New class of targeted radioactive treatment effective for men with metastatic prostate cancer

The Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) reports the interim results of its “TheraP” (ANZUP 1603) clinical trial at the American Society of Clinical Oncology (ASCO) Annual Scientific Virtual Meeting.

TheraP is the first randomised trial comparing $^{177}$Lu-PSMA-617 (Lu-PSMA), a novel radioactive treatment, to the current standard-of-care chemotherapy called cabazitaxel for men with metastatic castration-resistant prostate cancer. These men 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. A favourable response, defined by reduction of PSA by 50% or more, occurred in 66% of men 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. Patient follow-up is ongoing with initial results suggesting the new treatment may delay progression of prostate cancer.

Study Chair Prof. Michael Hofman, of the Peter MacCallum Cancer Centre, said “This clinical trial provides compelling evidence that Lu-PSMA represents a new class of effective therapy for men with advanced prostate cancer. The ability to see what you treat by using the same molecule for both scanning and treatment is remarkable. This enables a personalised and patient-centred care where patients most likely to benefit can carefully selected.”
“This is a great example of an academic clinical trial that has built on work done in Australia, supported by a large group of funders and stakeholders, performed by an outstanding group of clinicians and researchers, supported by the community, with amazing contributions from the trial participants, in a disease setting where we really need better outcomes. Just getting it done is a major achievement, but we have also shown that this new treatment can benefit some men with advanced prostate cancer,” said ANZUP Chair Professor Ian Davis.

"We are proud to partner with ANZUP on this cutting-edge clinical trial. Deaths from prostate cancer are avoidable, and research is key to saving lives. The interim findings from the TheraP trial demonstrate the tremendous value of Australian-based prostate cancer research towards a future free of prostate cancer,” said PCFA CEO Professor Jeff Dunn AO.

TheraP (ANZUP 1603) 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, It’s a Bloke Thing, Movember and CAN4CANCER.

The full interim results from the TheraP study will be available online on Friday 29 May (10:00PM AEST) as an Oral Presentation Session at the American Society of Clinical Oncology (ASCO) Annual Scientific Virtual Meeting. For additional study information, visit http://www.anzup.org.au/therap.

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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, collaborate with the best clinicians and researchers in GU cancer and communicate frequently and effectively with the broader community along the way. ANZUP receives valuable infrastructure support from the Australian Government through Cancer Australia.