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Medivation and Astellas Announce The Phase 3 PREVAIL Trial of Enzalutamide Meets Both Co-Primary Endpoints of Overall Survival and Radiographic Progression-Free Survival in Chemotherapy-Naïve Patients With Advanced Prostate Cancer

- Study Will Be Stopped Early and Enzalutamide Will Be Offered to All Qualified Study Participants -

- 30% Reduction in the Risk of Death, Hazard Ratio=0.70 (p<0.0001) -

- 81% Reduction in the Risk of Radiographic Progression or Death, Hazard Ratio=0.19 (p<0.0001) -

- Medivation to Hold Conference Call at 8:30 a.m. Eastern Time Today -

San Francisco, CA and Tokyo – October 22, 2013 – Medivation, Inc. (Nasdaq: MDVN) and Astellas Pharma Inc. (TSE: 4503) today announced that the Independent Data Monitoring Committee (IDMC) has informed the companies of positive results from a planned interim analysis of the global Phase 3 PREVAIL trial of enzalutamide in more than 1,700 men with metastatic prostate cancer that has progressed despite androgen deprivation therapy and who have not yet received chemotherapy. Given the observed benefits in the trial's co-primary endpoints of overall survival and radiographic progression-free survival, and considering the observed safety profile, the IDMC concluded enzalutamide demonstrated a favorable benefit-risk ratio. The IDMC recommended the study be stopped and patients treated with placebo be offered enzalutamide. Additional data from the Phase 3 PREVAIL results, including safety data, will be submitted for presentation at an upcoming medical conference.

The IDMC informed the companies of the following results:

- Patients treated with enzalutamide demonstrated a statistically significant overall survival advantage compared with patients receiving placebo (p<0.0001). Enzalutamide provided a 30% reduction in risk of death compared with placebo (Hazard Ratio=0.70; 95% confidence interval, 0.59-0.83).

- Patients treated with enzalutamide demonstrated a statistically significant radiographic progression-free survival advantage compared with patients receiving placebo ($p<0.0001$). Enzalutamide provided an 81% reduction in risk of radiographic progression or death compared with placebo (Hazard Ratio=0.19; 95% confidence interval, 0.15-0.23).
- The percentage of patients alive in the enzalutamide arm was 72% as compared with 65% in the placebo arm at the time of the interim analysis data cut-off date. Treatment with enzalutamide resulted in a calculated point estimate for median overall survival of 32.4 months (95% confidence interval, 31.5 months-upper limit not yet reached) versus 30.2 months (95% confidence interval, 28.0 months-upper limit not yet reached) for patients receiving placebo. Because the trial will be stopped early with the majority of patients still alive, the estimated median survivals are not as precise as the hazard ratio. The hazard ratio takes into account available information about the trial endpoint from all patients whereas the median is a single point estimate of a much smaller number of patients at risk.
- The median radiographic progression-free survival was not yet reached (95% confidence interval, 13.8 months-upper limit not yet reached) in the enzalutamide arm and was 3.9 months (95% confidence interval, 3.7-5.4) in the placebo arm.
- Given the overall survival benefit and the observed safety profile, the IDMC considered the overall benefit-risk ratio to favor the enzalutamide arm and recommended unequivocally that patients receiving placebo be offered treatment with enzalutamide.

Of the 1,715 patients treated in the blinded PREVAIL study, two patients were reported by investigators to have had a seizure event. The full analysis of the safety data will become available upon final database lock and unblinding.

“To my knowledge, the benefits in overall survival and radiographic progression-free survival reported in today's PREVAIL trial results are unprecedented in this patient population,” said Tomasz M. Beer, M.D., F.A.C.P., professor of medicine and deputy director of the Knight Cancer Institute at Oregon Health & Science University, and the co-principal investigator of the PREVAIL study.

“Achieving statistically-significant and clinically meaningful results in both co-primary endpoints – overall survival and radiographic progression-free survival –is an important outcome for patients and we are excited by the results of the Phase 3 PREVAIL trial,” said David Hung, M.D., founder, president and CEO, Medivation. “I extend my sincere thanks to the patients, physicians, study teams and other collaborators around the world, who have been instrumental in helping us achieve this important milestone.”

"We are very pleased about these results and will work closely with Medivation to pursue an expanded indication for enzalutamide," said Sef Kurstjens, M.D., Ph.D., Chief Medical Officer of Astellas. "We are committed to being at the forefront of the fight against prostate cancer by providing patients with treatment options to help them manage their disease.”

Medivation and Astellas will initiate meetings with and submissions to regulatory agencies beginning in early 2014.

About PREVAIL

The Phase 3 PREVAIL trial is a randomized, double-blind, placebo-controlled, multi-national trial that enrolled more than 1,700 patients at sites in the United States, Canada, Europe, Australia, Russia, Israel and Asian countries including Japan. The trial enrolled patients with metastatic

prostate cancer whose disease progressed despite treatment with androgen deprivation therapy and had not yet received chemotherapy. The co-primary endpoints of the trial are overall survival and radiographic progression-free survival. The trial was designed to evaluate enzalutamide at a dose of 160 mg taken orally once daily versus placebo. Targeted enrollment was completed in May 2012 and the interim analysis was pre-specified after 516 events (patient deaths).

Conference Call Information
Medivation will host a conference call today at 8:30 a.m. Eastern Time. To access the call, please dial (877) 303-2523 from the United States or +1 (253) 237-1755 internationally. In addition, the live conference call is being webcast and can be accessed on the "Events and Presentations" page of the "Investor Relations" section of the Company's website at www.medivation.com.

Enzalutamide Mechanism of Action
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 FDA 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 the Medivation/Astellas 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 and in breast cancer. The companies are jointly commercializing enzalutamide in the United States and Astellas has responsibility for commercializing enzalutamide outside the United States, pending further regulatory approval.

About Medivation
Medivation, Inc. is a biopharmaceutical company focused on the rapid development of novel small molecule drugs 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 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.

This press release contains forward-looking statements, including statements regarding the continued clinical development of enzalutamide and potential future progress related thereto, 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 potential regulatory approval and commercialization of enzalutamide, the progress, 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 and the risk that life-prolonging treatments could prevent ongoing or planned enzalutamide trials from succeeding or could reduce any potential survival benefit that may be shown in these trials even if they do succeed, difficulties or delays in enrolling and retaining patients in Medivation's clinical trials, including as a result of the availability of competing treatments or clinical trials of competing drugs for the same indication, 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 June 30, 2013, filed with the SEC on August 8, 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.