

30 April 2020

First patient enrolled in Sydney in worldwide prostate cancer trial

The first of 1,100 patients has been enrolled on a new cancer trial for treatment for men with high risk, clinically localised prostate cancer.

The DASL-HiCaP trial, led by the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP), enrolled its first patient at Chris O'Brien Lifehouse in Camperdown in Sydney this week.

Prostate cancer remains the most common cancer in Australian men and the leading cause of cancer related-mortality for men in developed countries.

The new randomised phase 3 study aims to demonstrate that the addition of the new potent oral hormonal therapy, darolutamide, to the standard radiation therapy and testosterone suppression improves the outcomes of men with localised high-risk prostate cancer.

Outcomes of the trial will be measured in terms of whether the addition of darolutamide decreases the risk of spreads of prostate cancer to other parts of the body as well as improving quality of life and potentially decrease the risk of prostate cancer death.

“At ANZUP we remain committed to running our clinical trials and delivering the best standard of care for those people impacted by genitourinary cancers. COVID-19 has presented challenges to each and every one of us across the globe, as it has with the day to day running of our trials, and the safety of our patients and site personnel remain our top priority.

“Men who are eligible for DASL-HiCaP need therapy that cannot be delayed. We have no evidence that darolutamide increases the risk of infections, and many of the clinical sites that will run the trial agreed with ANZUP that it is appropriate to activate the trial and be able to offer patients the opportunity to participate. We know clinical trials are the only way to find out the safety and effectiveness of new treatments and whether they should become the new gold standard for treatment in the future. We therefore remain dedicated to running these trials. It is very pleasing to see our DASL-HiCaP trial enrol its first participant, and help us move closer to our goal of improving outcomes for those men with high risk, clinically localised prostate cancer,” said ANZUP Chair, Professor Ian Davis.

The first patient enrolled marks the start of the journey to recruit and follow up 1,100 eligible patients across over 100 cancer centres across Australia, New Zealand, US, Canada, UK and Ireland.

Study Co-Chairs Associate Professor Tamim Niazi and Professor Christopher Sweeney are very optimistic with the potential this trial has for patients.

“DASL-HiCaP is specifically designed to assess whether this novel hormone treatment added to standard therapy can lessen the risk of recurrence of prostate cancer in men with prostate cancer with features with a high risk of spreading to other parts of the body. The patients in this study will be men treated with standard testosterone suppression along with radiation, or radiation after surgery. Our hope is that this trial might show new ways of improving outcomes for these men with prostate cancer,” said Professor Christopher Sweeney.

....ENDS....

Media Contact - ANZUP:

Nicole Tankard, Internal Communications & Project Manager
Mobile: +61 402 202 042, Email: nicole.tankard@anzup.org.au

The DASL-HiCaP Trial is a global collaborative investigator-initiated trial led by ANZUP and sponsored by the University of Sydney, in collaboration with the Canadian Cancer Trials Group, Dana-Farber Cancer Institute, Prostate Cancer Clinical Trials Consortium and Cancer Trials Ireland (enrolling patients from Ireland and the United Kingdom). The University of Sydney NHMRC Clinical Trials Centre provided central study coordination. Bayer is provided drug and financial support.

About High Risk, Clinically Localised Prostate Cancer

Approximately 90 percent of men who are diagnosed with prostate cancer have cancer confined to the prostate gland (clinically localised disease). Clinically localised prostate cancer is defined clinically localised prostate cancer as clinical stages T1–T3a, which includes tumours confined to the prostate (T1–T2) and tumours with extracapsular extension but without spread into the seminal vesicles (T3a).

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.

Prof. Davis is ANZUP chair and Prof. Sweeney are members of ANZUP's Scientific Advisory Committee. Both work at institutions that have received research financial support from and consulted for Bayer, who market darolutamide. Prof. Sweeney has received financial compensation for his consultancy from Bayer.

Study Co-Chair Associate Prof. Niazi works at the Jewish General Hospital, McGill University, Canada. He has received research financial support for Bayer and has received financial compensation for his advisory services from Bayer.