

ONXEO provides update on the Development Program for its first-in-class drug candidate AsiDNA™

- **Phase 1b/2 trial of AsiDNA™ in combination with olaparib initiated in the United States in recurrent ovarian, breast and metastatic castration-resistant prostate cancer**
- **Phase 1b/2 trial (REVOCAN), AsiDNA™ in combination with PARP inhibitors for the treatment of ovarian cancer in patients with rising CA125 levels: interim analysis demonstrates encouraging preliminary data**
- **Phase 1b/2 trial, of AsiDNA™ in combination with radiotherapy, in children and adolescents and young adults with relapsed high-grade glioma (HGG) is actively enrolling**

Paris (France), January 25th, 2023 – 6pm CET - Onxeo S.A. (Euronext Growth Paris: ALONX), hereafter “**Onxeo**” or the “**Company**”, a clinical-stage biotechnology company specializing in the development of innovative tumor specific drugs targeting tumor DNA Damage Response (DDR) and driver oncogenes, today provides an update on the clinical development program of its first-in-class drug candidate AsiDNA™.

Onxeo activated its first US clinical study site, Next Oncology San Antonio. This phase 1b/2 multicenter, basket trial intends to assess the safety and preliminary activity of AsiDNA™ in combination with olaparib in patients with recurrent ovarian, breast and metastatic castration-resistant prostate cancer (mCRPC) who have progressed on previous PARP inhibitor therapy. The primary endpoint of the study will assess the safety and tolerability of the combination as well as to determine the recommended Phase 2 dose. Key secondary endpoints will assess the preliminary activity and duration of response for the combination.

Shefali Agarwal, Chairwoman of the Board of Directors and CEO, said: *“We are delighted with the initiation of this important clinical trial in the US to further explore the potential of our first-in-class drug candidate, AsiDNA™. This investigational product has been in clinical development in Europe for the last few years, in recurrent solid tumors. In clinical studies AsiDNA™ appears to be well tolerated with encouraging clinical activity in the studied patients till date. The activation of this first study in the US is an important next step towards its global clinical development.*

The recent encouraging activity observed from the preliminary data in the REVOCAN study indicates the potential of AsiDNA™ to re sensitize patients to PARP therapy which potentially addresses an unmet need and could meaningfully impact patients living with recurrent ovarian cancer who have progressed on an initial treatment with a PARP inhibitor. Additionally, this lays a strong foundation for our next first in class drug candidate OX425 which is sourced from the same proprietary PlatON™ platform and is a PARP/DDR specific decoy agonist thereby possibly not inducing tumor resistance to treatment. This profile represents a potential differentiation in safety and activity from other targeted therapies such as PARP inhibitors and we are on track to file an IND in mid- 2023”.

The REVOCAN study is an open label, multicenter, phase 1b/2 study evaluating the safety and efficacy of AsiDNA™, in combination with PARP inhibitors in patients with relapsed platinum sensitive ovarian cancer already under treatment with a PARP inhibitor. The study is sponsored by Gustave Roussy Cancer Campus, Grand Paris, led by Dr Patricia PAUTIER and supported by ONXEO. The study team recently completed its first interim analysis (IA) of 10 patients. The combination of AsiDNA™ and PARPi was generally well tolerated with no new safety signals or dose limiting toxicities. The IA also demonstrated encouraging clinical activity with six patients achieving a stable disease (SD) and one patient demonstrating a complete response (CR) with disease control rate of around 70%. The study continues to enroll patients. The detailed results of the IA will be published by the investigator.



Additionally, *AsiDNA*TM is being evaluated in Children and young adults with recurrent high-grade glioma (HGG). This phase 1b/2 trial, sponsored by Institut Curie, is being conducted within the framework of the European ITCC consortium. The trial is evaluating the safety and clinical activity of *AsiDNA*TM in combination with radiotherapy in children or young adults with recurrent HGG. The trial has already been opened at 8 clinical trial sites in France and 5 patients have been enrolled. To date, the combination has been well tolerated. Further trial site activation is planned for 2023 in Italy, the Netherlands, and Germany.

About Onxeo

Onxeo (Euronext Paris) 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 highly differentiated, clinical-stage first-in-class candidate in the field of DNA damage response (DDR) applied to oncology. Its decoy and agonist mechanism acting upstream of multiple DDR pathways results in distinctive antitumor properties, including the ability to prevent or abrogate tumor resistance to targeted therapies such as PARP inhibitors and strong synergy with tumor DNA-damaging agents such as radiotherapy or chemotherapy. *AsiDNA* is currently being studied in Europe and US in combination with other treatment modalities in difficult-to-treat solid tumors.

OX425, the second compound from platON, is a novel DDR Decoy Agonist with high antitumor activity. It also mediates multiple immunostimulatory effects by activating the STING pathway. OX425 is currently in IND-enabling preclinical development.

For further information, please visit www.onxeo.com.

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