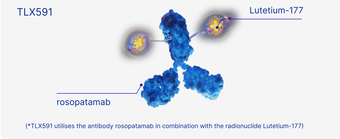
ProstACT GLOBAL: A Phase III study of ^{177}Lu rosopatamab tetraxetan (TLX591) plus standard of care (SoC) versus SoC alone in patients with metastatic castrate-resistant prostate cancer (mCRPC)

WHAT IS TLX591?

TLX591 comprises a radioactive isotope, Lutetium-177, attached to an antibody called rosopatamab.

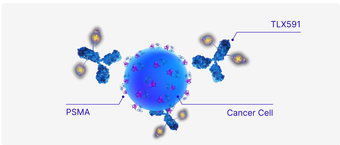
Rosopatamab targets prostate-specific membrane antigen (PSMA), a protein expressed on the surface of prostate cancer cells, which is low or absent on most normal healthy cells.



(*TLX591 utilises the antibody rosopatamab in combination with the radionuclide Lutetium-177)

WHAT IS PSMA?

When you have prostate cancer, you may have a lot more PSMA than normal, particularly in the prostate cancer cells and other areas where the cancer may have spread (called metastatic lesions). This can make PSMA a good target for treating advanced prostate cancer.



WHY PARTICIPATE IN THIS STUDY?

This global Phase III study is designed to investigate and confirm the benefits and risks associated with TLX591 administered together with standard of care (SoC), as compared to the best SoC alone. The study is being conducted in patients with metastatic castrate-resistant prostate cancer (mCRPC) that expresses PSMA, and has progressed despite prior treatment with hormone therapy.

WHAT WILL HAPPEN IN THE STUDY?

This study will be completed in 2 parts. Participants in Part 1 of the study will receive TLX591 + SoC. Participants in Part 2 of the study will be assigned randomly (by chance, not choice) to receive either TLX591 + SoC, or SoC alone.

TLX591 + SoC (includes Abiraterone + Prednisone, Enzalutamide or Docetaxel. Your doctor will decide which SoC is best for you)

or

SoC alone

WHO CAN TAKE PART IN THIS STUDY?

INCLUSION

Male 18 years of age or older with:

- Documented tumour of the prostate defined by biopsy
- A minimum of 12 weeks of prior therapy with an hormone therapy in any disease setting
- Disease which has spread beyond the prostate
- Castration-resistant prostate cancer
- PSMA-positive disease, as demonstrated by a 68Ga-PSMA-11 PET/CT or PET/MRI

EXCLUSION

- Prior therapy with TLX591, or any other PSMA-targeted therapy
- Prior chemotherapy (with the exception of docetaxel if more than 6 months prior to entering the study)
- Prior radiation therapy within 4 weeks of entering the study
- Prior treatment with radioisotopes

WHAT ARE WE AIMING TO FIND?

The primary objective of the ProstACT GLOBAL study is to determine how effective TLX591 in combination with SoC is in treating metastatic prostate cancer in comparison to SoC alone.

Your participation in this study will contribute to the knowledge of the development of future therapies for mCRPC.

OUR PURPOSE

We help people with cancer and rare diseases live longer, better quality lives

OUR MISSION

To deliver on the promise of precision medicine through targeted radiation

ADDITIONAL INFORMATION

For more information about this study, visit ClinicalTrials.gov ID: NCT06520345

For more about Telix's trials visit telixpharma.com

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