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Medivation and Astellas Announce XTANDI® (enzalutamide) is Now Available for Patients With Metastatic Castration-Resistant Prostate Cancer Previously Treated with Docetaxel

San Francisco, CA and Tokyo – September 13, 2012 – Medivation, Inc. (Nasdaq: MDVN) and Astellas Pharma Inc. (TSE: 4503) today announced the availability of XTANDI® (enzalutamide) capsules for patients with metastatic castration-resistant prostate cancer who have previously received docetaxel. XTANDI was approved by the U.S. Food and Drug Administration (FDA) on August 31, 2012. XTANDI is being distributed through a network of specialty pharmacies and specialty distributors.

"XTANDI was approved by the FDA nearly three months ahead of the action date and we are proud of our accelerated efforts to get this new treatment option to patients with metastatic castration-resistant prostate cancer who have previously received docetaxel," said David Hung, M.D., co-founder, president and chief executive officer, Medivation, Inc. "Together with Astellas, we are excited to deliver this life extending therapy to patients in the United States."

Astellas and Medivation also announced the launch of a comprehensive patient access support program for XTANDI capsules to ensure patients who are prescribed XTANDI can access the drug in a timely manner. The new program, XTANDI Access Services℠, will provide access and reimbursement support to physicians and patients and assist eligible patients without insurance. Examples of support available through this program include help with benefit verification and prior authorization, patient referral to independent non-profit organizations that can assist with out-of-pocket expenses, and prescription forwarding to specialty pharmacies in the network.

"It is our goal that this comprehensive set of services will help patients obtain access to XTANDI, regardless of their financial situation," said Mark Reisenauer, Vice President of Oncology Sales and Marketing, Astellas.

"We applaud the efforts that resulted in XTANDI becoming available to patients so quickly, and are pleased that a comprehensive access program is simultaneously available to help men and their physicians obtain this important new therapy," said Wendy Poage, president, Prostate Conditions Education Council.

XTANDI Access Services may be contacted Monday through Friday from 9:00 a.m. to 8:00 p.m. ET at 1-855-8XTANDI (1-855-898-2634) or by visiting www.XtandiAccess.com.

About XTANDI

XTANDI is an oral, once-daily androgen receptor inhibitor. XTANDI was approved by the FDA on August 31, 2012 for the treatment of metastatic castration-resistant prostate cancer for patients who have previously received docetaxel (chemotherapy).

The recommended dose of XTANDI is 160 mg (four 40 mg capsules) administered orally once daily. XTANDI can be taken with or without food and does not require concomitant steroid (e.g., prednisone) use. In the phase 3 clinical trial, 48% of XTANDI patients and 46% of patients in the placebo arm were treated with glucocorticoids.

The efficacy and safety of XTANDI were assessed in a randomized, placebo-controlled, multicenter phase 3 clinical trial. A total of 1,199 patients with mCRPC who had previously received docetaxel were randomized 2:1 to receive either XTANDI orally at a dose of 160 mg once daily (N = 800) or placebo (N = 399). Patients with a history of seizure, taking medications known to decrease the seizure threshold, or with other risk factors for seizure were excluded from the clinical trial. The primary endpoint of the trial was overall survival.

XTANDI-treated patients had a statistically-significant improvement in median overall survival compared to the placebo group: 18.4 months in the XTANDI group versus 13.6 months in the placebo group ($P < 0.0001$). XTANDI provided a 37% reduction in risk of death compared to placebo (hazard ratio = 0.631). Seizure occurred in 0.9% of patients on XTANDI and 0% of the placebo-treated patients. The most common adverse reactions (≥ 5%) are asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension. Grade 3 and higher adverse reactions were reported among 47% of XTANDI-treated patients and 53% of placebo-treated patients.

XTANDI Mechanism of Action

XTANDI (enzalutamide) is an androgen receptor inhibitor that acts on different steps in the androgen receptor signaling pathway. XTANDI has been shown to competitively inhibit androgen binding to androgen receptors, inhibit androgen receptor nuclear translocation and interaction with DNA. A major metabolite, N-desmethyl enzalutamide, exhibited similar in vitro activity to XTANDI. XTANDI decreased proliferation and induced cell death of prostate cancer cells in vitro, and decreased tumor volume in a mouse prostate cancer xenograft model.

Important Safety Information for XTANDI

Contraindications- XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant.

Warning and Precautions- In the randomized phase 3 clinical trial, seizure occurred in 0.9% of patients on XTANDI. No patients on the placebo arm experienced seizure. Patients experiencing a seizure were permanently discontinued from therapy. All seizures resolved. Patients with a history of seizure, taking medications known to decrease the seizure threshold, or with other risk factors for seizure were excluded from the clinical trial. Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others.

Adverse Reactions- The most common adverse drug reactions (≥ 5%) reported in patients receiving XTANDI in the randomized clinical trial were asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension.

Drug Interactions- Enzalutamide is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. 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 can alter the plasma exposure of XTANDI and should be avoided if possible. 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, please visit www.XtandiHCP.com.

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 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 becoming a global category leader in oncology, and has several oncology compounds in development in addition to XTANDI. For more information on Astellas Pharma Inc., please visit our website at www.astellas.com/en.