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MEDIVATION AND ASTELLAS ANNOUNCE FINAL RESULTS FROM THE PHASE 3 PREVAIL TRIAL OF ENZALUTAMIDE IN MEN WITH METASTATIC PROSTATE CANCER PROGRESSING ON ANDROGEN DEPRIVATION THERAPY

-- Study demonstrates statistically significant benefits in overall survival, radiographic progression-free survival, and a delay (17 months) in the time to initiation of chemotherapy--

SAN FRANCISCO, CA AND TOKYO, JAPAN – January 28, 2014 – Medivation Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. (TSE: 4503) announced final results on the primary and secondary efficacy endpoints from the Phase 3 PREVAIL trial of enzalutamide in patients with chemotherapy-naïve metastatic prostate cancer who have failed androgen deprivation therapy and have few or no symptoms. Data will be shared in a late-breaking oral presentation at the upcoming American Society of Clinical Oncology (ASCO) 2014 Genitourinary (GU) Cancers Symposium in San Francisco on Thursday, January 30, 2014.

“The PREVAIL study results demonstrate for the first time a statistically significant reduction both in the risk of death and a delay in cancer progression in men with metastatic prostate cancer who have a rising PSA and few, if any, symptoms," 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 co-principal investigator of the PREVAIL study. "The scope of the efficacy endpoints and the safety profile in PREVAIL, including the length of time that chemotherapy can be delayed, would represent a step forward for men with prostate cancer.”

The PREVAIL study results in men with metastatic prostate cancer who have progressed on androgen deprivation therapy are as follows:

- Treatment with enzalutamide demonstrated a statistically significant overall survival benefit compared with placebo treatment. Enzalutamide reduced the risk of death by 29% (HR=0.71; p<0.0001), compared with placebo. This benefit was observed despite substantial use of subsequent therapies (40% in the enzalutamide and 70% in the placebo groups).

- Treatment with enzalutamide significantly reduced the risk of radiographic progression or death by 81% compared with placebo treatment (HR=0.19; p<0.0001).

- Consistent benefits on these co-primary endpoints of overall survival and radiographic progression-free survival were observed across patient subgroups.

- Men taking enzalutamide experienced a 17-month delay in the time to initiation of chemotherapy compared with men taking placebo (28.0 months versus 10.8 months; HR=0.35; p<0.0001).

- The majority of men (58.8%) with soft tissue metastatic disease treated with enzalutamide versus 5% of patients treated with placebo had objective responses (complete responses or partial responses) including complete responses in 19.7% of enzalutamide patients compared with 1% of placebo patients.

- Enzalutamide extended the median time to PSA progression from 2.8 months (placebo) to 11.2 months (HR= 0.169; p < 0.0001).

- Nearly 4 out of 5 patients in the enzalutamide group experienced a PSA decline of 50% or more, compared to less than 4% in the placebo group (78% vs. 3.5%; p<0.0001).

- The median times to deterioration in a measure of prostate cancer-specific quality of life, the Functional Assessment of Cancer Therapy-Prostate or FACT-P, were 11.3 months for the enzalutamide-treated patients and 5.6 months for the placebo patients (HR=0.625, p < 0.0001).

- The median treatment duration for enzalutamide was more than 3 times longer than for placebo (16.6 versus 4.6 months).

- Common side effects occurring during treatment and more common in the enzalutamide treated men included fatigue, back pain, constipation and arthralgia. Hypertension was observed in 13.4% of enzalutamide versus 4.1% of placebo-treated patients. Grade 3 or higher cardiac adverse events were reported in 2.8% of enzalutamide versus 2.1% of placebo-treated patients. Investigators reported zero seizures in the enzalutamide-treated group and one in the placebo group prior to the data cutoff date. One seizure was reported in the enzalutamide group after the data cutoff date.

“Medivation's primary mission is to develop and make available to patients medically innovative therapies that provide clinically meaningful benefits and address major medical unmet needs among a spectrum of serious diseases,” said David Hung, M.D., founder, president and CEO of Medivation. “Should enzalutamide be approved for use in this patient population, it will be a meaningful advance in the field of prostate cancer therapy.”

“The PREVAIL study results are encouraging and we plan to submit, along with our partner Medivation, our regulatory applications to the U.S. Food and Drug Administration and European Medicines Agency in early 2014,” said Sef Kurstjens, M.D., Ph.D., and Chief Medical Officer of Astellas. "Astellas is committed to being a global category leader in the fight against cancer by providing patients with treatment options, such as enzalutamide, to manage their disease.”

Details of the presentation are as follows:

Title: Enzalutamide in men with chemotherapy-naïve metastatic prostate cancer (mCRPC): Results of Phase 3 PREVAIL Study

Presenter: Tomasz M. Beer, M.D., F.A.C.P., Knight Cancer Institute, Oregon Health & Science University

- Session Detail: Welcome and General Session 1: Integrating Androgen Axis Therapy across the Disease Spectrum
- Session Date/Time: January 30, 2014 from 7:45 a.m - 9:45 a.m.

About the PREVAIL Trial

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 were 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 pre-specified interim analysis was conducted after 516 events (patient deaths).

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 versus 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 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.

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, 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 September 30, 2013, filed on November 12, 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.