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DATA PRESENTED FROM PHASE 2 STUDY OF ENZALUTAMIDE IN ADVANCED ANDROGEN-RECEPTOR POSITIVE, TRIPLE-NEGATIVE BREAST CANCER

SAN FRANCISCO, CA and TOKYO – December 12, 2014 – Medivation, Inc. (Nasdaq: MDVN) and Astellas Pharma Inc. (Tokyo: 4503), announced today the presentation of Stage 1 and preliminary Stage 2 data from a Phase 2 study evaluating the use of enzalutamide as a single agent for the treatment of advanced androgen receptor positive (AR+), triple negative breast cancer (TNBC). Data was presented at the 37th Annual San Antonio Breast Cancer Symposium.

Title: Stage 1 Results from MDV3100-11: A 2-Stage Study of Enzalutamide (ENZA), an Androgen Receptor (AR) Inhibitor, in Advanced AR+ Triple-Negative Breast Cancer (TNBC) (Abstract # P5-19-09).

Patients with any amount of AR staining by immunohistochemistry could be enrolled in the study (n=42 in Stage 1, n=118 in total). The primary endpoint was clinical benefit rate, defined as the portion of Evaluable patients (≥10% AR staining in tumor cells and a post-baseline assessment) who had a complete response, partial response, or stable disease for at least 16 weeks. There was no limit to prior therapy. In Stage 1, 26 of the 42 enrolled women comprised the Evaluable population.

- In the 26 Evaluable women, the primary endpoint was achieved in 42% (11 of 26) including 1 partial response in a patient with measurable disease and 1 complete response in a patient with non measurable disease. Clinical benefit rate ≥24 weeks was achieved in 35% (9 of 26).
- The clinical benefit rate ≥ 16 weeks in Stage 1 was sufficiently high to enable both the expansion into Stage 2 and early rejection of the null hypothesis.
- While data are not yet mature (anticipated 2015), 1 additional complete response and 3 additional partial responses have been observed to date in the additional 76 patients enrolled following Stage 1, for a total of 6 complete or partial responses in both Stages as of November 10, 2014.

The most common adverse events reported in the Stage 1 intent to treat population (n=42) were fatigue (36%), nausea (33%), diarrhea (21%), decreased appetite (21%), back pain (14%),

headache (14%), hot flush (12%), insomnia (12%), vomiting (12%), pain (12%) and constipation (12%). To date, the safety and tolerability profile of the additional patients enrolled in Stage 2 are consistent with the profile seen in Stage 1. Patients will continue to be monitored for safety.

"The combined results from Stage 1 and 2 suggest that enzalutamide may provide a potential benefit to women with advanced androgen-receptor positive, triple-negative breast cancer," said Tiffany A Traina, M.D., primary investigator of the study and medical oncologist, Memorial Sloan Kettering Cancer Center. "This is encouraging for patients with this type of breast cancer because it is a particularly challenging subtype of the disease, for which the only available treatment option is chemotherapy."

Androgen-receptor positive TNBC is a recently-identified subtype that can express high levels of the androgen receptor. This Phase 2 study of single agent enzalutamide is the largest to date in patients with AR+ TNBC and the first to report objective responses to a hormonal therapy.

TNBC remains an area of significant unmet medical need. Currently, there are no approved targeted therapies for these patients, who are typically treated with multiple regimens of chemotherapy.

About the Phase 2 Study
The Phase 2 open label, single-arm study was initiated in June 2013 and completed enrollment in July 2014. 118 patients were enrolled in 2 Stages at sites in the United States, Canada and Europe. The primary endpoint of the trial is clinical benefit rate, defined as the proportion of patients with a best response of complete response, partial response or stable disease at ≥ 16 weeks. All patients receive enzalutamide at a dose of 160 mg to be taken orally once daily.

Enzalutamide Mechanism of Action
Enzalutamide is an androgen receptor inhibitor that acts on 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, and inhibit androgen receptor nuclear translocation and interaction with DNA. Clinical significance is unknown.

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).

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/PI

About Medivation

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 http://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.

About the Astellas/Medivation Collaboration
In October 2009, Medivation and Astellas 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.