

UNDER EMBARGO until
Sunday 2 June 6.30am CDT
Sunday 2 June 7.30am EDT
Sunday 2 June 12.30pm IST/BST
Sunday 2 June 9.30pm AEST
ASCO Abstract LBA2

ANZUP announces results of Phase 3 ENZAMET Study (ANZUP 1304) Evaluating Addition of Enzalutamide to Standard of Care Therapy for Metastatic Hormone-Sensitive Prostate Cancer

The Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) reports 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 80% chance of survival at 3 years with enzalutamide versus 72% with NSAA.

“The ENZAMET clinical trial is testimony for a global collaboration to answer an important question that has generated clinically impactful data. We are greatly encouraged by the ability of enzalutamide to increase the longevity of men with mHSPC. The data and the biological samples collected will guide future trials with the goal to make more advances,” said Co-Chairs Prof. Christopher Sweeney and Prof. Ian Davis.

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.

The side effects of addition of enzalutamide to standard of care were overall similar to what has been experienced with enzalutamide in previous clinical trials.

Full results from the ENZAMET study will be presented on Sunday 2 June in the Plenary Session at the American Society of Clinical Oncology (ASCO) Annual Scientific Meeting in Chicago. The details will be published simultaneously in the New England Journal of Medicine. For additional study information, visit <https://clinicaltrials.gov/ct2/show/NCT02446405?term=enzamet&rank=1>

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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.

**note that Astellas and Pfizer co-market enzalutamide in the USA, elsewhere in the world enzalutamide is marketed by Astellas*