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Enzalutamide receives U.S. FDA approval for treatment of men with metastatic hormone-sensitive prostate cancer

An oral androgen receptor inhibitor tested in metastatic hormone-sensitive prostate cancer (mHSPC) in ANZUP's ENZAMET trial, Co-Chaired by ANZUP's Chair Professor Ian Davis and Professor Christopher Sweeney, has become a standard first-line therapy in the United States.

The drug, enzalutamide (XTANDI™), was approved today by the U.S. Food and Drug Administration (FDA) for men with mHSPC - also referred to as metastatic castration-sensitive prostate cancer (mCSPC). Enzalutamide is a current standard of care in hormone-resistant prostate cancer and this approval helps make the drug available to men in the U.S. earlier in their cancer course. The ENZAMET trial is not included in FDA labelling but provides valuable clinical information documenting the overall survival benefit when enzalutamide is used in the mHSPC setting.

"Through the ENZAMET trial we discovered that adding enzalutamide to testosterone suppression in men with mHSPC can give much better cancer control and longer survival," said Sweeney. "This is true both for patients with high burden of disease, with multiple bone metastases or liver metastases, as well as men with a lower burden of disease. The new treatment option is especially relevant for men who cannot tolerate chemotherapy and have a lower burden of disease."

"This is a step forward and another option for men with mHSPC, although enzalutamide is not yet approved or reimbursed in Australia in this setting," says Davis.

The benefits of enzalutamide were borne out in the ANZUP-led international randomised, phase III ENZAMET trial, published in the *New England Journal of Medicine*. Sweeney, study Co-Chair, presented interim analysis earlier this year during the plenary session at the American Society of Clinical Oncology (ASCO) Annual Meeting. It is the only study with long enough follow up with high quality data to show the clear overall survival benefit from early enzalutamide. It is also the only study to date with any data looking at whether enzalutamide improved the survival of patients when added to testosterone suppression and docetaxel. At this early analysis, there is no apparent survival benefit in this subgroup and it is not recommended to combine enzalutamide with docetaxel and testosterone suppression at this time.

Men in the ENZAMET study with mHSPC who received testosterone suppression along with enzalutamide survived longer overall than those who were given testosterone suppression along with standard nonsteroidal androgen receptor inhibitors. Among trial participants, 80% of those treated with enzalutamide were alive after three years compared to 72% of the men who received the standard inhibitors. Read more on the ENZAMET trial here: https://anzup.org.au/content.aspx?page=enzamet

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About ENZAMET
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 were presented in the Plenary Session at the American Society of Clinical Oncology (ASCO) Annual Scientific Meeting in Chicago on Sunday 2 June 2019. The details were published simultaneously in the New England Journal of Medicine. For additional study information, visit https://clinicaltrials.gov/ct2/show/NCT02446405?term=enzamet&rank=1

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 an overall survival benefit, among patients with mHSPC, from the 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.

Professor Davis is ANZUP chair and Professor 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*. Professor Sweeney has received financial compensation for his consultancy from Pfizer and Astellas. Professor Davis has not received financial compensation from Pfizer or Astellas.

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