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Health-related quality of life (HRQoL) results in the ENZAMET randomised phase 3 trial of enzalutamide with standard first line therapy for metastatic, hormone-sensitive prostate cancer (mHSPC)

In June 2019, the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) reported that the ENZAMET clinical trial met its primary endpoint of improved survival at the planned first interim analysis. Men with metastatic hormone sensitive prostate cancer (mHSPC) received enzalutamide or non-steroidal anti-androgen therapy (NSAA: bicalutamide, nilutamide, or flutamide) in addition to standard of care therapy (androgen deprivation therapy, ADT), with or without docetaxel chemotherapy.

The ENZAMET trial showed a 33% improvement in overall survival and a 60% improvement in progression-free survival, for men who received enzalutamide. This translated into an 80% chance of survival at 3 years with enzalutamide versus 72% with NSAA.

Another important consideration for ANZUP researchers in the ENZAMET trial was the health-related quality of life of ENZAMET participants. ANZUP evaluated aspects of health-related quality of life such as comfort, happiness, and well-being in men who received enzalutamide, comparing their experience with men who received standard anti-androgen drug.

To study the experience of ENZAMET participants, 3 widely-regarded health-related quality of life questionnaires were used to assess the impact of treatment on important aspects of quality of life such as physical comfort, mood, appetite, sleep, and sexual function. Men rated their experience on these questionnaires covering all relevant domains.

The results of the quality of life evaluation revealed that men who received enzalutamide reported their general health status to be steady and maintained their overall quality of life. The use of enzalutamide delayed the emergence of unpleasant symptoms and signs. Although enzalutamide treatment influenced selected aspects of health-related quality of life early on, this did not outweigh the subsequent quality of life benefits in the men's cancer journey.

“The ENZAMET clinical trial results have shown that the addition of enzalutamide has increased the longevity of men with metastatic prostate cancer. The results of the secondary outcome of the trial – to measure the health-related quality of life of patients are equally pleasing, showing that the men who received the addition of enzalutamide maintained their overall quality of life,” said Co-Chairs Prof. Christopher Sweeney and Prof. Ian Davis.

The results of this study were presented as a poster discussion at the **European Society for Medical Oncology (ESMO)** in Barcelona on Sunday 29 September 2019.

ENZAMET (ANZUP 1304, NCT02446405, CCTG PR17) 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, and Cancer Trials Ireland (enrolling patients from Ireland and the United Kingdom). The University of Sydney NHMRC Clinical Trials Centre provided central study coordination. Astellas Pharma provided drug and financial support but was not involved in study conduct or data analysis.

About Metastatic Hormone - Sensitive Prostate Cancer

Metastatic prostate cancer is cancer that has spread from the prostate to other parts of the body which can be seen on conventional CT and/or bone scans. Patients with metastatic hormone sensitive prostate cancer are patients who are starting treatment for metastatic disease and will most likely respond to suppression of the male sex hormone testosterone. Recent advances have shown some patients live longer when docetaxel or abiraterone (an agent that suppresses other male hormones) are added to the testosterone suppression. ENZAMET is the first trial to show a survival benefit from addition of enzalutamide, and the first to include patients receiving docetaxel chemotherapy at the same time.

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 is a member of ANZUP's Scientific Advisory Committee. Both work at institutions that have received research financial support from and consulted for Astellas and Pfizer, who market enzalutamide*. Prof. Sweeney has received financial compensation for his consultancy from Pfizer and Astellas.

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