



ATO-101™: A THERAPEUTIC ADVANCE FOR THE TREATMENT OF NON-MUSCLE-INVASIVE BLADDER CANCER (NMIBC)

Saint-Herblain, France, March 31, 2025

Atonco is proud to announce that the preclinical and clinical study results have been published in the Cancers (MDPI) journal, highlighting the promising potential of its radiopharmaceutical ATO-101™ ([²¹¹At]At-girentuximab) in the alpha-immunotherapy treatment using astatine-211 of non-muscle-invasive bladder cancer (NMIBC) refractory to standard therapies, including BCG.

Non-muscle-invasive bladder cancer (NMIBC) presents a significant medical challenge, with a growing need for novel therapeutic options. A promising approach in this area is radioimmunotherapy targeting the CA-IX antigen (Carbonic Anhydrase IX), particularly the use of alpha-emitting radionuclides like astatine-211. The goal of our preclinical and clinical studies was to assess the potential of ATO-101™ in treating patients who do not respond to conventional treatments.

Preclinical studies demonstrated that ATO-101™ binds highly effectively to the CA-IX antigen, with a high binding affinity, and induces significant targeted cytotoxicity compared to other treatments such as [¹⁷⁷Lu]Lu-girentuximab. Additionally, biodistribution studies in healthy mice revealed minimal systemic diffusion of radioactivity, indicating the treatment's safety. After intravesical instillation of ATO-101™, no histological abnormalities were observed in the bladder wall, further reinforcing the safety of the approach.

In the PERTINENCE study ([NCT04897763](https://clinicaltrials.gov/ct2/show/study/NCT04897763)) sponsored by the Institut de Cancérologie de l'Ouest (ICO) in Nantes, PET/CT imaging using [⁸⁹Zr]Zr-girentuximab (supplied by Telix Pharmaceuticals) performed on 6 patients with NMIBC demonstrated no extravesical leakage, suggesting that the approach is localized and targeted effectively. Hot spots in the bladder wall were associated with areas of recurrence or inflammatory reaction, indicating that this treatment could effectively target residual tumor cells.

Furthermore, a dosimetric study suggested that intravesical alpha-immunotherapy using astatine-211 with ATO-101™ could offer enhanced efficacy and safety for NMIBC treatment. The clinical and preclinical data confirm the therapeutic potential of this approach and underscore its promising role in NMIBC management.

With this targeted therapy, we are paving the way for a more selective, less toxic, and more effective treatment for patients suffering from non-muscle-invasive bladder cancer, particularly those whose tumors are refractory to traditional treatments, including BCG.

 Learn more about this study: <https://www.mdpi.com/2072-6694/17/7/1190>

About Atonco:

ATONCO is a privately-owned French company that develops targeted molecular radiation products for oncological applications. Stemming from Nantes' world-class nuclear medicine hub, ATONCO and its partners are committed to the clinical use of alpha-emitting radionuclides, particularly astatine-211 (²¹¹At).

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