

Onxeo Announces Completion of Patient Enrollment in DRIIV-1b Study and Positive Interim Results

- **The last patient was treated with AsiDNA™ in combination with carboplatin and paclitaxel in this Phase 1b study in patients with advanced solid tumors.**
- **The good safety profile of AsiDNA™ is confirmed to date, with no serious adverse events related to AsiDNA™ and no dose-limiting toxicities observed.**
- **Of the first seven patients, four had a partial response or longer periods of control of their disease than with previous treatment lines; three patients are still being treated.**
- **These preliminary data represent a particularly encouraging signal of efficacy and support further clinical development of AsiDNA™ in combination with these reference chemotherapies.**

Paris (France), November 9, 2020 – 6 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 announced the completion of enrollment in the DRIIV-1b study and favorable interim results.

DRIIV-1b was designed to evaluate the safety and efficacy of AsiDNA™ in combination with carboplatin (n=3) and then carboplatin plus paclitaxel (n=6) in eligible patients with metastatic solid tumors, progressing at inclusion. The last planned patient has received treatment and will be followed until disease progression.

At this stage and on the first seven patients evaluated for safety, the favorable safety profile of AsiDNA™ in combination with carboplatine +/- paclitaxel is confirmed, as no serious adverse events related to AsiDNA™ and no dose-limiting toxicities have been observed in these patients.

In terms of efficacy, four of the seven patients experienced a partial response and/or longer durations of disease control than with previous treatment lines. Three patients are still being treated. These preliminary data represent a particularly encouraging signal of efficacy that supports further clinical development of AsiDNA™ in combination with these reference chemotherapies.

Olivier de Beaumont, Chief Medical Officer of Onxeo, said: *“AsiDNA™’s mechanism of action, which prevents tumor DNA repair, is particularly well suited for combination with ‘DNA breakers’ such as chemotherapy, a reference treatment of cancer, for which clinicians seek to maximize efficacy without increasing an already significant toxicity. In DRIIV-1b, we are looking for a signal of greater efficacy than that observed with previous treatment lines, without increasing toxicity. Analysis of the first seven patients, for whom we now have sufficient hindsight, shows particularly encouraging results. For three patients with advanced metastatic cancers, sometimes heavily pre-treated, the combination of AsiDNA™ with one or two chemotherapies resulted in particularly long periods of progression-free disease control, sometimes exceeding 8 months and always longer than those obtained with previous treatment lines, including immunotherapy. One patient achieved a partial response, an outcome which was never achieved under previous treatments, including another platinum-based chemotherapy. The two last patients have started their treatment, thus completing enrollment in this study. Subject, of course, to the duration of control for three patients still being treated, we expect topline results for the entire study in early 2021, while on the basis of these positive results, we are already preparing the continuation of the clinical development of AsiDNA™ through a phase 2 study in a selected indication with high medical needs.”*



About DRIIV-1b

DRIIV-1b is designed to evaluate the safety and efficacy of AsiDNA™ in combination with carboplatin (n=3) and carboplatin plus paclitaxel (n=6) in patients with advanced metastatic solid tumors progressing at inclusion. The efficacy of these combinations is evaluated every 6 to 8 weeks by medical imaging (Criteria for Evaluation of Response in Solid Tumors - RECIST). Out of the first seven evaluable patients, four patients, including three non-small cell lung cancer (NSCLC) patients, had a partial response and/or long control durations (no progression). For these four patients, the durations of control with either combination was consistently longer than those obtained with previous treatment lines, including other platinum-based chemotherapies or a first-line reference immunotherapy.

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.

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* 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