

**UNDER EMBARGO until**  
Sunday 5 June 6.30am CDT  
Sunday 5 June 7.30am EDT  
Sunday 5 June 12.30pm IST/BST  
Sunday 5 June 9.30pm AEST  
**ASCO Abstract 5000**

## **Three-year follow up results from the TheraP study for people with metastatic prostate cancer shows continued benefits**

The Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) reports the three-year follow up results of its TheraP (ANZUP 1603) clinical trial at the American Society of Clinical Oncology (ASCO) Annual Scientific Virtual Meeting in Chicago on 5 June 2022.

TheraP is the first randomised trial comparing <sup>177</sup>Lu-PSMA-617 (Lu-PSMA), a novel radioactive treatment, to the current standard-of-care chemotherapy called cabazitaxel for people with metastatic castration-resistant prostate cancer. These people had disease that had already progressed after standard chemotherapy.

This unique treatment involved two distinct parts. Firstly, a PET scan is used to ‘map’ the cancer. This is done by injecting a radioactive molecule called gallium-68 attached to a small molecule that rapidly localises to prostate specific membrane antigen (PSMA) on the surface of prostate cancer cells in the body. The result is the cancer cells ‘light up’, showing exactly where the disease is and enabling identification of patients that may benefit from this new therapy. The second part is the therapy itself: the Lu-177 radionuclide is attached to a similar molecule used in the scanning process, and Lu-PSMA is administered to the patient, targeting the tumours and killing the cancer cells while minimising damage to surrounding tissue.

The primary endpoint of the study was to compare the effects of the two treatments on change in PSA, a blood biomarker of prostate cancer. The results of the three-year follow up conclude a continued favourable response, defined by reduction of PSA by 50% or more, occurred in 66% of people assigned to receive Lu-PSMA compared to 37% with cabazitaxel. Results of the trial also demonstrated the treatment had less severe side effects than chemotherapy. The survival of people assigned to LuPSMA was similar to cabazitaxel, a proven life-prolonging treatment. Survival was considerable shorter for people screened for the trial but for whom treatment was not suitable because PSMA uptake was low on initial scans (11 months compared to 18.8 months for those on trial treatments).

Study Chair Prof. Michael Hofman, of the Peter MacCallum Cancer Centre, said “Three-year follow-up of the TheraP study provides compelling evidence that Lutetium-177 PSMA-617 is a new treatment option for people with prostate cancer, providing an alternative to cabazitaxel chemotherapy with better patient reported outcomes and lower side effects.”

“TheraP is a great partnership of researchers, scientists, supporting organisations, and the patients who participated and who are affected by prostate cancer. These most recent findings show that we continue to learn more about prostate cancer and how this novel and important LuPSMA therapy can be used most effectively,” said ANZUP Chair Professor Ian Davis.

"The findings from the TheraP three-year follow-up study add to a growing body of clinical evidence that Lutetium-177 PSMA-617 is a safe, effective, and superior treatment for people with advanced prostate cancer. PCFA and its collaborators will continue to support ongoing research into nuclear medicine theranostics for the management and treatment of prostate cancer. The application of Lu-PSMA therapy represents a substantial step forward for the management of advanced prostate cancer in the 21st century," said PCFA CEO Anne Savage.

For additional study information, visit <http://www.anzup.org.au/therap>.

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**About TheraP**

TheraP is a partnership between ANZUP Cancer Trials Group and the Prostate Cancer Foundation of Australia (PCFA) with support from the Australian Nuclear Science and Technology Organisation (ANSTO), Endocyte (now part of Advanced Accelerator Applications, now the Radioligand business of Novartis), Movember, The Distinguished Gentleman’s Ride, It’s a Bloke Thing and CAN4CANCER.

This study is being conducted by ANZUP in collaboration with the National Health and Medical Research Council (NHMRC) Clinical Trials Centre at the University of Sydney. ANZUP is supported by the Australian Government through Cancer Australia.

### **About Metastatic Castration-Resistant Prostate Cancer**

Metastatic prostate cancer is cancer that has spread from the prostate to other parts of the body, most commonly to bones and lymph nodes. This is treated by suppressing the male sex hormone testosterone which can drive tumour growth. Over time, tumours can be resistant to this hormone therapy and the disease is then called castration-resistant. This type of advanced disease is often a lethal condition and novel treatments are needed to improve outcomes.

### **About ANZUP**

ANZUP is the leading cancer-cooperative clinical trials group that brings together all of the professional disciplines and groups involved in researching and treating urogenital cancers and conduct high quality clinical research. ANZUP identifies gaps in evidence and areas of clinical need, collaborates with the best clinicians and researchers in GU cancer and communicates frequently and effectively with the broader community along the way. ANZUP receives valuable infrastructure support from the Australian Government through Cancer Australia.