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U.S. FDA Approves New Indication for the Use of XTANDI® (enzalutamide) Capsules for Patients with Metastatic Castration-Resistant Prostate Cancer

Approval based on improved overall survival, delayed time to radiographic progression and an overall positive benefit-risk profile

SAN FRANCISCO, CA and TOKYO, JAPAN – September 10, 2014 – Medivation, Inc. (Nasdaq: MDVN) and Astellas Pharma Inc. (Tokyo: 4503) announced today that the U.S. Food and Drug Administration (FDA) approved a new indication for the use of XTANDI® (enzalutamide) capsules to treat patients with metastatic castration-resistant prostate cancer (CRPC). This new approved use follows a priority review of the supplemental New Drug Application (sNDA) that was based on results of the Phase 3 PREVAIL trial.

The FDA initially approved XTANDI, an oral, once-daily androgen receptor inhibitor, in August 2012 for use in patients with metastatic CRPC who previously received docetaxel (chemotherapy). The new indication approves XTANDI for use in men with metastatic CRPC who have not received chemotherapy. Metastatic CRPC is defined as a cancer that has spread beyond the prostate gland and has progressed despite treatment to lower testosterone (i.e., with a gonadotropin-releasing hormone (GnRH) therapy or with removal of the testes).

“The FDA’s priority review and approval of this new indication for XTANDI now enables the use of an important therapy by patients with metastatic castration-resistant prostate cancer at all stages of their disease,” said Sef Kurstjens, M.D., Ph.D., chief medical officer of Astellas Pharma Inc. and president of Astellas Pharma Global Development, Inc. “We are pleased that these patients now have XTANDI available as a treatment option.”

“All of us at Medivation extend our thanks to the clinicians and patients who participated in the PREVAIL clinical trial culminating in today’s approval,” said David Hung, M.D., founder, president and chief executive officer, Medivation, Inc. “As a company dedicated to the rapid development of novel therapies to treat serious diseases, we are pleased to see XTANDI approved in this important patient population.”

In the Phase 3 PREVAIL trial, men receiving XTANDI and GnRH therapy exhibited a statistically significant improvement in both overall survival and delayed time to radiographic progression or death as compared to those on placebo and GnRH therapy.

- XTANDI significantly reduced the risk of radiographic progression or death by 83% compared with placebo (HR=0.17; $p < 0.0001$).
- XTANDI significantly reduced the risk of death by 29% compared with placebo (HR=0.71; $p < 0.0001$).

When compared to placebo, treatment with XTANDI also delayed time to initiation of chemotherapy and time to a skeletal related event.

The safety profile for XTANDI was updated to reflect data from both the AFFIRM and PREVAIL Phase 3 trials.

- Seizure occurred in 0.9% of patients receiving XTANDI who previously received docetaxel and 0.1% of patients who were chemotherapy-naive.
- The most common adverse reactions (≥ 10%) that occurred more commonly (≥ 2% over placebo) in the XTANDI-treated patients from the two randomized clinical trials 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.

“Enzalutamide has been studied and is approved for patients with metastatic prostate cancer that is resistant to primary hormonal therapy, a disease state we call castration-resistant prostate cancer. In this setting, enzalutamide has been shown to extend overall survival and significantly delay the progression of prostate cancer,” said Tomasz M. Beer, M.D., F.A.C.P., co-principal investigator of the PREVAIL study, deputy director of the Knight Cancer Institute and professor of medicine at Oregon Health & Science University. “Furthermore, in the PREVAIL trial, the median time to initiating chemotherapy was delayed by 17 months with enzalutamide treatment as compared to placebo, so the result is a meaningful period of time during which men have their disease controlled without the need for chemotherapy.”

A variation application to amend the European Marketing Authorization Application based on the results of PREVAIL was validated for review by the European Medicines Agency on April 24, 2014.

The approval of this new indication for XTANDI triggers $90 million in milestone payments to Medivation under its collaboration agreement with Astellas.

Enzalutamide Mechanism of Action
Enzalutamide is an androgen receptor inhibitor that acts on three different steps in the androgen receptor signaling pathway.

About XTANDI® (enzalutamide) capsules
XTANDI (enzalutamide) was approved by the FDA on September 10, 2014 for the treatment of patients with metastatic CRPC.

Important Safety Information

Contraindications: XTANDI (enzalutamide) capsules can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant.

Warnings and Precautions: In Study 1, conducted in patients with metastatic castration-resistant prostate cancer (CRPC) who previously received docetaxel, seizure occurred in 0.9% of patients who were treated with XTANDI and 0% treated with placebo. In Study 2, conducted in patients with chemotherapy-naïve metastatic CRPC, seizure occurred in 0.1% of patients who were treated with XTANDI and 0.1% treated with placebo. Patients experiencing a seizure were permanently discontinued from therapy and all seizure events resolved. There is no clinical trial experience re-administering XTANDI to patients who experienced a seizure, and limited clinical trial experience in patients with predisposing factors for seizure. Study 1 excluded the use of concomitant medications that may lower threshold, whereas 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.

Adverse Reactions: The most common adverse reactions (≥ 10%) reported from the two combined clinical trials that occurred more commonly (≥ 2% over placebo) in the XTANDI-treated 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.

Other Adverse Reactions include:
• Laboratory Abnormalities: In the two studies, Grade 1-4 neutropenia occurred in 15% of patients treated with XTANDI (1% Grade 3-4) and in 6% of patients treated with placebo (0.5% Grade 3-4). The incidence of Grade 1-4 thrombocytopenia was 6% of patients treated with XTANDI (0.3% Grade 3-4) and 5% of patients on placebo (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of patients treated with XTANDI (0.2% Grade 3-4) and 16% of patients treated with placebo (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of patients treated with XTANDI (0.1% Grade 3-4) and 2% of patients treated with placebo (no Grade 3-4).
• Infections: In Study 1, 1% of XTANDI versus 0.3% of placebo patients and in Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.
• Falls: In the two studies, falls including fall-related injuries occurred in 9% of XTANDI patients vs 4% treated with placebo. 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: In the two studies, hypertension was reported in 11% of patients receiving XTANDI and 4% of patients receiving placebo. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of XTANDI or placebo treated patients.

Drug Interactions:
• Effect of Other Drugs on XTANDI - Administration of strong CYP2C8 inhibitors can increase the plasma exposure to XTANDI. Co-administration of XTANDI with strong CYP2C8 inhibitors should be avoided if possible. If co-administration of XTANDI cannot be avoided, reduce the dose of XTANDI. Co-administration of XTANDI with strong or moderate CYP3A4 and CYP2C8 inducers may alter the plasma exposure of XTANDI and should be avoided if possible.
• Effect of XTANDI on Other Drugs -XTANDI is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. 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 www.XtandiHCP.com/PI

Medivation Conference Call Information
Medivation will host a live conference call and webcast on September 11, 2014 at 5:30am PT. To access the call, please dial 877-303-2523 from the United States or +1-253-237-1755 internationally. Individuals may access the live audio webcast by visiting www.medivation.com and going to the Investor Relations section. A replay of the webcast will be available on the Company's website (www.medivation.com) for 30 days following the live event.

About Astellas Pharma Inc.
Astellas Pharma Inc. is a pharmaceutical company dedicated to improving the health of people around the world through provision of innovative and reliable pharmaceuticals. The organization is committed to being a global category leader in Oncology and Urology, and has several oncology compounds in development in addition to enzalutamide. For more information on Astellas Pharma Inc., please visit our website at www.astellas.com/en.

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 http://www.medivation.com.

About the Astellas/Medivation Collaboration
In October 2009, Medivation and Astellas 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 that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding the potential benefit of XTANDI in the indicated patient population. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause

Medivation's actual results to differ significantly from those projected, including, without limitation, the risk that unanticipated developments could delay or prevent the launch and commercialization of XTANDI in the new indication, as well as other risks detailed in Medivation's filings with the Securities and Exchange Commission, including its quarterly report on Form 10-Q for the quarter ended June 30, 2014, filed on August 7, 2014 with the SEC. 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 or revise any forward-looking statements contained in this press release.

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