XTANDI™▼ (ENZALUTAMIDE) AUTHORISED IN THE EUROPEAN UNION (EU) FOR ADVANCED PROSTATE CANCER

Enzalutamide authorised in 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; 24 June, 2013: Today, Astellas Pharma Europe Ltd., the European Headquarters of Tokyo-based Astellas Pharma Inc. (TSE:4503), and Medivation, Inc. (Nasdaq: MDVN), announce that following the regulatory review process by the European Medicines Agency (EMA) and a positive Committee for Medicinal Products for Human Use (CHMP) opinion on 25th April 2013,[2] the European Commission (EC) has granted the marketing authorisation 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.[3] It inhibits multiple steps in the androgen receptor (AR) signalling pathway, which has been shown to decrease cancer cell growth and induce cancer cell death (apoptosis).[3]

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, said: “This is a major development in prostate cancer therapeutics that will provide an important new treatment option for patients with advanced prostate cancer following chemotherapy.”

Professor de Bono, who is also Head of the Drug Development Unit, a joint facility between The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, located at The Royal Marsden, added: “Enzalutamide, an oral drug, improves the quality of life and survival time for patients who have an advanced form of this common disease and is generally well tolerated.”

The EU authorisation 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.[4] The phase III AFFIRM trial was 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.[4]

Advanced prostate cancer is defined as cancer that has spread outside of the prostate to other areas of the body (metastasised).[4] A high number of men with advanced prostate cancer eventually develop resistance to androgen deprivation treatment, which is called castration-resistant prostate cancer (CRPC).[5] Around 10-20% of patients with prostate cancer present at an advanced stage, and up to 40% of men diagnosed with prostate cancer will eventually develop advanced disease.[6,7]

Dr Erik Briers, Executive Director, European Cancer Patient Coalition (ECPC) and member of the strategic committee of Europa Uomo comments: “Unfortunately prostate cancer can evolve into a life threatening castration resistant metastatic condition where treatment options are needed because all patients are not identical. A new treatment such as enzalutamide is one more option that will give selected patients a new chance if other options fail. Patients with advanced prostate cancer are very concerned about their quality of life, so they favour treatments with fewer side effects. Enzalutamide has been shown to be generally well tolerated.”

Upon receiving marketing authorisation in Europe, Astellas will provide Medivation with a $15 million milestone payment, as reflected in Astellas’ current fiscal year (from 1st April 2013 to 31st March 2014) financial forecast.

Enzalutamide was licensed by the U.S. Food and Drug Administration on 31st August, 2012 and launched in the U.S. in September 2012 for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who have previously received docetaxel (chemotherapy).[8]

The EC grant of the marketing authorisation applies in all European Union (EU) Member States, as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

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Notes to Editors:

About Prostate Cancer

Prostate cancer is the most frequently diagnosed cancer among European men and it is becoming more common. [6,9]

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.[7]

About Enzalutamide

Enzalutamide is a novel, oral, once-daily androgen receptor signalling inhibitor.[3,4]

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.[3,4]

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.[4]

The AFFIRM study was conducted at sites in the United States, Canada, Europe, Australia, South America and South Africa.[4]

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).[4]

In the phase III AFFIRM trial, enzalutamide was generally well tolerated.[4] The most common adverse reactions were hot flushes and headache.[10] Seizure was reported in 0.8% of enzalutamide-treated patients.[10] 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.[4]

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 over 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.

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 authorisation. To date, enzalutamide has been filed in Japan, Switzerland and Brazil, and has received authorisation in the US, Canada and the EU.

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