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NEW ENZALUTAMIDE DATA IN TRIPLE-NEGATIVE BREAST CANCER PRESENTED AT THE 2015 AMERICAN SOCIETY OF CLINICAL ONCOLOGY ANNUAL MEETING

TOKYO and NORTHBROOK, Ill. – June 1, 2015 – Astellas Pharma Inc. (Tokyo: 4503) announced that data from a Phase 2 study evaluating the investigational use of enzalutamide as a single agent for the treatment of advanced androgen receptor (AR) positive, triple-negative breast cancer (TNBC) were presented during an oral abstracts session at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. The study met its primary endpoint and the abstract was also selected to be featured in the upcoming 'Best of ASCO' meetings.

The Phase 2 open label single arm, multicenter trial enrolled 118 women with advanced TNBC in two stages. The primary endpoint of the trial was clinical benefit rate at 16 weeks (CBR16), defined as the proportion of women with a complete response (CR), partial response (PR) or stable disease for at least 16 weeks. Two patient populations were evaluated in this study: the Evaluable patient population had at least 10 percent of the cells in their primary tumor sample test positive for the AR and had at least one follow up tumor assessment, while the Intent-To-Treat population (ITT) received at least one dose of enzalutamide and their breast cancer had any amount of AR immunohistochemistry staining present. 75 patients met the criteria for the Evaluable population and a total of 118 patients were included in the ITT population. There was no limit to the number of prior treatments received.

- In the 75 Evaluable patients, CBR16 was achieved in 35% (95% CI: 24-46) including six CR/PR (8%). Clinical benefit rate at ≥ 24 weeks (CBR24) was achieved in 29% (95% CI: 20-41). The median progression-free survival (PFS) was 14.7 weeks (95% CI: 8.1-19.3).
- In the ITT population, CBR16 was achieved in 25% (95% CI: 17-33) including seven CR/PR (6%). CBR24 was achieved in 20% (95% CI: 14-29). Median PFS was 12.6 weeks (95% CI: 8.1-15.7).

Data collected in this study enabled the development of a novel genomic assay. The diagnostic assay, which was also introduced during a poster abstract session at ASCO, was assessed for its ability to identify patients who may benefit from enzalutamide. Approximately 50 percent of the ITT population were diagnostic positive and data according to this methodology were as follows:

- In the ITT, 39% (95% CI: 27-53) of patients with diagnostic positive AR TNBC achieved CBR16 and 36% achieved CBR24 (95% CI: 24-49), whereas 11% (95% CI: 5-21) of patients with diagnostic negative AR TNBC achieved CBR16 and only 6% (95% CI: 2-16) achieved CBR24. Median PFS was 16.1 weeks (95% CI: 13.3, 27.4) compared with 8.1 weeks (95% CI: 7.4, 12.6), respectively.
- Diagnostic positive AR TNBC patients treated with enzalutamide as their first or second line of treatment in the ITT population demonstrated a median PFS of 40.4 weeks (95% CI: 16.1- not yet reached) compared with 8.9 weeks (95% CI: 7.3, 15.7) in patients with diagnostic negative AR TNBC disease.

The most common (reported in ≥10%) related adverse events in the ITT were fatigue (34%), nausea (25%), decreased appetite (13%), diarrhea and hot flush (10% each).

Best of ASCO
The 'Best of ASCO' Meetings condense the most cutting-edge science and education from the world's premier oncology event, the ASCO Annual Meeting, into a two-day program. The abstracts chosen for presentation and discussion reflect the foremost research and strategies in oncology that have the greatest potential to directly impact patient care.

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 in the Evaluable population with a best response of complete response, partial response or stable disease at ≥ 16 weeks. All patients received enzalutamide at a dose of 160 mg to be taken orally once daily.

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
Astellas is a pharmaceutical company dedicated to improving the health of people around the world through provision of innovative and reliable pharmaceuticals. For more information on Astellas, please visit our website at www.astellas.us, follow us on Twitter at www.twitter.com/AstellasUS or like our Facebook page at www.facebook.com/AstellasUS.

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 Statements
Certain of the statements in this press release, are forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws. Forward-looking statements involve risks and uncertainties that could cause Medivation's actual results to differ significantly from those projected, including, without limitation: risks related to the timing, progress and results of Medivation's clinical trials, including the risk that adverse clinical trial results could alone or together with other factors result in the delay or discontinuation of the commercialization of XTANDI or some or all of Medivation's product development activities; Medivation's dependence on the efforts of and funding by Astellas for the development, manufacturing and commercialization of XTANDI; the risk of unanticipated expenditures or liabilities; 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, 2015, which was filed on May 7, 2015. 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.

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