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ASTELLAS AND MEDIVATION ANNOUNCE NEW ENZALUTAMIDE DATA PRESENTED DURING PLENARY PRESENTATIONS AT THE 2015 EUROPEAN ASSOCIATION OF UROLOGY CONGRESS

TOKYO, JAPAN and SAN FRANCISCO, Calif., March 24, 2015 -- Astellas Pharma Inc. (Tokyo: 4503) and Medivation, Inc. (Nasdaq: MDVN) today announced new data from the Phase 2 TERRAIN trial of enzalutamide compared to bicalutamide in metastatic castration-resistant prostate cancer (CRPC), as well as an updated overall survival analysis from the placebo-controlled Phase 3 PREVAIL trial of enzalutamide in chemotherapy-naive metastatic CRPC. The data were presented during a plenary session at the 2015 European Association of Urology (EAU) Congress in Madrid, Spain.

“The late breaking data presented at this year's EAU Congress further demonstrate the breadth and depth of the enzalutamide development program and is reflective of the many potential benefits enzalutamide may offer to men with metastatic prostate cancer,” said Claire Thom, Pharm.D., senior vice president and Oncology therapeutic head, Astellas Pharma Global Development, Inc. “We are excited to see that enzalutamide continues to generate promising data for men with advanced prostate cancer and their loved ones.”

Highlights of Key Enzalutamide Data

Title: A randomized, double-blind, phase 2, efficacy and safety study of enzalutamide vs. bicalutamide in metastatic castrate resistant prostate cancer: TERRAIN trial

The Phase 2 TERRAIN trial enrolled 375 patients in North America and Europe. The trial enrolled patients with metastatic prostate cancer whose disease progressed despite treatment with a luteinizing hormone-releasing hormone (LHRH) analogue therapy or following surgical castration. The primary endpoint of the trial was progression-free survival (PFS), defined as time from randomization to centrally confirmed radiographic progression, skeletal-related event, initiation of new anti-neoplastic therapy or death, whichever occurred first. The trial was designed to evaluate enzalutamide at a dose of 160 mg taken orally once daily versus bicalutamide at a dose of 50 mg taken once daily, the approved dose in combination with an LHRH analogue.

“The results of the TERRAIN trial, if confirmed, have the potential to impact the treatment landscape of metastatic castration-resistant prostate cancer,” said Axel Heidenreich, M.D., Ph.D., professor and director, Department of Urology, University hospital, Aachen, Germany. “The study demonstrated an improvement with enzalutamide over the standard practice of the addition of bicalutamide to a luteinizing hormone-releasing hormone therapy.”

- The study achieved its primary objective of a statistically significant increase in PFS for enzalutamide compared to bicalutamide. The median PFS in the enzalutamide arm was 9.9 months longer compared to that in the bicalutamide arm (15.7 vs. 5.8 months, respectively) with a Hazard Ratio (HR) of 0.44 (95% confidence interval [CI], 0.34-0.57; p<0.0001);
- The median time to PSA progression was 13.6 months longer with enzalutamide (19.4 months) relative to bicalutamide treatment (5.8 months) with an HR of 0.28 (p<0.0001);
- 82% of enzalutamide-treated patients achieved ≥ 50% PSA reduction from baseline by week 13 vs. 21% of bicalutamide-treated patients;
- The median time on enzalutamide treatment was 11.7 months compared to 5.8 months on bicalutamide;
- The safety profile of the enzalutamide-treated patients in TERRAIN is consistent with the known safety profile of enzalutamide.
    - Serious adverse events (AEs) were reported in 31.1% of enzalutamide vs. 23.3% of bicalutamide patients and Grade 3 or higher cardiac AEs were observed in 5.5% of enzalutamide vs. 2.1% of bicalutamide patients. Two seizures were reported with enzalutamide and one with bicalutamide;
    - The common (≥10%) AEs reported more frequently with enzalutamide vs. bicalutamide were fatigue (27.9% vs. 20.1%), back pain (19.1% vs. 18.0%), hot flush (14.8% vs. 11.1%), hypertension (14.2% vs. 7.4%), diarrhea (11.5% vs. 9.0%), weight decrease (10.9% vs. 7.9%) and pain in extremities (10.9% vs. 5.3%).

Title: Enzalutamide in men with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC): Final overall survival analysis of the phase 3 PREVAIL study

The Phase 3 PREVAIL trial, a randomized, double-blind, placebo-controlled, multi-national trial, enrolled 1,717 patients at sites in the United States, Canada, Europe, Australia, Russia, Israel and Asia, including Japan. The trial enrolled patients with chemotherapy-naïve metastatic prostate cancer whose disease progressed on androgen deprivation therapy (i.e., a LHRH therapy or after bilateral orchiectomy). The co-primary endpoints of the trial were overall survival (OS) and radiographic PFS. The trial was designed to evaluate enzalutamide at a dose of 160 mg taken orally once daily versus placebo.

"This study demonstrates that starting patients on enzalutamide at the point when their castration-resistant prostate cancer becomes metastatic has the potential to prolong survival,” said Bertrand Tombal, M.D., Ph.D., professor and chairman, Department of Urology, Université catholique de Louvain, Cliniques universitaires Saint-Luc, Brussels, Belgium. “The overall survival analysis from the PREVAIL trial confirms significant overall survival benefit despite many patients receiving subsequent treatments.”

- An updated overall survival analysis was conducted at 784 deaths and found a statistically significant overall survival benefit with a 23% reduction in risk of death (OS: HR 0.77; 95% CI 0.67–0.88; p=0.0002) and a 4-month improvement in median survival with enzalutamide

(35.3 months [95% CI 32.2 – not yet reached]) over placebo (31.3 months [95% CI 28.8 – 34.2]). As of the June 2014 cut-off date with a median follow-up duration of 31 months:
    - 52% of enzalutamide and 81% of placebo patients received ≥1 subsequent life-extending prostate cancer therapy.

For Full Prescribing Information for XTANDI (enzalutamide) capsules, please visit www.XtandiHCP.com/PI

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

Enzalutamide Mechanism of Action
Enzalutamide is an androgen receptor inhibitor that acts on three different steps in the androgen receptor signaling pathway.

Important Safety Information
Contraindications: XTANDI (enzalutamide) capsules can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings in animals. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant.

Warnings and Precautions: In Study 1, conducted in patients with metastatic castration-resistant prostate cancer (CRPC) who previously received docetaxel, seizure occurred in 0.9% of patients who were treated with XTANDI and 0% treated with placebo. In Study 2, conducted in patients with chemotherapy-naïve metastatic CRPC, seizure occurred in 0.1% of patients who were treated with XTANDI and 0.1% treated with placebo. Patients experiencing a seizure were permanently discontinued from therapy and all seizure events resolved. There is no clinical trial experience re-administering XTANDI to patients who experienced a seizure, and limited clinical trial experience in patients with predisposing factors for seizure. Study 1 excluded the use of concomitant medications that may lower threshold, whereas 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.

Adverse Reactions: The most common adverse reactions (≥ 10%) reported from the two combined clinical trials that occurred more commonly (≥ 2% over placebo) in the XTANDI-treated 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.
Other Adverse Reactions include:
- Laboratory Abnormalities: In the two studies, Grade 1-4 neutropenia occurred in 15% of patients treated with XTANDI (1% Grade 3-4) and in 6% of patients treated with placebo (0.5% Grade 3-4). The incidence of Grade 1-4 thrombocytopenia was 6% of patients treated with XTANDI (0.3% Grade 3-4) and 5% of patients on placebo (0.5% Grade 3-4). Grade 1-4 elevations in ALT occurred in 10% of patients treated with XTANDI (0.2% Grade 3-4) and 16% of patients treated with placebo (0.2% Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of patients treated with XTANDI (0.1% Grade 3-4) and 2% of patients treated with placebo (no Grade 3-4).

- Infections: In Study 1, 1% of XTANDI versus 0.3% of placebo patients and in Study 2, 1 patient in each treatment group (0.1%) had an infection resulting in death.
- Falls: In the two studies, falls including fall-related injuries occurred in 9% of XTANDI patients vs 4% treated with 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.
- Hypertension: In the two studies, hypertension was reported in 11% of patients receiving XTANDI and 4% of patients receiving placebo. No patients experienced hypertensive crisis. Medical history of hypertension was balanced between arms. Hypertension led to study discontinuation in < 1% of XTANDI or placebo treated patients.

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 may 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 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.

About Medivation Inc.
Medivation, Inc. is a biopharmaceutical company focused on the rapid development 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 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.

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