



Astellas Contact:

For Media

Tyler Marciniak
Director, Communications
(847) 736-7145

tyler.marciniak@astellas.com

For Investors

So Sekine
Senior Manager, Investor Relations
(847) 224-9557

sou.sekine@astellas.com

Medivation Contacts:

Samina Bari
Vice President, Communications
(415) 543-3470

Anne Bowdidge
Senior Director, Investor Relations
(650) 218-6900

AST Tweet: We're proud to announce initiation of a new Phase 3 trial of enzalutamide [bit.ly to press release]

Pivotal Phase III Trial of enzalutamide Initiated in Metastatic Hormone Sensitive Prostate Cancer

TOKYO and SAN FRANCISCO, CA, March 24, 2016 – Astellas Pharma Inc. (TSE: 4503) and Medivation, Inc. (NASDAQ: MDVN) today announced that the ARCHES (**AR** Inhibition with **C**hemo**H**ormonal Therapy in Men with **ME**tastatic Castrate **S**ensitive Prostate Cancer) Phase III registrational trial, which will evaluate the efficacy and safety of enzalutamide with androgen deprivation therapy (ADT) versus placebo with ADT in metastatic hormone sensitive prostate cancer (mHSPC) patients, has been initiated and the first patient has been randomized.

Prostate cancer is the most commonly diagnosed cancer and the second-leading cause of cancer death in men in the United States. According to the American Cancer Society, approximately 181,000 new cases of prostate cancer will be diagnosed, and 26,000 men will die of prostate cancer in the United States in 2016.ⁱ Androgen deprivation therapy, which reduces the levels of androgens (male hormones), is the standard of care for patients with mHSPC. The ARCHES trial will investigate whether the addition of enzalutamide to ADT may benefit this patient population compared to ADT alone.

"Dosing of the first patient in this trial demonstrates our ongoing commitment to continuing to investigate enzalutamide," said Claire Thom, Pharm D., senior vice president and oncology therapeutic area head, Astellas.

"This trial targets an important patient population as we advance the development of enzalutamide," said Mohammad Hirmand, M.D., interim chief medical officer, Medivation. "The initiation of this trial demonstrates our ongoing commitment to fully develop enzalutamide in this serious disease."

The global, Phase III, randomized, double-blind, placebo-controlled study, which is being led by Astellas, will evaluate the efficacy and safety of enzalutamide with ADT versus placebo with ADT in patients with mHSPC. ARCHES will enroll approximately 1,100 patients with mHSPC at approximately 250 centers globally. The

primary endpoint of the trial is radiographic progression-free survival (rPFS), defined as the time from randomization to the first objective evidence of radiographic disease progression as assessed by central review or death, whichever occurs first. The trial will evaluate enzalutamide at a dose of 160 mg to be taken orally once daily versus placebo, administered with ADT.

For more information about this trial, visit www.clinicaltrials.gov, trial identifier NCT02677896.

Enzalutamide is being developed through a collaboration between Astellas and Medivation. Enzalutamide, which is known by the brand name XTANDI[®], is not approved for use in patients with metastatic hormone sensitive prostate cancer (mHSPC).

About XTANDI[®]

XTANDI (enzalutamide) capsules is an androgen receptor inhibitor that blocks multiple steps in the androgen receptor signaling pathway within the tumor cell. In preclinical studies, enzalutamide has been shown to competitively inhibit androgen binding to androgen receptors, and inhibit androgen receptor nuclear translocation and interaction with DNA. The clinical significance of this MOA is unknown.

XTANDI is approved by the U.S. Food and Drug Administration for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

Important Safety Information

Contraindications XTANDI is not indicated for women and is contraindicated in women who are or may become pregnant. XTANDI can cause fetal harm when administered to a pregnant woman.

Warnings and Precautions

Seizure In Study 1, conducted in patients with metastatic castration-resistant prostate cancer (CRPC) who previously received docetaxel, seizure occurred in 0.9% of XTANDI patients and 0% of placebo patients. In Study 2, conducted in patients with chemotherapy-naïve metastatic CRPC, seizure occurred in 0.1% of XTANDI patients and 0.1% of placebo patients. There is no clinical trial experience re-administering XTANDI to patients who experienced a seizure, and limited safety data are available in patients with predisposing factors for seizure. Study 1 excluded the use of concomitant medications that may lower threshold; Study 2 permitted the use of these medications. Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity during which sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Posterior Reversible Encephalopathy Syndrome (PRES) In post approval use, there have been reports of PRES in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XTANDI in patients who develop PRES.

Adverse Reactions

The most common adverse reactions ($\geq 10\%$) reported from two combined clinical studies that occurred more commonly ($\geq 2\%$ over placebo) in XTANDI patients were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo.

In Study 1, Grade 3 and higher adverse reactions were reported among 47% of XTANDI patients and 53% of placebo patients. Discontinuations due to adverse events were reported for 16% of XTANDI patients and 18% of placebo patients. In Study 2, Grade 3-4 adverse reactions were reported in 44% of XTANDI patients and 37% of placebo patients. Discontinuations due to adverse events were reported for 6% of both study groups.

- Lab Abnormalities: Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and 6% of placebo patients (0.5% Grade 3-4). Grade 1-4 thrombocytopenia occurred in 6% of XTANDI patients (0.3% Grade 3-4) and 5% of placebo patients (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of

XTANDI patients (0.2% Grade 3-4) and 16% of placebo patients (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients (0.1% Grade 3-4) and 2% of placebo patients (no Grade 3-4).

- Infections: In Study 1, 1% of XTANDI patients compared to 0.3% of placebo patients died from infections or sepsis. In Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.
- Falls (including fall-related injuries), occurred in 9% of XTANDI patients and 4% of placebo patients. Falls were not associated with loss of consciousness or seizure. Fall-related injuries were more severe in XTANDI patients, and included non-pathologic fractures, joint injuries, and hematomas.
- Hypertension occurred in 11% of XTANDI patients and 4% of placebo patients. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of all patients.

Drug Interactions

Effect of Other Drugs on XTANDI Avoid strong CYP2C8 inhibitors, as they can increase the plasma exposure to XTANDI. If co-administration is necessary, reduce the dose of XTANDI. Avoid strong CYP3A4 inducers as they can decrease the plasma exposure to XTANDI. If co-administration is necessary, increase the dose of XTANDI.

Effect of XTANDI on Other Drugs Avoid CYP3A4, CYP2C9, and CYP2C19 substrates with a narrow therapeutic index, as XTANDI may decrease the plasma exposures of these drugs. If XTANDI is co-administered with warfarin (CYP2C9 substrate), conduct additional INR monitoring.

For Full Prescribing Information for XTANDI (enzalutamide) capsules, please visit <http://www.astellas.us/docs/us/12A005-ENZ-WPI.pdf?v=1>

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

About Medivation, Inc.

Medivation, Inc. is a biopharmaceutical company focused on the development and commercialization of medically innovative 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 <http://www.medivation.com>

About the Medivation/Astellas Collaboration

In October 2009, Medivation (NASDAQ: MDVN) and Astellas (TSE: 4503) entered into a global agreement to jointly develop and commercialize enzalutamide. The companies are collaborating on a comprehensive development program that includes studies to develop enzalutamide across the full spectrum of advanced prostate cancer as well as advanced breast cancer. The companies jointly commercialize XTANDI in the United States and Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing XTANDI outside the United States.

Forward-Looking Statements

This press release contains forward-looking statements, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements, and involve risks and uncertainties that could cause Medivation's actual results to differ significantly from those projected herein, including, without limitation, risks related to Medivation and Astellas' continued collaboration and development of enzalutamide; the timing and results of the ARCHES clinical trial, which may not demonstrate enzalutamide's safety or efficacy in combination with ADT in men with metastatic castrate sensitive prostate cancer; risk that adverse clinical trial results could alone or together with other factors result in the delay or discontinuation of some or all of Medivation's enzalutamide development activities and/or the development activities of Medivation's other product candidates; and other 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, 2015, which was filed on February 26, 2016. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Medivation disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

XTANDI is a registered trademark of Astellas Pharma Inc.

###

¹ American Cancer Society. Key Statistics for Prostate Cancer. 2016