

## ***Onxeo Enters Clinical Research Agreement with Gustave Roussy to Conduct Clinical Trial of AsiDNA™ for Treatment of Relapsed Ovarian Cancer***

***The REVOCAN phase 1b/2 study, sponsored by Gustave Roussy, will evaluate the effect of AsiDNA™ on the acquired resistance to PARP inhibitor niraparib in 2<sup>nd</sup> line maintenance treatment of relapsed ovarian cancer***

Paris (France), January 29, 2020 – 07:00 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 targeting tumor DNA Damage Response (DDR), in particular against rare or resistant cancers, today announces that the Company has entered into a Clinical Research Agreement with Gustave Roussy (“Gustave Roussy”), the leading European cancer center, to conduct the REVOCAN<sup>1</sup> phase 1b/2 study designed to evaluate the effect of AsiDNA™, Onxeo’s first-in-class DDR inhibitor, on the acquired resistance to PARP inhibitor (PARPi) niraparib in its approved indication for 2<sup>nd</sup> line maintenance treatment of relapsed ovarian cancer.

*“This is a major clinical milestone for Onxeo as we embark in this key study aiming to demonstrate that the addition of AsiDNA™ abrogates the tumor resistance to PARP inhibitors, which would in turn improve patients’ progression-free survival,” said Olivier de Beaumont, Chief Medical Officer of Onxeo. “We are excited and honored to be collaborating with Gustave Roussy, one of the world’s leading academic institutions, in a study that would open the way to AsiDNA™ becoming a must-have treatment to prevent or abrogate resistance to targeted therapies in cancer treatment.”*

*“Gustave Roussy and Onxeo will conduct an original proof-of-concept study of the reversion of the mechanism of resistance to a major therapeutic class. If positive, this first study, labeled by the GINECO<sup>2</sup> group, may pave the way for further combination studies with this therapeutic class, in ovarian cancer but also in other pathologies, and offer patients who benefit from these treatments an additional opportunity to control their disease,” said Patricia Pautier, MD, oncologist, head of the Gynecological Cancers Committee at Gustave Roussy and principal investigator of the study.*

While niraparib significantly delayed cancer progression in both patients with and without a BRCA mutation<sup>3</sup>, treatment efficacy diminishes overtime as tumors establish new repair pathways and resist to treatment. In preclinical studies, AsiDNA™ has consistently demonstrated its capacity to prevent or abrogate the acquired resistance of the tumors to PARP inhibitors, regardless of tumor mutations.

Gustave Roussy and Onxeo have collaborated on REVOCAN multi-center trial design that Gustave Roussy will submit, as study sponsor, to the French health authority (ANSM) and Ethics Committee in the coming weeks, with the aim to start enrolling patients in the first semester of 2020 and obtain preliminary results before year-end.

<sup>1</sup> REVOCAN = REV (REVersion of resistance) – OC (in Ovarian Cancer) – A (with AsiDNA™) – N (and Niraparib)

<sup>2</sup> ARCAGY - GINECO is an independent, non-profit, academic clinical research group specializing in gynecological oncology. For more information:: <http://www.arcagy.org/arcagy-gineco-organisation-et-recherche/>

<sup>3</sup> Mansoor R. Mirza, M.D et. al. Niraparib Maintenance Therapy in Platinum-Sensitive, Recurrent Ovarian Cancer N Engl J Med 2016; 375:2154-2164



### About Gustave Roussy

**Gustave Roussy** is the leading Cancer Centre in Europe. It is a centre where all the skills in cancer care are focused on the patient. It comprises 3,100 professional staff who are engaged in care, research and teaching.

For more information, please visit [www.gustaveroussy.fr/en](http://www.gustaveroussy.fr/en)

### About Onxeo

**Onxeo** (Euronext Paris, NASDAQ Copenhagen: ONXEO) is a clinical-stage biotechnology company developing innovative oncology drugs targeting tumor DNA-binding functions through unique mechanisms of action in the sought-after field of DNA Damage Response (DDR). The Company is focused on bringing early-stage first-in-class or disruptive compounds from translational research to clinical proof-of-concept, a value-creating inflection point appealing to potential partners.

**platON™** is Onxeo's proprietary chemistry platform of oligonucleotides acting as decoy agonists, which generates new innovative compounds and broaden the Company's product pipeline.

**AsiDNA™**, the first compound from platON™, is a first-in-class, highly differentiated DNA Damage Response (DDR) inhibitor based on a decoy and agonist mechanism acting upstream of multiple DDR pathways. Translational research has highlighted the distinctive properties of AsiDNA™, notably its ability to abrogate tumor resistance to PARP inhibitors regardless of the genetic mutation status. AsiDNA™ has also shown a strong synergy with other tumor DNA-damaging agents such as chemotherapy and PARP inhibitors. The DRIIV-1 (DNA Repair Inhibitor-administered IntraVenously) phase I study has evaluated AsiDNA™ by systemic administration (IV) in advanced solid tumors and confirmed the active doses as well as a favorable safety profile in man. The ongoing DRIIV-1b study is assessing the safety and efficacy of a 600 mg dose of AsiDNA™ in combination with carboplatin and then with carboplatin and paclitaxel, in multi-treated patients with solid tumors who are eligible for such treatments. Preliminary results from the first cohort with carboplatin alone have shown good tolerance, stabilized disease and increased durations of treatment vs. previous lines.

**OX401** is a new drug candidate from platON™, optimized to be a next-generation PARP inhibitor acting on both the DNA Damage Response and the activation of immune response, without inducing resistance. OX401 is undergoing preclinical proof-of-concept studies, alone and in combination with immunotherapies.

Onxeo's portfolio also includes **belinostat**, an HDAC inhibitor (epigenetics). Belinostat is already conditionally FDA-approved in the US as a 2<sup>nd</sup> line treatment for patients with peripheral T cell lymphoma and marketed in the US under the name Beleodaq® (belinostat IV form).

For more 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 5.7.1.4 "Risk Factors" ("*Facteurs de Risque*") of the 2018 registration document filed with the *Autorité des marchés financiers* on April 25, 2019 under number D.19-0282, 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)).

### Contacts

#### Onxeo

Valérie Leroy,  
Investor Relations

[investors@onxeo.com](mailto:investors@onxeo.com)

+33 1 45 58 76 00

#### Media Relations

Nicolas Merigeau  
NewCap

[onxeo@newcap.eu](mailto:onxeo@newcap.eu)

+33 1 44 71 94 98

#### Investor Relations / Strategic Communication

Dušan Orešanský / Emmanuel Huynh  
NewCap

[onxeo@newcap.eu](mailto:onxeo@newcap.eu)

+33 1 44 71 94 92



**Investor Relations US**

Brian Ritchie

LifeSci Advisors

[britchie@lifesciadvisors.com](mailto:britchie@lifesciadvisors.com)

+1 212 915 2578