7.1.4 "Risk Factors" ("*Facteurs de Risque*") of the 2017 registration document filed with the *Autorité des marchés financiers* on April 25, 2018 under number D.18-0389, 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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