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BLADDER CANCER, a first in France.

Spotlight on astatine-211, an alpha-emitting radionuclide with high cytotoxic potential, which represents a major step forward in nuclear medicine, within the highly promising field of targeted radiotherapy.

A collaboration between Atonco and the Institut de Cancérologie de l'Ouest

- **ATONCO** designs and develops targeted treatments for cancers resistant to conventional approaches, notably using astatine-211.
- **ICO** has obtained authorization for the first Phase I clinical trial, PERSEVERANCE EU, using astatine-211 in the treatment of bladder cancer.

● PRESS RELEASE

A deep dive into cutting-edge medicine with an ultra-targeted radiotherapeutic treatment.

The PERSEVERANCE EU clinical trial evaluating the safety, tolerance, and response to ATO-101™ authorized: a first in France with astatine-211.

The Institut de Cancérologie de l'Ouest (ICO) has been authorized to launch the Phase I PERSEVERANCE EU clinical trial (NCT07260162), entitled A First In Human Phase I Trial Evaluating Safety, Tolerability and Response of [211At]At-Girentuximab (ATO-101™) in Patients With Non-Muscle-Invasive Bladder Cancer Refractory to Standard Treatment.

This trial aims to evaluate the safety, tolerability, and response to ATO-101™ treatment in patients with non-muscle-invasive bladder cancer refractory to standard treatments. The study marks an important milestone in the development of innovative therapeutic treatments based on alpha emitters.

An innovative treatment using astatine-211

ATO-101™ ([²¹¹At]At-girentuximab), supplied by Atonco, consists of an antibody directed against the CA-IX antigen (girentuximab) coupled with astatine-211, an alpha-emitting radionuclide with high cytotoxic potential. Its very short particle range should enable it to effectively target tumor cells while preserving surrounding healthy tissue.

*"This trial follows on from the PERTINENCE study (NCT04897763), which validated the feasibility of imaging and the safety of administering a radiopharmaceutical (composed of the same antibody, girentuximab, but coupled with zirconium-89) via the intravesical route, both for the patient and with regard to staff radiation protection. This study notably demonstrated that the product remained exclusively in the bladder, which is precisely what is sought in this type of cancer without metastatic spread, and which suggests minimal or even non-existent whole-body toxicity in the PERSEVERANCE EU trial," explains **Dr. Caroline Rousseau, ICO Principal investigator of the PERSEVERANCE EU study.***

*"PERSEVERANCE EU fully illustrates Atonco's medical ambition: to offer targeted treatments using alpha emitters for patients with limited therapeutic options. With ATO-101™, the objective is to demonstrate that astatine-211 can provide local tumor control while preserving healthy tissues as much as possible, thereby paving the way for a new generation of innovative radiotherapies in urothelial oncology," states **Dr. Jean-François Chatal, Chief Medical Officer of Atonco.***

The experimental drug will be produced by GIP Arronax and Nantes University Hospital, two leading French institutions in the field of radiopharmacy and nuclear medicine research.

A first in France

This is the first clinical trial in France involving astatine-211, paving the way for a new generation of targeted radiotherapy treatments. The first patients will be enrolled at the ICO in Saint-Herblain as soon as all the prerequisites are met.

*“ATONCO is taking a decisive step by entrusting the sponsorship of this pioneering study to ICO. This collaboration marks a first for the ICO Sponsorship Department! The patients enrolled will be the first to benefit from this therapeutic breakthrough, ushering in a new era of innovative care,” add **Ms. Nadia Allam and Ms. Laëtitia Himpe, ICO Project Managers for this study.***

*“The authorization of the PERSEVERANCE EU trial confirms the potential of our targeted radiotherapy approaches and Atonco’s ability to bring its innovative radiopharmaceuticals to the clinical trial stage. We are fully committed to ensuring that developments such as ATO-101™ translate into tangible benefits for patients, with the highest standards of quality, safety and clinical evidence,” says **Alexandra Paillard, Chief Operating Officer of Atonco.***

● ABOUT

ATONCO

Atonco is a French biotechnology company specializing in the development of innovative radiopharmaceutical therapies based on alpha emitters, particularly astatine-211. In collaboration with research centers and hospital partners, Atonco designs and develops targeted treatments for cancers that are resistant to conventional approaches. Its mission is to offer new safe, effective, and personalized therapeutic options for cancer patients.

For more information, please visit www.atonco-pharma.com

ClinicalTrials.gov – NCT07260162

Institut de Cancérologie de l'Ouest (ICO) : an expert center

ICO is a non-profit Comprehensive Cancer Center, with no extra billing, fulfilling public hospital service missions. As an expert center for care pathway coordination, it aims to make its expertise and specific skills in oncology available to patients and partners. Accredited by OECl in 2023, it received the High Quality of Care designation from HAS in January 2024. Each year, ICO’s 1,600 professionals welcome nearly 48,000 patients across its two sites in Angers and Saint-Herblain.

CUTTING-EDGE MEDICINE IN THE SERVICE OF PATIENTS

Specialized in oncology, ICO professionals support patients at every stage of their care pathway in a personalized, innovative and multidisciplinary manner. From rapid diagnosis to surgery,

chemotherapy and radiotherapy, care also includes highly developed supportive care services.

INTEGRATING CARE, RESEARCH AND INNOVATION

Research activity at ICO is a full mission in its own right, ranging from fundamental research to clinical trials, including translational research. It spans all oncology disciplines: medical oncology, radiotherapy, surgery, anesthesia, nuclear medicine, medical imaging, supportive care and human sciences. Being treated at ICO means benefiting from privileged access to cutting-edge clinical trials in oncology.

Through its teaching mission and academic expertise, the institution contributes to training the next generation of oncology professionals.

With its four missions, Prevention, Care, Research and Teaching, ICO provides comprehensive, high-level expertise across the region, exclusively dedicated to oncology.

● **CONTACT US**

Press contacts

● **Sylvain FANIER – ATONCO**

President

Tel. : +33 6 07 59 01 67

Email : sylvain.fanier@atonco-pharma.com

● **Édith LEGRAND – Institut de Cancérologie de l'Ouest**

Communication project manager

Tel : +33 2 41 35 27 26 / 06 74 38 26 71

Email : edith.legrand@ico.unicancer.fr

● **Sophie NOBLET – Institut de Cancérologie de l'Ouest**

Communication Director

Tel : +33 2 40 67 98 68 / +33 6 82 20 81 47

Email : sophie.noblet@ico.unicancer.fr

WWW.INSTITUT-CANCEROLOGIE-OUEST.COM