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Astellas and Medivation Announce Submission of Application for Marketing Approval of Enzalutamide, an Oral Androgen Receptor Inhibitor, in Japan

Tokyo, Japan and San Francisco, CA – May 24, 2013 – Astellas Pharma Inc. (TSE: 4503) and Medivation, Inc. (NASDAQ: MDVN) today announced that Astellas has submitted an application for marketing approval of enzalutamide (generic name) to the Ministry of Health, Labour and Welfare in Japan for the treatment of prostate cancer.

Enzalutamide is a novel, once-daily, oral androgen receptor signaling inhibitor. It inhibits multiple steps in the androgen receptor signaling pathway, which has been shown to decrease cancer cell growth and can induce cancer cell death (apoptosis).

This filing application is based mainly on results obtained from the global Phase 3 trial (the AFFIRM trial)* and a Phase 1-2 trial conducted in Japan** .

* A multi-country, double-blind, placebo-controlled study in patients with advanced castration-resistant prostate cancer who had previously undergone docetaxel-based chemotherapy.

** An open-label, study. Phase 1 enrolled patients with advanced castration-resistant prostate cancer and Phase 2 enrolled patients with advanced castration-resistant prostate cancer who had received docetaxel therapy.

About XTANDI®

XTANDI® (enzalutamide) capsules 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). A Marketing Authorization Application for XTANDI is currently under review by the European Medicines Agency (EMA).

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.

Warnings and Precautions- In the randomized 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. Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and in 6% on placebo (no Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients and 2% on placebo. One percent of XTANDI patients compared to 0.3% on placebo died from infections or sepsis. Falls or injuries related to falls occurred in 4.6% of XTANDI patients vs 1.3% on 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. Grade 1 or 2 hallucinations occurred in 1.6% of XTANDI patients and 0.3% on placebo, with the majority on opioid-containing medications at the time of the event.

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 can 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, 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

Astellas Pharma US, Inc., located in Northbrook, Illinois, is a U.S. affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in oncology, and has several oncology products on the market and compounds in development. Astellas is proud to be an award recipient of the CEO Gold Standard Accreditation from the CEO Roundtable on Cancer. For more information on Astellas Pharma Inc., please visit our website at www.astellas.us.

Forward-looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws. 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, those detailed in Medivation's filings with the Securities and Exchange Commission, including its quarterly report on Form 10-Q for the three months ended March 31, 2013, filed on May 10, 2013 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.