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Medivation and Astellas Initiate Phase 3 Study of Enzalutamide in Non-Metastatic Castration-Resistant Prostate Cancer

San Francisco, CA and Tokyo – December 3, 2013 – Medivation, Inc. (Nasdaq: MDVN) and Astellas Pharma Inc. (Tokyo: 4503) announced enrollment of the first patient in a global Phase 3 clinical trial, known as PROSPER, which will evaluate the safety and efficacy of enzalutamide in patients with non-metastatic (often referred to as M0) castration-resistant prostate cancer (CRPC). Currently no prescription medicine is specifically approved for the treatment of patients with non-metastatic CRPC in the United States.

"PROSPER targets an important patient population as we and Astellas look to advance the development of enzalutamide further upstream in the prostate cancer treatment paradigm," said David Hung, M.D., president and chief executive officer of Medivation, Inc. "The initiation of this trial underscores our commitment to develop enzalutamide as a potential treatment for those touched by this disease."

About PROSPER

The Phase 3 randomized, double-blind, placebo-controlled, multi-national trial plans to enroll approximately 1,500 patients with non-metastatic castration-resistant prostate cancer at sites in the United States, Canada, Europe, South America and the Asia Pacific region. PROSPER will enroll a high-risk subgroup of patients with prostate cancer who are progressing despite androgen deprivation therapy, but who are asymptomatic with no prior or present evidence of metastatic disease. The primary endpoint of the trial is metastasis-free survival. The trial will evaluate enzalutamide at a dose of 160 mg to be taken orally once daily versus placebo, plus androgen deprivation therapy. Information about patient eligibility and enrollment can be obtained by calling the PROSPER hotline toll-free at 855-977-3825. For more information on the PROSPER trial go to www.clinicaltrials.gov.

About Enzalutamide

Enzalutamide is an androgen receptor inhibitor that acts on different steps in the androgen receptor signaling pathway. Enzalutamide has been shown to competitively inhibit androgen binding to androgen receptors, and inhibit androgen receptor nuclear translocation and interaction with DNA.

About XTANDI® (enzalutamide) capsules
XTANDI was approved by the U.S. Food and Drug Administration on August 31, 2012 and is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who have previously received docetaxel.

Important Safety Information for XTANDI from the approved prescribing information

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 for XTANDI (enzalutamide) capsules, 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 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 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.

Note Regarding Forward-Looking Statement - Medivation
This press release contains forward-looking statements, including statements regarding the continued clinical development of enzalutamide and potential future progress related thereto, the therapeutic potential of enzalutamide in non-metastatic prostate cancer, our strategy, and the continued effectiveness of, and continuing collaborative activities and benefits under, Medivation's collaboration agreement with Astellas, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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, risks related to the timing and results of Medivation's clinical trials, including the risk that adverse clinical trial results could alone or together with other factors result in the delay or discontinuation of some or all of Medivation's product development activities, the risk that positive results seen in our clinical trials may not be predictive of the results of our ongoing or planned clinical trials, difficulties or delays in enrolling and retaining patients in Medivation's clinical trials, Medivation's dependence on the efforts of and funding by Astellas for the development of enzalutamide, the achievement of development, regulatory and commercial milestones under Medivation's collaboration agreement with Astellas, the manufacturing of Medivation's product candidates, the industry and competitive market, the adequacy of Medivation's financial resources, unanticipated expenditures or liabilities, Medivation's outstanding convertible senior notes, intellectual property matters, and 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 September 30, 2013, filed with the SEC on November 12, 2013. 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.