

New indication for prostate cancer drug gives hope to men with cancer recurrence

SYDNEY, Australia, 13 March, 2025 – A new indication for Astellas XTANDI® (enzalutamide) has unlocked the drug for use earlier on in the treatment pathway, improving quality of life for patients whose cancer has returned after treatment.

The new indication for XTANDI, an androgen receptor pathway inhibitor (ARPI), is for patients with non-metastatic hormone-sensitive prostate cancer (nmHSPC) with biochemical recurrence at high-risk for metastasis (high-risk BCR)¹.

Prostate cancer is the most commonly diagnosed cancer in Australia and is the second most common cause of death from cancer in Australian men, behind lung cancer.²

Of men who have undergone definitive prostate cancer treatment, including radical prostatectomy, radiotherapy, or both, an estimated 20-40% will experience biochemical recurrence (BCR) within 10 years³. BCR is a rise in the blood level of prostate-specific antigen (PSA) in prostate cancer patients after treatment with surgery or radiation.

About nine out of 10 men with high-risk BCR will develop metastatic disease, and one in three will die as a result of their metastatic prostate cancer⁴.

“Although prostate cancer is the most commonly diagnosed cancer in Australia, there still exists challenges when it comes to treatment equity and access,” said Henry Woo, a Professor of Urology at the College of Science and Medicine of the Australian National University.

“Expanding the use of enzalutamide so it can be used in an earlier prostate cancer treatment setting, is a step forward in treatment access for Australian men.”

XTANDI works by decreasing how often androgens connect with an androgen receptor, and thereby slows the growth of prostate cancer tumours and cells. This is the first and only registered ARPI for the treatment of patients with nmHSPC with biochemical recurrence at high risk for metastasis¹.

The new indication is based on results from the Phase 3 EMBARK trial. The EMBARK trial demonstrated that enzalutamide, both in combination with leuprolide and as monotherapy, significantly improved metastasis-free survival in men with high-risk biochemical recurrence of prostate cancer, compared to leuprolide alone⁵.

Prof Woo, who was involved in the EMBARK trial said; “For men with high-risk recurrent prostate cancer, conventional androgen-deprivation therapy offers some benefit, but disease progression remains inevitable. The addition of enzalutamide significantly delays the onset of metastatic disease and is likely to extend survival, without the cost of diminishing quality of life.”

“There is a likely correlation between metastasis-free survival and overall survival. In the EMBARK study, the use of enzalutamide plus leuprolide or enzalutamide monotherapy, resulted in longer metastasis-free survival which is a very promising outcome.”

Metastasis-free survival (MFS) is measured as the length of time from the start of treatment for cancer that a patient is still alive and the cancer has not spread to other parts of the body. MFS has been shown to be predicative of overall survival⁶.

“From the patients’ perspective, when prostate cancer progresses, it can cause loss of energy, pain and loss of function. A treatment that can delay the development of cancer progression by delaying metastatic disease, will positively impact the quality of life of these patients,” said Prof Woo.

The EMBARK trial⁵ found:

- Enzalutamide plus leuprolide was superior in delaying disease progression.
- Enzalutamide monotherapy also outperformed leuprolide alone, offering an alternative treatment approach.
- Safety profile: Enzalutamide was well-tolerated, with no major adverse effects beyond those observed in previous studies.
- Quality of life: The treatment did not appear to negatively impact patients' quality of life.

Detailed results from the EMBARK trial have been published in the [New England Journal of Medicine](#).

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Issued by London Agency on behalf of Astellas Australia. For media enquiries, please contact:
Annette Stenhouse annette.stenhouse@londonagency.com.au 0416 861 732

XTANDI® (ENZALUTAMIDE) Australian Product Information

About XTANDI

XTANDI® (enzalutamide) is an androgen receptor signalling inhibitor. XTANDI is a standard of care and has received regulatory approvals in one or more countries around the world for use in men with metastatic hormone-sensitive prostate cancer (mHSPC; also known as metastatic castration-sensitive prostate cancer or mCSPC), metastatic castration-resistant prostate cancer (mCRPC), non-metastatic castration-resistant prostate cancer (nmCRPC) and nonmetastatic hormone-sensitive prostate cancer (nmHSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR). XTANDI is currently approved for one or more of these indications in more than 90 countries, including in the U.S., European Union and Japan. Over one million patients have been treated with XTANDI globally.

About Astellas

Astellas is a global life sciences company committed to turning innovative science into VALUE for patients. We provide transformative therapies in disease areas that include oncology, ophthalmology, urology, immunology and women's health. Through our research and development programs, we are pioneering new healthcare solutions for diseases with high unmet medical need. Learn more at www.astellas.com.

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References:

- 1 XTANDI (enzalutamide) TGA Approved Product Information, February 2025
- 2 Australian Institute of Health and Welfare (2024). [Cancer data in Australia. \[online\]](#)
- 3 Ward JF, Moul JW. Rising prostate-specific antigen after primary prostate cancer therapy. *Nat Clin Pract Urol.* 2005 Apr;2(4):174-82. doi: 10.1038/ncpuro0145. PMID: 16474760.
- 4 Antonarakis, Emmanuel S et al. "The natural history of metastatic progression in men with prostate-specific antigen recurrence after radical prostatectomy: long-term follow-up." *BJU international* vol. 109,1 (2012): 32-9. doi:10.1111/j.1464-410X.2011.10422.
- 5 Freedland SJ et al. Improved Outcomes with Enzalutamide in Biochemically Recurrent Prostate Cancer. *N Engl J Med* 2023;389(16):1453–1465 [online].
- 6 Smith, M.R. et al. (2020) 'Relationship between metastasis-free survival and overall survival in patients with nonmetastatic castration-resistant prostate cancer', *Clinical Genitourinary Cancer*, 18(2). doi:10.1016/j.clgc.2019.10.030.

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