

Initial IND application for AsiDNA Granted “Study May Proceed” by the U.S. FDA

Onxeo to initiate its first phase 1b/2 trial in the United States in patients with solid tumors

Paris (France), June 30, 2022 – 07:00 pm CEST - Onxeo S.A. (Euronext Growth Paris: ALONX, Nasdaq First North Copenhagen: ONXEO), hereafter “**Onxeo**” or the “**Company**”, a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage Response (DDR), today announced that the U.S. Food and Drug Administration (FDA) has cleared the initial IND for its first-in-class drug candidate AsiDNA. This is the first US IND Onxeo filed since the US team came on board in April 2022.

This FDA decision enables the Company to initiate a Phase 1b/2 multicenter, basket trial to assess the safety and efficacy of AsiDNA in combination with the PARP inhibitor Olaparib in patients with epithelial ovarian cancer, breast cancer and metastatic castration-resistant prostate cancer (mCRPC) who have demonstrated progression on previous PARP inhibitor therapy. The Company plans to initiate the trial in the second half of 2022 at 3-5 potential clinical sites across the United States.

“I am very proud that our team has been able to file and obtain FDA clearance of its first US IND in a very short period. We are now ready to start our first clinical trial with AsiDNA in the US, with the full support of our clinical and regulatory teams,” said Dr. Shefali Agarwal, Chairwoman of the Board of Directors and CEO. “We believe that our drug candidate has the potential to meaningfully impact the lives of patients with recurrent solid tumors who have progressed on an initial treatment with a PARP inhibitor. This is consistent with the preclinical findings of AsiDNA, which increased our understanding of its potential against acquired resistance to PARP inhibitors and which formed the basis for our first-in-human study.”

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 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 radio-chemotherapy. AsiDNA is currently being studied in Europe in combination with other treatment modalities in difficult-to-treat solid tumors.

OX400 is a series of new drug candidates from platON, designed to be a next-generation PARP inhibitor acting on both the DNA Damage Response and the activation of immune response, without inducing resistance. The lead OX400 candidate is currently being optimized and 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 the risk factors described in the most recent Company's registration document or in any other periodic financial report and in any other press release, which are available free of charge on the websites of the Company Group (www.onxeo.com) and/or the AMF (www.amf-france.org).

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