Astellas Contacts
For Media
Tyler Marciniak
Director, Communications and Advocacy
(847) 736-7145
tyler.marciniak@astellas.com

For Investors
So Sekine
Associate Manager, Investor Relations
+81-3-3244-3202
sou.sekine@astellas.com

Medivation Contacts

Rick Bierly
Chief Financial Officer
(415) 543-3470

Anne Bowdidge
Senior Director, Investor Relations
(650) 218-6900

ASTELLAS AND MEDIVATION ANNOUNCE NEW ENZALUTAMIDE DATA PRESENTED AT THE 2015 AMERICAN UROLOGICAL ASSOCIATION ANNUAL MEETING

TOKYO and SAN FRANCISCO – May 17, 2015 – Astellas Pharma, Inc (TSE:4503) and Medivation, Inc (NASDAQ: MDVN) today announced data from the Phase 2 STRIVE trial comparing enzalutamide and bicalutamide in non-metastatic (M0) and metastatic (M1) prostate cancer patients whose disease progressed despite treatment with a luteinizing hormone-releasing hormone (LHRH) analogue therapy or following surgical castration. The data were presented during an oral plenary session at the 2015 American Urological Association (AUA) annual meeting in New Orleans, Louisiana.

Highlights of Key Enzalutamide Data

Title: A multicenter phase 2 study of enzalutamide versus bicalutamide in men with nonmetastatic or metastatic castration-resistant prostate cancer: STRIVE trial

- The study achieved its primary endpoint demonstrating a statistically significant increase in progression-free survival (PFS) for enzalutamide compared with bicalutamide (Hazard Ratio = 0.24; 95% confidence Interval (CI), 0.18-0.32; p<0.0001). The median PFS was 19.4 months in the enzalutamide arm and 5.7 months in the bicalutamide arm;
- Treatment with enzalutamide also demonstrated significant improvement in the secondary endpoints of radiographic PFS, time to PSA progression, and PSA response rates compared to bicalutamide;
- For the subset of patients with M0 disease, at the time of the analysis the median PFS had not yet been reached for patients in the enzalutamide arm and was 8.6 months in the bicalutamide arm with a Hazard Ratio (HR) of 0.24 (95% CI, 0.14-0.42; p<0.0001). For patients with M1 disease, the median PFS was 16.5 months in the enzalutamide arm and 5.5 months in the bicalutamide arm with a HR of 0.24 (95% CI, 0.17-0.34; p<0.0001).

- The safety profile of enzalutamide-treated patients in STRIVE was consistent with the known safety profile of enzalutamide:

- The median duration of treatment was 14.7 months with enzalutamide and 8.4 months with bicalutamide.
- Serious adverse events (AEs) were reported in 29.4% of enzalutamide-treated patients and 28.3% of bicalutamide-treated patients. Grade 3 or higher cardiac AEs were reported in 5.1% of enzalutamide-treated patients versus 4.0% of bicalutamide-treated patients. One seizure was reported in the enzalutamide group and none in the bicalutamide group;
- The most common side effects noted more frequently in the enzalutamide-treated versus bicalutamide-treated patients included fatigue, back pain, hot flush, fall, hypertension, dizziness and decreased appetite, consistent with the known safety profile of enzalutamide.

"Results from the STRIVE trial are of key interest to the medical community as they mark the second head-to-head trial of enzalutamide versus bicalutamide," said Celestia S. Higano, M.D., FACP, co-principal investigator of the STRIVE trial and professor, medicine and urology, University of Washington. "The analyses from STRIVE are in line with previous data from the TERRAIN trial demonstrating that patients treated with enzalutamide have improved clinical outcomes versus the common practice of adding bicalutamide to a luteinizing hormone-releasing hormone therapy."

About the STRIVE Trial
The Phase 2 STRIVE trial enrolled 396 castration-resistant prostate cancer patients in the United States. The trial randomized 257 patients with metastatic prostate cancer and 139 patients with non-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, defined as time from randomization to radiographic (bone or soft tissue) progression, PSA progression (defined by Prostate Cancer Working Group 2 criteria), or death due to any cause, whichever occurs first. The trial was designed to evaluate enzalutamide at a dose of 160 mg taken once daily versus bicalutamide at a dose of 50 mg taken once daily, the approved dose in combination with a LHRH analogue.

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

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 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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