

**TheraP (ANZUP 1603) Clinical Trial Results in *Lancet Oncology*:
Lutetium PSMA-617 is an alternative to Cabazitaxel Chemotherapy in
Extended Follow-Up Study**

This week the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) TheraP trial (ANZUP 1603) featured in *The Lancet Oncology* reported overall survival and other secondary outcomes of this randomised, open-label, phase 2 trial.

The TheraP trial reported greater reductions in prostate-specific antigen levels with lutetium-177 [¹⁷⁷Lu]Lu-PSMA-617 (Lu-PSMA) compared to cabazitaxel in people with metastatic castration-resistant prostate cancer progressing after docetaxel. The *Lancet Oncology* article reports the secondary endpoint of overall survival with mature follow-up, and an updated imaging biomarker analysis.

From February 2018 to September 2019, 200 people were eligible and randomly assigned to treatment with Lu-PSMA or cabazitaxel. After a median follow up of 35.7 months, the overall median survival was similar in both groups (about 19 months), with a better quality of life and less side effects reported by those receiving Lu-PSMA. This suggests that use of Lu-PSMA in this setting might be a reasonable alternative to cabazitaxel chemotherapy, which was the previous best standard of care.

TheraP is the first randomised trial comparing Lu-PSMA, a novel radioactive targeted treatment, to the current standard-of-care chemotherapy called cabazitaxel, for people with metastatic castration-resistant prostate cancer that had already progressed after standard treatment.

This novel treatment strategy 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 who may benefit from this new therapy. The second part is the therapy itself: the Lu-177 radioactive atom is attached to a PSMA-targeting molecule similar to that used in the scanning process, and the resulting Lu-PSMA is administered to the patient, targeting the tumours and killing the cancer cells while minimising damage to surrounding tissue.

Study Chair Prof. Michael Hofman, of the Peter MacCallum Cancer Centre, said “The results of the study show that Lutetium-177 PSMA-617 is a very useful treatment option for some people with prostate cancer. Survival is similar and patients experience less side effects and improved quality of life. We also show that PET scans performed prior to treatment can help determine whether a response is likely. This can help personalise management for each individual patient.”

“The TheraP study is a great example of the clinical and research community working with industry, other stakeholders, and people affected by prostate cancer. TheraP has already changed clinical practice around the world. This latest work adds more detail and better understanding of how LuPSMA can give benefit, and we hope it will help people when they come to make treatment decisions,” said ANZUP Chair Professor Ian Davis.

PCFA Chief of Mission and Head of Research, Professor Jeff Dunn AO, said the findings would give clinicians greater confidence in managing and treating prostate cancer.

“The latest findings from the TheraP clinical trial give experts the evidence they need to make early decisions about treatment pathways for men with advanced and aggressive forms of prostate cancer, in the hope of improving the patient’s response to treatment and overall survival.

“This is just the latest great outcome from the TheraP study, which earlier proved the superiority of Lu-PSMA compared to cabazitaxel chemotherapy in slowing the progression of prostate cancer for people with metastatic castration-resistant forms of the disease.

“To date, this world-leading research has proven that Lu-PSMA works to reduce PSA, shrinks prostate cancer tumours, slows down tumour spread, and causes fewer and less severe side-effects compared to standard of care.

“Ultimately, this research provides great hope that an emerging arsenal of nuclear medicines being developed right here in Australia can keep deadly prostate cancers at bay and lengthen people’s survival time.”

You can [read the article online at Lancet Oncology here](#).

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

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Media Contact - ANZUP:

Nicole Tankard, Communications Manager

Mobile: +61 402 202 042, Email: nicole.tankard@anzup.org.au

About TheraP

The TheraP trial 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 (a Novartis company), 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 receives infrastructure funding from 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.