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Medivation and Astellas Announce New Data From XTANDI(R) (enzalutamide) Pivotal Study

AFFIRM Study Data Presented Today at European Society of Medical Oncology (ESMO)

SAN FRANCISCO, CA and TOKYO -- (Marketwire) -- 09/30/12 -- Medivation Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. (TSE: 4503) announced that new data for enzalutamide (XTANDI® capsules), an oral androgen receptor inhibitor, were presented today at the 2012 European Society of Medical Oncology (ESMO) Annual Meeting in Vienna, Austria. The data from the randomized, global, placebo-controlled phase 3 AFFIRM study highlight the effect of enzalutamide on pain-related secondary endpoints and a post hoc analysis of the survival impact of baseline corticosteroid use among men with advanced prostate cancer.

"Findings from the corticosteroid analysis showed that patients in both the enzalutamide and the placebo groups taking glucocorticoids had an inferior survival compared to those who did not take glucocorticoids," said Dr. Howard I. Scher, chief, Genitourinary Oncology Service, Sidney Kimmel Center for Prostate and Urologic Cancers, Memorial Sloan-Kettering Cancer Center, and co-principal investigator for AFFIRM. "Patients on enzalutamide fared better than those on placebo whether or not they were taking corticosteroids, which confirmed the survival benefit associated with enzalutamide while suggesting the impact of corticosteroids on outcomes be explored further."

"Additionally, the pain-related data presented today provide additional information to help those of us who treat prostate cancer on a daily basis to assess the benefits of enzalutamide for the individual patients," Scher said.

Title: Association of baseline corticosteroid with outcomes in a multivariate analysis of the Phase 3 AFFIRM study of enzalutamide (ENZA), an androgen receptor signaling inhibitor (Abstract # 899PD)

Dr. Scher presented results from a post hoc AFFIRM analysis evaluating the impact of baseline corticosteroid use on efficacy outcomes.

Approximately 30 percent of patients in both the AFFIRM enzalutamide and placebo arms were receiving corticosteroids at baseline. The analyses presented showed:

- Baseline corticosteroid use was associated with reduced survival regardless of study treatment (i.e., enzalutamide or placebo).
- Enzalutamide was consistently superior to placebo on overall survival (OS), radiographic progression-free survival (rPFS) and time to PSA progression (TTPP) regardless of baseline corticosteroid use.
- After adjustment for the effects of other prognostic factors, the analysis demonstrated baseline corticosteroid use was still associated with poorer overall survival outcome.

Title: Impact of enzalutamide, an androgen receptor signaling inhibitor, on time to first skeletal related event (SRE) and pain in the phase 3 AFFIRM study (Abstract #8960)

Karim Fizazi, MD, PhD, head of the Department of Cancer Medicine at the Institut Gustave Roussy, Villejuif, France, presented data on AFFIRM pain-related quality-of-life endpoints which demonstrate:

- Pain reduction assessed by patient diaries was achieved by 45 percent of enzalutamide patients vs. 7 percent of placebo patients (p=0.0079).
- Patients taking enzalutamide demonstrated less pain progression and improved median time to pain progression as compared to those taking placebo.
- Enzalutamide-treated patients also experienced improvements over placebo in mean reduction in pain severity, and pain interference with daily activity.
- Enzalutamide-treated participants also experienced delayed time to first skeletal-related event (SRE): 16.7 months as compared to 13.3 months for those on placebo (HR=0.69 p=0.0001), representing a 31 percent reduction in SRE risk.

In the Phase 3 AFFIRM trial common side effects observed more frequently in XTANDI as compared with placebo-treated patients included fatigue, diarrhea and hot flush. Seizure was reported in < 1% of enzalutamide-treated patients. Serious adverse events, adverse events causing patients to stop treatment, and adverse events causing death all were lower in the enzalutamide group than in the placebo group.

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

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 the randomized, placebo-controlled, global phase 3 AFFIRM 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 OS.

XTANDI-treated patients had a statistically-significant improvement in median OS 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 ($\geq 5\%$) 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 ($\geq 5\%$) 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.

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding therapeutic potential of XTANDI. 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, the risk that unanticipated developments could interfere with the commercialization of XTANDI, as well as 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, 2012, filed on August 9, 2012 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.

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