POSITIVE CHMP OPINION FOR XTANDI™ (ENZALUTAMIDE) IN ADVANCED PROSTATE CANCER[1]

Enzalutamide recommended for approval in the European Union (EU) for the treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy[1]

Chertsey, England and San Francisco, CA; 26 April, 2013: Today, Astellas Pharma Europe Ltd., the European Headquarters of Tokyo-based Astellas Pharma Inc. (TSE:4503), and Medivation, Inc. (Nasdaq: MDVN) have received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), recommending European Commission (EC) approval for XTANDI (enzalutamide) capsules for the treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy.[1]

Enzalutamide is a novel, once-daily, oral androgen receptor signalling inhibitor.[2] It inhibits multiple steps in the androgen receptor (AR) signalling pathway, which has been shown to decrease cancer cell growth and can induce cancer cell death (apoptosis).[2] The positive CHMP opinion is based on results from the phase III AFFIRM study which confirmed that enzalutamide demonstrated a statistically significant improvement ($p<0.0001$) in overall survival compared to placebo, with a median survival of 18.4 months in the enzalutamide group versus 13.6 months in the placebo group, an advantage of 4.8 months [hazard ratio (HR) = 0.631]. The study also concluded that enzalutamide was generally well tolerated by patients and met all secondary endpoints.[3]

The CHMP's positive recommendation will be reviewed by the European Commission (EC), which has authority to approve medicines for the European Union. Astellas anticipates a final decision from the EC shortly, as this usually occurs approximately 60 days after a CHMP recommendation.

Professor Johann de Bono, Professor of Experimental Cancer Medicine at The Institute of Cancer Research, London, and Head of the Drug Development Unit at The Royal Marsden NHS Foundation Trust, comments: "This is an important development in prostate cancer therapeutics that will provide a critically important new treatment option for patients with

advanced prostate cancer. Enzalutamide has a major impact on quality of life and survival from this common disease, and will hopefully become a key component of prostate cancer treatment initially in late stage disease following chemotherapy."

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For further information please contact:

Astellas Pharma Europe Ltd.:

Claire Nicholson
Red Health
claire.nicholson@redconsultancy.com
Tel: +44 207 025 6524

Mindy Dooa
Communications Director
Astellas Pharma Europe Ltd.
Mindy.Dooa@astellas.com

Notes to Editors:

About Prostate Cancer

Prostate cancer is the most frequently diagnosed cancer among European men and it is becoming more common.[4,5] Advanced prostate cancer is defined as cancer that has spread outside of the prostate to other areas of the body (metastasised).[6] A high number of men with advanced prostate cancer eventually develop a resistance to first-line treatment, which is called castration-resistant prostate cancer (CRPC).[7]

Patients with metastatic CRPC currently have few treatment options. There is an unmet need in this area for new compounds that target the cancer differently and which may provide alternative therapeutic options for patients at this late stage of their disease.[8]

About Enzalutamide

Enzalutamide is a novel, oral, once-daily androgen receptor signalling inhibitor.[2,3]

Enzalutamide inhibits androgen receptor signalling 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. [2,3]

XTANDI™ (enzalutamide) was approved by the U.S. Food and Drug Administration on August 31, 2012 for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who have previously received docetaxel (chemotherapy).

About AFFIRM

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 metastatic castration-resistant prostate cancer 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.[3]

The AFFIRM study was conducted at sites in the United States, Canada, Europe, Australia, South America and South Africa.[3]

The primary endpoint of the AFFIRM trial was overall survival. Key secondary endpoints included time to prostate-specific antigen (PSA) progression, radiographic progression free survival (rPFS) and time to first skeletal-related event (SRE).[3]

In the phase III AFFIRM trial, enzalutamide was generally well tolerated.[3] The most common adverse reactions were hot flushes and headache.[9] Seizure was reported in 0.8% of enzalutamide-treated patients.[9] Serious adverse events, adverse events causing patients to stop treatment, and adverse events causing death were all lower in the enzalutamide group than in the placebo group.[3]

About Astellas Pharma Europe

Astellas Pharma Europe Ltd., located in the UK, is the European Headquarters 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. As a global company, Astellas is committed to combining outstanding research and development (R&D) and marketing capabilities to continue to grow in the world pharmaceutical market. Astellas Pharma Europe Ltd. manages 21 affiliate offices located across Europe, the Middle East and Africa. In addition, the Company has an R&D site and three manufacturing plants in Europe. The company employs approximately 4,300 staff across these regions. For more information about Astellas Pharma Europe, please visit http://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.

This press release includes forward-looking statements made pursuant to the safe harbor provisions of the U.S. federal securities laws, including statements regarding the potential timing of further regulatory action. Forward-looking statements involve risks and uncertainties that could cause actual results to differ significantly from those projected, including risks detailed in Medivation's filings with the Securities and Exchange Commission, or SEC, including its annual report on Form 10-K for the year ended December 31, 2012, filed with the SEC on February 28, 2013. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. Medivation disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

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.

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