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CHMP Issues Positive Opinion to Include New Data in European Label for XTANDI® (enzalutamide)

-- TERRAIN Trial Showed Statistically Significant PFS Improvement with Enzalutamide Versus Bicalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer --

TOKYO and SAN FRANCISCO, April 7, 2016 – Astellas Pharma Inc. (TSE: 4503) and Medivation, Inc. (NASDAQ: MDVN) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval of a type II variation to include data from the head-to-head TERRAIN trial of enzalutamide versus bicalutamide in the European label for XTANDI® (enzalutamide) capsules.

The positive CHMP opinion is based on results from the TERRAIN study, which enrolled 375 patients in North America and Europe with metastatic prostate cancer whose disease progressed despite treatment with a luteinizing hormone-releasing hormone (LHRH) analogue therapy or following surgical castration. The trial showed statistically significant progression free survival (PFS) improvement with enzalutamide versus bicalutamide [median PFS 15.7 months vs 5.8 months, HR = 0.44 (95% CI: 0.34, 0.57), $p < 0.0001$].The median time on treatment in the TERRAIN trial was 11.7 months in the enzalutamide group versus 5.8 months in the bicalutamide group. Grade 3 or higher cardiac adverse events were reported in 5.5% of enzalutamide-treated patients versus 2.1% of bicalutamide-treated patients. Two seizures were reported in the enzalutamide group and one in the bicalutamide group. The most common side effects occurring during treatment and more common in the enzalutamide-treated versus bicalutamide-treated patients included fatigue, hot flush, hypertension, diarrhea, weight decreased and pain in extremity. These results were published in *Lancet Oncology* in January 2016.

“We are pleased that the CHMP has recommended inclusion of the TERRAIN data in the European label for XTANDI,” said Claire Thom, Pharm D., senior vice president and oncology therapeutic head, Astellas.

“We are very pleased with the CHMP’s decision to update the XTANDI label to include these data,” said David Hung, M.D., founder, president & chief executive officer of Medivation. “TERRAIN was the first and largest head-to-head trial comparing enzalutamide against bicalutamide in the treatment of patients with metastatic CRPC.”

The EMA is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the 28 countries of the European Union. The CHMP's positive recommendation does not change indications or contradictions, meaning that no European Commission decision is needed for this variation

before implementation of the update to the Summary of Product Characteristics. The label update will take effect immediately and will be applicable in all of the European Union.

XTANDI is approved in the European Union for the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated and for the treatment of adult men with metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy.

About the TERRAIN trial
The 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 LHRH analogue therapy or following surgical castration. The primary endpoint of the trial was 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 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-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 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 regulatory filings globally, as well as commercializing XTANDI outside the United States.

Forward-Looking Statement

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 which may cause actual results to differ significantly from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, our dependence on our collaboration relationship with Astellas to support the continued commercialization of XTANDI® (enzalutamide) capsules despite increasing competitive, reimbursement and economic challenges; risks that unexpected adverse events could impact sales of XTANDI; the inherent uncertainty associated with the regulatory approval process; 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.

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