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FDA Accepts For Review Supplemental New Drug Application for XTANDI® (enzalutamide) Capsules in Metastatic Castration-resistant Prostate Cancer with Data from Head-to-Head Studies of Enzalutamide Versus Bicalutamide

TOKYO and SAN FRANCISCO, February 22, 2016 – Astellas Pharma Inc. (TSE: 4503) and Medivation, Inc. (Nasdaq: MDVN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a supplemental New Drug Application (sNDA) that they have submitted for XTANDI® (enzalutamide) capsules in metastatic castration-resistant prostate cancer (mCRPC), which includes findings from the Phase 2 TERRAIN and STRIVE studies, to update the relevant clinical sections within the current indication. Enzalutamide is approved by the FDA for the treatment of patients with mCRPC. The Prescription Drug User Fee Act (PDUFA) goal date for a decision by the FDA is October 22, 2016.

A Type-II variation to update the Summary of Product Characteristics (SmPC) has also been submitted to the European Medicines Agency.

About the TERRAIN trial
The Phase 2 TERRAIN trial enrolled 375 patients in North America and Europe. The trial enrolled patients with metastatic prostate cancer whose disease progressed despite treatment with a luteinizing hormone-releasing hormone (LHRH) analogue therapy or following surgical castration. The primary endpoint of the trial was progression-free survival (PFS), defined as time from randomization to centrally confirmed radiographic progression, skeletal-related event, initiation of new anti-neoplastic therapy or death, whichever occurred first. The trial was designed to evaluate enzalutamide at a dose of 160 mg taken orally once daily versus bicalutamide at a dose of 50 mg taken once daily, the approved dose in combination with an LHRH analogue.

About the STRIVE trial
The Phase 2 STRIVE trial enrolled 396 CRPC patients in the U.S. The trial randomized 257

patients with metastatic prostate cancer and 139 patients with non-metastatic prostate cancer whose disease progressed despite treatment with a LHRH analogue therapy or following surgical castration. The primary endpoint of the trial was PFS, defined as time from randomization to radiographic (bone or soft tissue) progression, prostate-specific antigen (PSA) progression (defined by Prostate Cancer Working Group 2 criteria), or death due to any cause, whichever occurs first. The trial was designed to evaluate enzalutamide at a dose of 160 mg taken once daily (n=198) versus bicalutamide at a dose of 50 mg taken once daily (n=198), the approved dose in combination with a LHRH analogue.

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

Enzalutamide Mechanism of Action
Enzalutamide 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.

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-naive 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 (≥ 10%) reported from two combined clinical studies that occurred more commonly (≥ 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 us at 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 regarding the supplemental New Drug Application (sNDA) for XTANDI® (enzalutamide) capsules, 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. Actual results may differ substantially for a number of reasons, including if the data from STRIVE and/or TERRAIN are not incorporated into the prescribing information for XTANDI and other risks detailed in Medivation's filings with the Securities and Exchange Commission, or SEC, including its quarterly report on Form 10-Q for the quarter ended September 30, 2015, which was filed on November 6, 2015. 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.

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