

Onxeo announces positive intermediate results from the first part of the DRIIV-1b study evaluating AsiDNA™ in combination with chemotherapy

- > Stabilized disease without tumor progression for two of the three treated patients who are still receiving treatment with AsiDNA™ plus carboplatin
- > Satisfactory tolerance allowing the continuation of the study
- > Start of the second part of the study to evaluate AsiDNA™ in combination with carboplatin and paclitaxel, a reference treatment protocol for many cancers
- Preliminary results from this second part are expected at the end of the year

Paris (France), September 18, 2019 – 6.00 pm CEST - Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO - FR0010095596), ("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 announced positive results from the first group of patients in the DRIIV 1b study, evaluating AsiDNA™, first-in-class inhibitor of tumor DNA repair, in combination with chemotherapy and the start of the second part of the study to evaluate the combination of AsiDNA™ with carboplatin and paclitaxel in patients with solid metastasized tumors who are eligible for this treatment.

In this first part, three patients with metastatic cancer and eligible for carboplatin therapy (non-small cell lung cancer, triple negative breast cancer, gastric cancer), whose disease was progressing at the time of their inclusion in the study, were treated with the combination of a 600mg active dose of AsiDNA™ administered intravenously and a standard carboplatin administration protocol.

No dose-limiting toxicity (DLT) or severe adverse effect was observed in any of these three patients. The tolerance of the combination was considered good and led the independent committee of experts in charge of the monitoring of the study (DSMB) to recommend the continuation of the study aiming at evaluating $AsiDNA^{TM}$ in combination with carboplatin and paclitaxel, a reference protocol for many solid tumors such as lung, breast, ovary or head and neck cancers.

Two of the three treated patients show tumor control (stable disease demonstrated by medical imaging according to the RECIST solid tumor response assessment criteria) since the start of their treatment, i.e. for more than 4 and 5 months. As provided for in the protocol, treatment is continued until the tumor has progressed or in the event of an intolerance to carboplatin.

Olivier de Beaumont, Onxeo Medical Director, said: "We are very satisfied with these initial results. First, $AsiDNA^{TM}$ confirms its good tolerance profile, even in combination with chemotherapy, and also, two of the three patients treated are still assessed as stable, after almost 5 to 6 months of treatment.. These good results make possible the start the second part of the study to evaluate $AsiDNA^{TM}$ in combination with carboplatin and paclitaxel, a standard of treatment used for several solid tumors. Initial results on this combination are expected at the end of the year, and will represent a major proof of concept for $AsiDNA^{TM}$ in combination with chemotherapy."

The combination of carboplatin, a platinum salt chemotherapy, and paclitaxel is considered a reference protocol treatment, which is widely used to treat many cancers, including breast cancer, ovarian cancer and lung cancer. However, a resumption of tumor progression is frequent, in the more or less short term, thus leaving patients with no therapeutic option.



AsiDNA™ is a first-in-class tumor DNA repair inhibitor that exhausts the repair pathways without causing resistance. Combined with its good tolerance, which is already clinically proven, this highly innovative mechanism of action makes it particularly well suited for combination with treatments such as chemotherapies including carboplatin, which causes DNA breaks. The combination of the two treatments could increase the effectiveness of chemotherapy alone, which is what DRIIV-1b aims to demonstrate.

Upcoming events

•	October 3, 2019	Investir Day for more information & free registration: www.investirday.fr	Paris, France
•	October 23-24, 2019	Galien MedStart'Up Conference	Boston, MA, USA
•	October 26-30, 2019	AACR-NCI-EORTC Meeting - 'Molecular Targets & Cancer Therapeutics'	Boston, MA, USA
•	November 6, 2019	Direct Dirigeants	Paris, France

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 carboplatin and paclitaxel, in patients with solid tumors who are eligible for such treatments. DRIIV-1b is being conducted in Belgium at two investigation centers. First safety and efficacy results are expected at the end of the year.

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. In vivo preclinical proof-of-concept data are expected early Q4 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 Beleodag® (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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