PRESS RELEASE

Onxeo Announces Treatment of First Patient in DRIIV-1b, a Phase 1b Clinical Trial of AsiDNA™ in Combination with Chemotherapy

- **DRIIV-1b is designed to assess the clinical potential of AsiDNA™ in combination with carboplatin and with carboplatin plus paclitaxel in patients with solid tumors eligible to such treatments**
- **Initial results are expected in the second half of 2019**

Paris (France), Mai 6, 2019 – 6:00 pm 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 oncology, in particular against rare or resistant cancers, today announces a new milestone in the clinical development of AsiDNA™ with the treatment of the first patient in DRIIV-1b, a phase 1b clinical study of AsiDNA™, a first-in-class tumor DNA repair inhibitor, in combination with carboplatin and with carboplatin plus paclitaxel, in patients with solid tumors eligible to such treatments.

DRIIV-1b is an extension of the DRIIV-1 (**DNA R**epair **I**nhibitor administered **I**ntra**V**enously) phase 1 study currently being completed, in which AsiDNA™, administered intravenously (IV) demonstrated its intratumoral activity by inducing a significant increase in its activity biomarkers in the tumor cells of patients, with a favorable safety profile at various active doses.

At the active dose of 600 mg, among the three patients included in the cohort, two patients with relapsed, multi-treated metastatic colorectal cancer were controlled with medical imaging, which showed no further disease progression after the second treatment cycle, and continued their treatment with AsiDNA™ for three months. The 600 mg active dose was considered to be optimal for further development of AsiDNA™ in combination with chemotherapy.

DRIIV-1b aims at showing the safety and efficacy of a 600 mg dose of AsiDNA™ in combination with carboplatin, and carboplatin plus paclitaxel, in up to 18 patients with solid tumors eligible for such treatments (lung, breast, ovarian or head and neck cancers, …). The efficacy of the combinations will be evaluated every six to eight weeks by medical imaging in accordance with RECIST criteria (Response evaluation criteria in solid tumors). The study will take place in Belgium, and initial results are expected in the second half of 2019.

Dr Nuria Kotecki of the Institute Jules Bordet in Brussels commented: *"The «DDR» (DNA Damage Response) approach represents a particularly interesting alternative in cancer treatment. Indeed, combining AsiDNA™, a tumor DNA repair inhibitor, with agents such as carboplatin, that causes breaks in that same DNA, is a very promising approach in terms of synergistic efficacy. On the basis of the safety profile of AsiDNA™ observed in monotherapy, this combination can be considered as we are looking for greater efficacy without aggravating the toxicity observed with chemotherapy. We are thrilled to start this DRIIV-1b study, which should enable us to confirm the preclinical and clinical results already obtained."*

This first combination trial represents a major milestone in the clinical development of AsiDNA™. Thanks to its highly differentiated mechanism of action, confirmed by exhaustive preclinical studies, the combination of AsiDNA™ with various anti-cancer treatments appears especially relevant to increase their efficacy and avoid the occurrence of resistance from tumors.

DRIIV-1b is the first combination study of AsiDNA™ by IV administration, aimed at confirming such synergistic efficacy on tumors for which the medical needs remain immense. Positive results from this study will represent

a proof of the interest of AsiDNA™ combined with chemotherapy and will open the door to further clinical development of AsiDNA™ IV in a phase 2 program in one or several indications.

Olivier de Beaumont, Onxeo's Chief Medical Officer, concluded: "*This study marks the start of the clinical development of AsiDNA™ in combination with chemotherapy. The results, expected by the end of the year, will enable us to confirm the potential of our flagship product in indications with strong medical needs. Other combination studies are also being prepared to further support the growing interest in AsiDNA™ and its broad clinical potential. We are very pleased to be continuing our collaboration with Dr Nuria Kotecki, a clinical investigator already involved in the DRIIV-1 study, and we thank her for her help and support in this promising research program.*"

Upcoming events

- **Shareholder's ordinary general meeting** : May 22, 2019 (Paris, France)
- **Bio International Convention:** June 3-6, 2019 (Philadelphia, USA)

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 (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, highly differentiated DNA Damage Response (DDR) inhibitor based on a decoy & agonist mechanism acting upstream of multiple DDR pathways. Translational research has highlighted the distinctive properties of AsiDNA™, notably its ability to oppose and even reverse tumor resistance to PARP inhibitors regardless of the genetic mutation status, and its 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 to evaluate AsiDNA™ by systemic administration (IV) in advanced solid tumors has confirmed the active doses and a favorable human safety profile. The ongoing DRIIV-1b extension study is designed to assess the safety and effectiveness of a 600 mg dose of AsiDNA™ in combination with carboplatin, and carboplatin and paclitaxel, in patients with solid tumors who are eligible for such treatments.

AsiDNA™ is the first compound generated from **platON™**, the Company's proprietary chemistry platform of decoy oligonucleotides dedicated to generate new innovative compounds and broaden Onxeo's product pipeline. A new compound will begin preclinical trials in the first half of 2019.

Onxeo's portfolio 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 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 2018 registration document filed with the *Autorité des marchés financiers* on April 5, 2019 under number D.19-0282, 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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