

High-Grade Glioma Relapse in Children: Onxeo announces the enrollment of the first patient in the phase 1b/2 clinical study conducted by the European ITCC consortium and sponsored by Institut Curie

Paris (France), September 1st, 2022 – 8 pm CEST - Onxeo S.A. (Euronext Growth: ALONX, Nasdaq First North¹: ONXEO), a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage Response (DDR) in particular against rare or resistant forms of cancer, today announced that the first patient has been enrolled and treated in the phase 1b/2 clinical study that aims to evaluate the efficacy and tolerability of AsiDNA², Onxeo's first-in-class DDR inhibitor, combined with radiotherapy in children, adolescents or young adults with relapsed High-Grade Glioma (HGG). The clinical validation of this innovative therapy offers the hope of providing better care and treatment for these high-risk pediatric cancers.

High Grade Gliomas (HGG), which represents approximately 20% of tumors of the central nervous system (CNS) in children, continue to have a very poor prognosis with a 5-year survival rate of less than 20%. Surgery combined with radiotherapy or chemotherapy often allows the disease to be controlled. However, this disease control is not durable due to the development of treatment-resistant tumor cells. Studies conducted in preclinical models as well as initial clinical trials conducted in adults³ have highlighted AsiDNA's synergetic effect when combined with treatments that target and destroy the DNA, such as radiotherapy.

This phase 1b/2 trial, sponsored by Institut Curie, is being conducted within the framework of the European ITCC⁴ consortium, in order to evaluate AsiDNA's efficacy and tolerability by enrolling a maximum of 32 patients (children, adolescents or young adults) with relapsed HGG. A first patient has been enrolled in the study at the Institut Curie's SIREDO (*Soins, Innovation, Recherche en cancérologie de l'Enfant, l'Adolescent et l'adulte jeune*, i.e. care, innovation, research in cancer in children, adolescents and young adults) Center. Additionally, other French centers as well as European countries are planned to be initiated in the coming months. The study's first interim results are projected in the first quarter of 2024.

Shefali Agarwal, Onxeo's President and Chief Executive Officer, stated: *"Onxeo is proud of its clinical collaboration with Institut Curie, and would like to thank Professor François Doz – the study's lead investigator – for his involvement in this project. We hope that the combination of AsiDNA and radiotherapy in this type of cancer will provide a real benefit to patients suffering from a recurrent form of high-grade glioma"*.

"The enrollment of the first patient is a major step in this proof-of-concept study whose goal is to evaluate the efficacy and good tolerability of the systemic administration of AsiDNA in combination with a new radiotherapy. We hope that this study will provide encouraging evidence enabling an improvement in the prognostic outcome of a disease that is a key unmet need", added **Prof. François Doz**, pediatric oncologist, deputy head of clinical research, innovation and teaching at Institut Curie's SIREDO Center and this study's lead investigator.

This phase 1b/2 study is supported by a grant from the European Fight Kids Cancer⁵ program.

¹ The company reminds shareholders that the delisting of Onxeo shares from the First North Growth market in Copenhagen has been approved and the last day of trading on this market will be November 8, 2022. The company will keep its primary listing on Euronext Growth Paris.

² In 2016, Onxeo acquired DNA Therapeutics, a spin-off of Institut Curie building on the innovative work of Marie Dutreix, CNRS research director research at Institut Curie, which led to the development of AsiDNA.

³ *"First-in-human phase I study of the DNA repair inhibitor DT01 in combination with radiotherapy in patients with skin metastases from melanoma."* Le Tourneau C et al. Br J Cancer. 2016 May 24;114(11):1199-205.

⁴ The [Innovative Therapies for Children with Cancer](#) (ITCC) consortium is a non-profit organization incorporating 63 European pediatric oncology departments with expertise in conducting early-stage trials in children and adolescents and 25 European research laboratories.

⁵ [Fight Kids Cancer](#) is a European call for projects, a joint initiative of France's Imagine for Margo association, Belgium's KickCancer foundation and Luxembourg's Kribskrank Kanner foundation.

About Institut Curie

Institut Curie, French leading center for the fight against cancer, has an internationally renowned research center and a state-of-the-art group that treats all types of cancer, including the rarest. Founded in 1909 by Marie Curie, Institut Curie employs more than 3,700 researchers, physicians and healthcare professionals on three sites (Paris, Saint-Cloud and Orsay) who contribute to its three missions that are treatment, research and teaching. A private foundation recognized as a public interest organization authorized to receive donations and bequests, Institut Curie can, thanks to the support of its donors, accelerate discoveries and thus improve cancer patients' treatment and quality of life.

For further information: www.curie.fr

Since 2011, Institut Curie is "*Institut Carnot Curie Cancer*" certified. The Carnot label is a label of excellence awarded to academic research structures that have demonstrated quality and involvement in collaborative research. Curie Cancer offers industrial partners an opportunity to set up research cooperation while benefiting from Institut Curie teams' expertise in developing innovative therapeutic solutions to fight cancer, from therapeutic target to clinical validation. Curie Cancer is a member of the Carnot FINDMED network, a group of thirteen Carnot institutes, in order to facilitate access to their technological platforms and innovation capabilities for very small, small and medium-sized companies, SMEs and SMIs in the pharmaceutical sector.

For further information: www.instituts-carnot.eu/fr/institut-carnot/curie-cancer

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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