

Onxeo Announces Approval of the REVocan Study By Regulatory Authorities

**The REVocan study aims to evaluate the abrogation by AsiDNA™
of tumor resistance to a PARP inhibitor in relapsed ovarian cancer**

**The first treatments could begin in the next few weeks,
with the objective of first results late 2020/early 2021**

Paris (France), May 29, 2020 – 7.30 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 targeting tumor DNA Damage response (DDR), in particular against rare or resistant cancers, today announced that the REVocan¹ phase 1b/2 designed to evaluate the effect of AsiDNA™, Onxeo’s first-in-class DDR inhibitor, on the acquired resistance to PARP inhibitor (PARPi) niraparib for 2nd line maintenance treatment of relapsed ovarian cancer, has received approval from the French National Agency for the Safety of Medicines and Health Products (ANSM) and the Ethics Committee (CPP).

From a regulatory standpoint, the study can now be initiated. REVocan will first start at three internationally renowned French centers, which are recognized experts in medical oncology:

- Gustave Roussy (Paris), the study sponsor under a clinical research agreement signed with Onxeo in early 2020;
- the Western Cancer Institute (Institut de Cancérologie de l’Ouest – Nantes/St Herblain);
- The University Hospital Center of Lyon (Hospices Civils de Lyon – CHU Lyon Sud).

The first patients could be recruited as early as the third quarter of 2020, with the aim of obtaining preliminary results at the end of 2020 or early in 2021.

"I would like to warmly thank the teams at Onxeo and Gustave Roussy who, despite the confinement and difficulties of the current health situation, have worked tirelessly to provide patients suffering from recurrent ovarian cancer with the fastest possible access to AsiDNA™ in this clinical study, which is critical for Onxeo as well as for the medical community," said Olivier de Beaumont, Chief medical Officer of Onxeo. "Given AsiDNA™'s unique mechanism of action, this novel proof-of-concept study of the reversion mechanism of resistance to a PARP inhibitor could pave the way for further combination trials with other targeted therapies in other major diseases and offer patients who benefit from these treatments an increased opportunity to control their disease."

Niraparib has significantly delayed ovarian cancer progression in patients with and without BRCA mutation², but treatment efficacy declines over time as tumors establish new repair pathways and resist treatment. In [preclinical studies](#) that replicated the conditions of the REVocan study³, AsiDNA™ demonstrated its ability to halt the acquired resistance of tumors to PARP inhibitors (class effect). REVocan is therefore particularly important as it would provide proof-of-concept of the tolerability of such a combination and AsiDNA™'s ability to reverse resistance to this major therapeutic class.

¹ REVocan = REV (REVersion of resistance) – OC (in Ovarian Cancer) – A (with AsiDNA™) – N (and Niraparib)

² Mansoor R. Mirza, M.D et. al. Niraparib Maintenance Therapy in Platinum-Sensitive, Recurrent Ovarian Cancer N Engl J Med 2016; 375:2154-2164.

³ [Acquired resistance to PARP inhibitors evolves from drug-tolerant persister cells vulnerable to AsiDNA™](#) - Abstract accepted at the AACR 2020 Virtual Meeting, to be presented on June 22, 2020.



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 human safety profile. The ongoing DRIIV-1b extension 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 patients with solid tumors who are eligible for such treatments. Preliminary results from the first cohort with carboplatin alone showed good tolerability, stabilization of the disease and an increase in the duration of treatment compared to previous treatments.

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.

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 chapter 3 "Risk Factors" ("*Facteurs de Risque*") of the Company's universal registration document filed with the *Autorité des marchés financiers* (www.amf-france.org) on April 27, 2020 under number D.20-0362, which is available on the websites of the *Autorité des marchés financiers* (www.amf-france.org) and the Company (www.onxeo.com).

Contacts

Onxeo

Valerie Leroy,
Investor Relations
investors@onxeo.com
+33 1 45 58 76 00

Media Relations

Nicolas Merigeau
NewCap
onxeo@newcap.eu
+33 1 44 71 94 98

Investor Relations / Strategic Communication

Dušan Orešanský / Emmanuel Huynh
NewCap
onxeo@newcap.eu
+33 1 44 71 94 92

Investor Relations US

Brian Ritchie
LifeSci Advisors
britchie@lifesciadvisors.com
+1 212 915 2578