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ASTELLAS AND MEDIVATION INITIATE PHASE III TRIAL OF ENZALUTAMIDE IN PATIENTS WITH TRIPLE-NEGATIVE BREAST CANCER

TOKYO and SAN FRANCISCO, **JUNE 2, 2016** – Astellas Pharma Inc. (TSE: 4503) and Medivation, Inc. (NASDAQ: MDVN) today announced plans to commence a Phase III clinical trial to investigate the use of enzalutamide for the treatment of triple-negative breast cancer (TNBC). The ENDEAR (A Phase III, Randomized, International Study Comparing the Efficacy and Safety of **EN**zalutami**D**e in Combination With Paclitax**E**l Chemotherapy or as Monotherapy Versus Placebo With Paclitaxel in Patients With **A**dvanced, Diagnostic-Positive, Triple-Negative B**R**east Cancer) trial will evaluate the efficacy and safety of enzalutamide in combination with paclitaxel chemotherapy or as monotherapy versus placebo with paclitaxel in patients with locally advanced or metastatic TNBC whose tumors test positive for a novel gene expression profile, which is referred to as diagnostic-positive TNBC. The trial, which will be led by Medivation, is expected to begin patient enrollment in the fourth quarter of 2016.

In the United States, breast cancer is one of the most commonly diagnosed cancers and the second leading cause of cancer deaths in women. According to the American Cancer Society, approximately 246,000 new cases of breast cancer will be diagnosed in women and 40,000 women will die of breast cancer in 2016.[1] Approximately 15-20 percent of breast cancers are triple negative or basal-like, the subtype that the ENDEAR trial will study.[2] Patients with TNBC have a poor prognosis[3] and there are currently no therapies specifically approved to treat this patient population.

"Our initiation of this trial represents our commitment to explore the potential of enzalutamide in patients with advanced TNBC," said Mohammad Hirmand, M.D., interim chief medical officer, Medivation.

"The initiation of the ENDEAR trial reflects our ongoing commitment to investigate the full clinical utility of enzalutamide," said Claire Thom, Pharm D., senior vice president and oncology therapeutic area head, Astellas.

Enzalutamide, which is known by the brand name XTANDI®, is not approved for use in patients with TNBC.

About ENDEAR
ENDEAR will be a Phase III, randomized, international trial, enrolling approximately 780 patients with advanced diagnostic-positive TNBC who have received either no or one prior line of systemic therapy for advanced disease. The primary efficacy endpoint is progression-free survival (PFS), defined as the time from randomization to the first evidence of disease progression or death, whichever occurs first. The trial will evaluate enzalutamide at a dose of 160 mg per day taken orally, either with paclitaxel (90 mg/m^2) administered intravenously once weekly for 16 weeks (or longer at investigator discretion), or as monotherapy compared to placebo with paclitaxel.

About XTANDI® (enzalutamide) capsules
XTANDI (enzalutamide) capsules are an androgen receptor inhibitor that blocks multiple steps in the androgen receptor signaling pathway within the tumor cell. In preclinical studies, enzalutamide has been shown to competitively inhibit androgen binding to androgen receptors as well as inhibit androgen receptor nuclear translocation and interaction with DNA. The clinical significance of this MOA is unknown.

XTANDI is approved by the U.S. Food and Drug Administration for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).

Important Safety Information

Contraindications XTANDI is not indicated for women and is contraindicated in women who are or may become pregnant. XTANDI can cause fetal harm when administered to a pregnant woman.

Warnings and Precautions

Seizure In Study 1, conducted in patients with metastatic castration-resistant prostate cancer (CRPC) who previously received docetaxel, seizure occurred in 0.9% of XTANDI patients and 0% of placebo patients. In Study 2, conducted in patients with chemotherapy-naive metastatic CRPC, seizure occurred in 0.1% of XTANDI patients and 0.1% of placebo patients. There is no clinical trial experience re-administering XTANDI to patients who experienced a seizure, and limited safety data are available in patients with predisposing factors for seizure. Study 1 excluded the use of concomitant medications that may lower threshold; Study 2 permitted the use of these medications. Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity during which sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Posterior Reversible Encephalopathy Syndrome (PRES) In post approval use, there have been reports of PRES in patients receiving XTANDI. PRES is a neurological disorder which can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XTANDI in patients who develop PRES.

Adverse Reactions The most common adverse reactions (≥ 10%) reported from two combined clinical studies that occurred more commonly (≥ 2% over placebo) in XTANDI patients were asthenia/fatigue, back pain, decreased appetite, constipation, arthralgia, diarrhea, hot flush, upper respiratory tract infection, peripheral edema, dyspnea, musculoskeletal pain, weight decreased, headache, hypertension, and dizziness/vertigo.

In Study 1, Grade 3 and higher adverse reactions were reported among 47% of XTANDI patients and 53% of placebo patients. Discontinuations due to adverse events were reported for 16% of XTANDI patients and 18% of placebo patients. In Study 2, Grade 3-4 adverse reactions were reported in 44% of XTANDI patients and 37% of placebo patients. Discontinuations due to adverse events were reported for 6% of both study groups.

- Lab Abnormalities: Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and 6% of placebo patients (0.5% Grade 3-4). Grade 1-4 thrombocytopenia occurred in 6% of XTANDI patients (0.3% Grade 3-4) and 5% of placebo patients (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of XTANDI patients (0.2% Grade 3-4) and 16% of placebo patients (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients (0.1% Grade 3-4) and 2% of placebo patients (no Grade 3-4).

- Infections: In Study 1, 1% of XTANDI patients compared to 0.3% of placebo patients died from infections or sepsis. In Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.

- Falls (including fall-related injuries), occurred in 9% of XTANDI patients and 4% of placebo patients. 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.

- Hypertension occurred in 11% of XTANDI patients and 4% of placebo patients. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of all patients.

Drug Interactions

Effect of Other Drugs on XTANDI Avoid strong CYP2C8 inhibitors, as they can increase the plasma exposure to XTANDI. If co-administration is necessary, reduce the dose of XTANDI. Avoid strong CYP3A4 inducers as they can decrease the plasma exposure to XTANDI. If co-administration is necessary, increase the dose of XTANDI.

Effect of XTANDI on Other Drugs 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 http://www.astellas.us/docs/us/12A005-ENZ-WPI.pdf?v=1

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

About Astellas
Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

About Medivation Inc.
Medivation, Inc. is a biopharmaceutical company focused on the development and commercialization of medically innovative 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 http://www.medivation.com

About the Medivation/Astellas Collaboration
In October 2009, Medivation (NASDAQ: MDVN) and Astellas (TSE: 4503) 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 as well as advanced breast cancer. The companies jointly commercialize XTANDI in the United States and Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing XTANDI outside the United States.

Forward-Looking Statement
Certain of the statements made in this press release, including the company's commencement of the Phase III ENDEAR clinical trial and expectations regarding patient enrollment, are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are subject to risks and uncertainties which may cause actual results to differ significantly from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, the inherent uncertainty associated with pharmaceutical product development and clinical trials; difficulties or delays in completing initiation activities or receiving regulatory clearance to enroll patients into the clinical trial; the risk that unfavorable results or unexpected adverse events from other clinical trials involving enzalutamide could delay or cause us to discontinue our development of enzalutamide; difficulties or delays in manufacturing or supplying product for the clinical trial; our dependence on our collaboration relationship with Astellas to support the continued development of enzalutamide; and other risks detailed in Medivation's filings with the Securities and Exchange Commission, or SEC, including its quarterly report on Form 10-Q for the quarter ended March 31, 2016, which was filed on May 5, 2016. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Medivation disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

References

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