ANZUP
Cancer Trials Group Limited

**UNDER EMBARGO until**
Sunday 5 June 6.30am CDT
Sunday 5 June 7.30am EDT
Sunday 5 June 12.30pm IST/BST
Sunday 5 June 9.30pm AEST
**ASCO Abstract LBA5004**

# The updated results from the ENZAMET clinical trial show a clinically meaningful survival benefit from novel hormone therapy for people with metastatic hormone sensitive prostate cancer

The Australian-led clinical trial ENZAMET has shown that the addition of hormone therapy with a medicine called enzalutamide to standard therapy (ADT alone to ADT plus docetaxel) can improve overall survival for people with advanced, hormone-sensitive prostate cancer.

In June 2019, the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) presented the interim results from the ENZAMET study in the Plenary Session at the American Society of Clinical Oncology (ASCO) Annual Meeting.

Today, at the ASCO 2022 Annual Meeting in Chicago, ANZUP presented the planned analysis results of the ENZAMET study, after patients had been followed on average for more than 5 years.

ENZAMET showed that people with this sort of cancer who receive enzalutamide added to standard treatment are 30% less likely to die compared to people receiving standard treatment alone.

People 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. This translated into 67% chance of being alive at the 5-year mark with enzalutamide compared to a 57% chance for people receiving standard treatment plus non-steroidal anti-androgen therapy.

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Study Co-Chair and Board Chair of ANZUP, Professor Ian Davis, said, "ENZAMET is a unique collaboration of clinicians and scientists from Australia, New Zealand, Ireland, UK, Canada, and the USA, all coming together to work with the community to find better ways of treating prostate cancer. ENZAMET won the 2020 Trial of the Year Award, as well as awards for community involvement, and for high quality statistical conduct. Now we have very mature results confirming that the benefit of enzalutamide treatment persists even after much longer follow-up, and we continue to see other informative results emerging from this very important trial."

"Although ENZAMET was not primarily designed to assess the impact of testosterone suppression plus enzalutamide plus docetaxel (ie potent hormonal-chemotherapy) over testosterone suppression plus enzalutamide (potent hormonal therapy without chemotherapy), the data would suggest that the addition of concurrent docetaxel to potent hormonal therapy may only benefit people who are fit for docetaxel and have the poorest prognosis disease (ie presentation of a higher volume of metastatic disease as first diagnosis of prostate cancer). For all other patients, such as those not fit for docetaxel or not likely to benefit from docetaxel, potent hormonal therapy with testosterone suppression plus enzalutamide is one of the life prolonging treatment plans we should be discussing with all of our patients who are starting hormonal therapy for metastatic disease," said Study Co-Chair Professor Christopher Sweeney.

Furthermore, Professor Sweeney, Medical Oncologist at the Dana-Farber Cancer Institute, noted, "ENZAMET had the flexibility to allow physicians and patients to decide whether concurrent docetaxel was an appropriate option for each unique patient and this has helped provide insights as to which patients benefit from which combination therapy. This was only possible because of the patients' and research teams' commitment to the clinical research process".

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.

**….ENDS….**

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**About ENZAMET**

ENZAMET (ANZUP 1304, NCT02446405) 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 design, conduct or data analysis.

Updated results from the ENZAMET study were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on Sunday 5 June 2022. Interim results from the study were presented in the plenary session at the ASCO Annual Meeting in 2019.

The study results were recognised as one of the most important clinical research advances of the past year in the Clinical Cancer Advances 2020: ASCO's Annual Report on Progress Against Cancer.

ENZAMET won all three of the Australian Clinical Trials Alliance (ACTA) Trial of the Year Awards in 2020: ACTA Trial of the Year Award, ACTA STInG Award for Excellence in Trial Statistics and The Consumer Involvement Award.

The ENZAMET trial data also supported the TGA Australia, Japan MHLW, European EMA and FDA approval of enzalutamide in the treatment of metastatic hormone-sensitive prostate cancer.

**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, collaborates with the best clinicians and researchers in GU cancer and communicates 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.

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

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