

For UK consumer and medical media

Embargoed until 00.01 Thursday 11th July 2013

New treatment for the management of advanced prostate cancer after failure on first-line hormonal treatments and docetaxel chemotherapy, now available for use in the UKⁱ

Prostate cancer is the most common cancer amongst males in the UK,ⁱⁱ with approximately 40,000 new cases diagnosed every yearⁱⁱ

Chertsey, UK, 11 July 2013 – Available today, XTANDI™ ▼ (enzalutamide) has been licensed for the treatment of men with advanced prostate cancer whose disease has become resistant to first-line hormonal treatments and has progressed following docetaxel chemotherapyⁱ, marking an important step in managing prostate cancer, which is the most common cancer among males in the UK.ⁱⁱ The UK licence has been granted based on pivotal trial data showing a 37% reduction of the risk of death versus placebo for patients taking enzalutamide during the study.ⁱⁱⁱ Enzalutamide was also shown to be generally well tolerated.ⁱⁱⁱ Enzalutamide is the latest in a new generation of drugs which can prolong and improve the quality of life for men with incurable advanced prostate cancer.ⁱⁱⁱ

*Professor Johann de Bono, Professor of Experimental Cancer Medicine at The Institute of Cancer Research, London, and Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust, and Global Chief Investigator in the AFFIRM trial said: “**Enzalutamide is a much needed development in prostate cancer treatment and will provide a new option for the increasing number of men with advanced prostate cancer in the UK, whose disease has become resistant to first-line hormonal treatments and who have had docetaxel chemotherapy. Enzalutamide has already demonstrated a positive impact on quality of life whilst increasing the life-span of patients with this common disease. Its use will bring significant benefits, establishing it as a key component of advanced prostate cancer treatment in the UK.**”*

Prostate cancer is the second most common cause of cancer death in men in the UK.ⁱⁱ Although early stage disease can often be cured, when prostate cancer spreads to other parts of the body (known as advanced or metastatic prostate cancer), most commonly the bones, the disease is incurable.^{iv} In patients who present with advanced disease, 72% will die within 5 years of diagnosis.^v

Many men with advanced disease eventually develop resistance to first-line hormone treatment; this is called castration-resistant prostate cancer (CRPC).^{vi} On average, 10-20% of prostate cancer patients develop CRPC within approximately 5 years of follow up, and of those almost 84% have metastatic disease at the time of diagnosis.^{vii}

Enzalutamide is a once-daily, oral treatment administered without the need for routine product-specific monitoring.ⁱ Steroids are not required to be taken with enzalutamide, however, they can be prescribed at the judgement of a doctor.ⁱ

Enzalutamide works differently from other treatments for patients with advanced prostate cancer: enzalutamide works at three steps in the androgen receptor (AR) signalling pathway within the cancer cells stopping the cancer growing.ⁱ In advanced prostate cancer enzalutamide has been shown to decrease cancer cell growth and can cause cancer cell death.^{i,iii}

The granting of the UK licence for enzalutamide follows the submission of data from the AFFIRM trial – a multinational study evaluating enzalutamide (160 mg/day) versus placebo in 1,199 men with advanced prostate cancer who were previously treated with docetaxel-based chemotherapy.ⁱⁱⁱ From today, enzalutamide will provide UK clinicians with a treatment option which improves overall survival by an average of 4.8 months versus placebo, whilst potentially helping to maintain a good quality of life.^{i,iii} Enzalutamide is available in England via the Cancer Drugs Fund.^{viii}

Ends

For further information, please contact:

Alan McDougall	Katy Gray
Medical Director	Senior Account Manager
Astellas Pharma Ltd.	Reynolds-MacKenzie
Tel: + 44 (0) 20 3379 8700	Tel: + 44 (0) 20 7861 2806

Notes to editors

About advanced prostate cancer

Advanced (or metastatic) prostate cancer refers to a cancerous tumour which has extended beyond the prostate and moved to other parts of the body, most commonly the bones.^{ix,x} These 'advanced' prostate tumours cannot be cured.^{iv} Treatment of advanced prostate cancer usually involves reducing testosterone either by surgical or medical methods.^{iv} However, advanced prostate cancer can become resistant to this type of therapy at which stage it is known as metastatic castration-resistant prostate cancer (mCRPC).^{xi} When prostate cancer is advanced, treatment can usually be given to slow the progression of the cancer, relieve symptoms and improve quality of life.^{xii}

About enzalutamideⁱ

Enzalutamide is a novel, oral, once-daily androgen receptor signalling inhibitor which works in three distinct ways: it inhibits 1) testosterone binding to androgen receptors; 2) nuclear translocation of androgen receptors; and 3) DNA binding and activation by androgen receptors.

Enzalutamide is licensed in Europe for the treatment of adult men with mCRPC whose disease has progressed on or after docetaxel therapy.ⁱ

Enzalutamide was licensed by the U.S. Food and Drug Administration on August 31, 2012 for the treatment of patients with mCRPC who have previously received docetaxel therapy.^{xiii}

About AFFIRMⁱⁱⁱ

The phase III AFFIRM trial is a randomised, double-blind, placebo-controlled, multinational trial evaluating enzalutamide (160 mg/day) versus placebo in 1,199 men with progressive mCRPC who were previously treated with docetaxel-based chemotherapy. Enrolment was completed in November 2010 and the interim analysis was triggered at 520 events. The median age of study participants was 69 years at baseline.

The AFFIRM study was conducted at sites in the United States, Canada, Europe, Australia, South America and South Africa.

About Astellas Pharma Europe

Astellas Pharma Europe Ltd., located in the UK, is a European subsidiary of Tokyo based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. The organisation is committed to becoming a global company by combining outstanding R&D and marketing capabilities and continuing to grow in the world pharmaceutical market. Astellas Pharma Europe Ltd. is responsible for 21 affiliate offices located across Europe, the Middle East and Africa, an R&D site and three manufacturing plants. The company employs approximately 4,300 staff across these regions. For more information about Astellas Pharma Europe, please visit www.astellas.eu.

About Medivation

Medivation, Inc. is a biopharmaceutical company focused on the rapid development of novel therapies to treat serious diseases for which there are limited treatment options. Medivation aims to transform the treatment of these diseases and offer hope to critically ill patients and their families. For more information, please visit us at www.medivation.com.

About the Medivation/Astellas Collaboration

In October 2009, Medivation and Astellas entered into a global agreement to jointly develop and commercialise enzalutamide (formerly MDV3100). The companies are collaborating on a comprehensive development programme that includes studies to develop enzalutamide across the full spectrum of advanced prostate cancer. The companies are jointly commercialising enzalutamide in the United States and Astellas will have responsibility for commercialising enzalutamide outside the U.S, pending further regulatory approval.

###

References

-
- ⁱ European Medicines Agency, Xtandi (enzalutamide) Summary of Product Characteristics, 2013
- ⁱⁱ Cancer Research UK, Prostate Cancer, available at http://publications.cancerresearchuk.org/downloads/Product/CS_KF_PROSTATE.pdf, last accessed May 2013
- ⁱⁱⁱ Scher H I, et al. Increased Survival with Enzalutamide in Prostate Cancer after Chemotherapy, *New England Journal of Medicine*, *N Engl J Med* 2012; 367:1187-1197
- ^{iv} Cancer Research UK, Treatment options for prostate cancer, available at <http://www.cancerresearchuk.org/cancer-help/type/prostate-cancer/treatment/types/treatment-options-for-prostate-cancer>, last accessed June 2013
- ^v National Cancer Institute, SEER Fast Statistics, available at, http://seer.cancer.gov/csr/1975_2009_pops09/results_merged/topic_survival.pdf, last accessed June 2013.
- ^{vi} Macmillan Cancer Support. Treatment for advanced prostate cancer/hormonal therapy. Available at: <http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Prostate/Treatmentforadvancedprostatecancer/Hormonaltherapy.aspx>, last accessed June 2013
- ^{vii} Kirby M, Hurst C, Crawford ED. Characterising the castration-resistant prostate cancer. *Int J Clin Pract* 2011;65:1180-92
- ^{viii} NHS England, National Cancer Drugs Fund List, updated June 18th 2013, available at <http://www.england.nhs.uk/wp-content/uploads/2013/06/ncdf-list1.pdf>, last accessed June 2012
- ^{ix} Prostate cancer UK, what is advanced prostate cancer? Available at http://prostatecanceruk.org/media/11550/advanced_prostate_cancer.pdf, last accessed May 2013
- ^x Cancer Research UK: The Stages of Prostate Cancer – key fact available at <http://www.cancerhelp.org.uk/type/prostate-cancer/treatment/the-stages-of-prostate-cancer>, last accessed June 2013
- ^{xi} Maluf, F, Smaletz O, Herchenhorn, D, Castration-resistant prostate cancer: systemic therapy in 2012, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3317249/>, last accessed June 2013
- ^{xii} Macmillan Cancer Support. Treatment for advanced prostate cancer. Available at: <http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Prostate/Treatmentforadvancedprostatecancer/Overview.aspx>, last accessed June 2013
- ^{xiii} FDA, Xtandi (enzalutamide), prescribing information, 2012