

MEDIA RELEASE

International trial with strong Irish involvement reports new treatment prevents relapse of very high-risk local and locally advanced prostate cancer

Interim findings from the DASL-HiCaP trial jointly led by the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) and the Sydney Clinical Trials Centre at the University of Sydney in collaboration with Cancer Trials Ireland, and others, report that adding darolutamide (Nubeqa®), an oral androgen receptor inhibitor, to standard of care for this population, decreases the risk of spread of prostate cancer in people affected with very high-risk localised or locally advanced prostate cancer.

The findings were presented in a Presidential Symposium at the European Society for Medical Oncology (ESMO) Congress (23-27 October) in Madrid on 24 October by the study global co-chair Associate Professor Tamim Niazi, signifying the global significance and practice-changing implications of this study for prostate cancer treatment and patient outcomes.

About 4,500 men are diagnosed with prostate cancer each year in Ireland, and 1 in 6 men will be diagnosed with prostate cancer during their lifetime.¹ Prostate cancer is the most common invasive cancer diagnosed in men in Ireland (excluding non-melanoma skin cancer).² In 2022, there were 616 deaths from prostate cancer in Ireland.³ People with very high-risk localised or locally advanced prostate cancer remain at risk of their cancer returning or spreading despite current treatment approaches.⁴

Current standard treatment for people affected by prostate cancer that has not spread beyond the pelvis combines radiation therapy with androgen deprivation therapy (ADT), which lowers testosterone levels. While this approach improves outcomes, there remains a need for new treatment strategies that can further reduce the risk of disease progression.

The DASL-HiCaP trial investigated whether adding an oral androgen receptor inhibitor (darolutamide) to this standard treatment could decrease the risk of the cancer spreading to other parts of the body. The trial's primary endpoint was metastasis-free survival, defined as the time from the start of treatment until cancer recurrence or spread was detected on standard scans, or death from any cause.

According to this positive analysis, participants who received darolutamide experienced longer metastasis-free survival than those who received placebo. The analysis also observed fewer prostate cancer deaths and fewer patients in whom their prostate-specific antigen (PSA) levels rose, indicating a recurrence. These results, from the first planned analysis of the trial, establish the trial's main finding. Follow-up of participants is continuing to provide further information on longer-term outcomes, including overall survival, with a further analysis planned when approximately 130 metastasis-free survival events have occurred.

The DASL-HiCaP trial recruited 1,106 patients worldwide. Cancer Trials Ireland is EU and UK sponsor for the trial, with 95 patients recruited in the region, (36 in Ireland and 59 the UK). The trial was open in nine Irish sites: Bon Secours/UPMC in Cork, Mater Misericordiae University Hospital, Mater Private Hospital, St. Luke's Radiation Oncology Network (SLRON) at Rathgar



and St. James's Hospital, Galway
University Hospital, Cork University
Hospital.

University Hospital, Tallaght
Hospital and The Beacon Private

Prof Paul Kelly, Consultant Radiation Oncologist at Bon Secours Hospital Cork and Co-Chair of the Cancer Trials Ireland Genitourinary Disease Specific Sub-Group, said: “These findings show that adding darolutamide to standard radiation therapy and hormone therapy reduces the risk of cancer recurring in people with very high-risk prostate cancer. From prior work we know major decreases in recurrences ultimately lead to a decreased chance of dying from prostate cancer. We will therefore continue the study to detail the impact on long-term survival. We look forward to presenting the full results of the first analysis at ESMO and discussing their implications with the international medical community, and I want to pay tribute to my colleague in the UK, Dr Simon Hughes and his excellent work in helping to recruit 59 UK patients to this trial.”

The DASL-HiCaP trial was jointly led by ANZUP and the Sydney Clinical Trials Centre (formerly the NHMRC Clinical Trials Centre), in collaboration with Cancer Trials Ireland, the Canadian Cancer Trials Group, Memorial Sloan Kettering Cancer Center, and the Prostate Cancer Clinical Trials Consortium in the US, and was funded by Bayer.

Cancer Trials Ireland CEO, Angela Clayton-Lea, said: “A diagnosis of very high-risk local and locally advanced prostate cancer is challenging for patients and their families, particularly given the risk of the cancer returning or spreading despite treatment. These findings are encouraging and contribute to our understanding of how outcomes for people affected by this disease may be improved. We are grateful to the patients who volunteered for the trial and to the researchers and clinicians whose collaboration made this international study possible, particularly Prof. Ray McDermott who was instrumental in bringing this trial to Ireland.”

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About DASL-HiCaP trial

The DASL-HiCaP trial is investigator-initiated and one of the largest of its kind, enrolling 1,106 participants across Australia, New Zealand, Canada, the United States, Ireland and the United Kingdom. It is an international, randomised, placebo-controlled, double-blind study. All participants received state-of-the-art standard treatment (radiation therapy plus ADT) and were then randomly assigned to also receive either the study medicine or an identical placebo tablet. The trial has closed to recruitment, and participants will continue to be followed over the longer term.

About Cancer Trials Ireland

Cancer Trials Ireland (www.cancertrials.ie) is a registered charity and the leading cancer research trials organisation in Ireland. As the national cancer clinical trials network in Ireland, Cancer Trials Ireland aims to provide every patient with cancer access to high-quality and potentially life-altering cancer trials, and to make Ireland a highly attractive location in which to open cancer trials.

Established in 1996, Cancer Trials Ireland is partly funded by the Health Research Board and the Irish Cancer Society. It also receives funding for academic studies from pharmaceutical



companies and international through philanthropic giving and public.

research groups, as well as donations from members of the

About ANZUP

ANZUP (<https://www.anzup.org.au>) is the leading cancer-cooperative trials group bringing together all of the professional disciplines and groups involved in researching and treating urogenital cancers to conduct high-quality cancer research. ANZUP's mission is to improve the lives of people affected by bladder, kidney, testicular, penile, and prostate cancers, towards a vision of living life without fear of cancer. ANZUP identifies gaps in evidence and areas of clinical need, collaborates with the best clinicians and researchers in genitourinary 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 and research funding from Prostate Cancer Foundation of Australia.

About the Sydney Clinical Trials Centre

The Sydney Clinical Trials Centre is a flagship research centre of the Faculty of Medicine and Health at the University of Sydney that designs and manages clinical trials. This includes responsibility for study coordination, monitoring, data acquisition and management and statistical analysis. The Sydney Clinical Trials Centre has health economics, biostatistics, systematic reviews and biomarker teams work with trial data and inform healthcare providers about best practice. For further details, please visit its website at <https://www.ctc.usyd.edu.au>

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