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Under embargo until 11pm AEST

ANZUP's ENZAMET trial results recognised as one of the most important clinical research advances of the past year

Today, on World Cancer Day Tuesday 4 February, the American Society of Clinical Oncology, Inc. (ASCO) released its *Clinical Cancer Advances 2020: ASCO's Annual Report on Progress Against Cancer*. This report highlights the most important clinical research advances of the past year and identifies priority areas where ASCO believes research efforts should be focused moving forward.

The Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) is proud to announce that our ENZAMET study, "*Enzalutamide with Standard First-Line Therapy in Metastatic Prostate Cancer*," has been selected for inclusion in this year's edition.

The landmark Australian led clinical trial, ENZAMET, showed that hormone therapy with a drug called enzalutamide can improve the survival of some men with advanced, hormone-sensitive prostate cancer.

Findings from the ENZAMET trial, led by ANZUP, showed that men with this sort of cancer who receive enzalutamide with standard treatment have a 33% improvement in survival compared to men receiving standard treatment alone.

ANZUP Chair, Professor Ian Davis, said metastatic prostate cancer was still the second-leading cause of cancer death in Australian men after lung cancer.

"The benefits of enzalutamide had already been established for prostate cancers that are no longer responding to hormonal therapy. ENZAMET showed that adding enzalutamide to standard treatment for men starting hormonal therapy for prostate cancer led to 33% reduction in the chance of dying of prostate cancer, and a 60% improvement in the time it takes to detect the cancer growing again. These results were much better than we thought they might be when we started the trial.

"Prostate cancer is complex and so are the benefits, side effects and risks of multiple treatments.

"Clinical trials are the most effective way of determining which treatments, alone or in combination, will provide the greatest survival benefit to the patient with the least adverse outcomes."

Professor Christopher Sweeney, co-chair with Professor Davis of the ENZAMET trial, said, "Inclusion in ASCO's Annual Report is testament to the fact that this is one of the most significant findings yet in clinical trials for men with metastatic hormone-sensitive prostate cancer – and a great example of effective international collaboration."

Since 1992,¹ there have been nearly 25 consecutive years of decline in overall incidence and mortality rates for all types of cancer.² In addition, the number of people living 5 years or more after a cancer diagnosis is projected to increase 31% by 2026,³ representing an increase of more than four million survivors in less than a decade. Cancer research, including the advances in this report, helps make progress possible.

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Media Contact - ANZUP:

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

About ENZAMET

ENZAMET (ANZUP 1304, NCT02446405, CTG 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 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.

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.

About Clinical Cancer Advances

ASCO's Clinical Cancer Advances report highlights current trends in the field and identifies cancer research priorities that have great potential to advance progress against cancer. The report, now in its 15th edition, is developed by a 20+ member editorial board of experts in a range of cancer types, subspecialties, and care issues. The editors reviewed scientific literature published in peer-reviewed journals or presented at major medical conferences, primarily from October 2018 to September 2019, and selected advances that improve meaningful patient outcomes and have a strong scientific impact. The editors also proposed priority areas of research that address vital unmet needs in cancer care and have the potential to improve the knowledge base for clinical decision-making.

About ASCO

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO) is committed to making a world of difference in cancer care. As the world's leading organisation of its kind, ASCO represents more than 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured and every survivor is healthy.

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