

Medivation Contacts: Patrick Machado Chief Business & Financial Officer (415) 829-4101

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



Astellas Contacts: Jenny Kite Corporate Communications (847) 682-4530

Mike Beyer Sam Brown, Inc (media for both companies) (773) 463-4211

Medivation and Astellas Initiate Phase 2 Study of Enzalutamide in Breast Cancer Patients

San Francisco, CA and Tokyo – June 26, 2013 – Medivation, Inc. (Nasdaq: MDVN) and Astellas Pharma Inc. (TSE: 4503) today announced enrollment of the first patient in a global Phase 2 clinical trial evaluating enzalutamide as a single agent for the treatment of advanced, androgen receptor (AR)-positive, triple-negative breast cancer (TNBC). Medivation is conducting this study under its agreement with Astellas.

"The initiation of this Phase 2 study marks an important milestone as we expand our enzalutamide development program beyond prostate cancer to explore the clinical efficacy of enzalutamide in triple-negative breast cancer, where there is a significant unmet medical need," said David Hung, M.D., president and chief executive officer of Medivation, Inc. "We plan to present the results from the Phase 1 study in breast cancer at an upcoming scientific conference."

The Phase 2 open label, single-arm, multicenter trial plans to enroll approximately 80 patients with AR-positive, TNBC 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 \geq 16 weeks. All patients will receive enzalutamide at a dose of 160 mg to be taken orally once daily. Information about patient eligibility and enrollment can be obtained by calling 800-888-7704 ext. 5473 or e-mailing clintrials.info@us.astellas.com.

TNBC is a type of cancer which does not express any of the three most commonly targeted receptors in breast cancer: estrogen, progesterone and HER2. 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. AR-positive breast cancer is a recently-identified subtype of TNBC that can express high levels of the androgen receptor.

About Enzalutamide

Enzalutamide is an androgen receptor inhibitor that acts on different steps in the androgen receptor signaling pathway. Enzalutamide has been shown to competitively inhibit androgen

binding to androgen receptors, and inhibit androgen receptor nuclear translocation and interaction with DNA.

Please visit <u>www.XtandiHCP.com</u> for full Prescribing Information for XTANDI[®] (enzalutamide) capsules.

About XTANDI[®] (enzalutamide) capsules

XTANDI is indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who have previously received docetaxel.

Important Safety Information for XTANDI

Contraindications- XTANDI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. XTANDI is not indicated for use in women. XTANDI is contraindicated in women who are or may become pregnant.

Warnings and Precautions- In the randomized clinical trial, seizure occurred in 0.9% of patients on XTANDI. No patients on the placebo arm experienced seizure. Patients experiencing a seizure were permanently discontinued from therapy. All seizures resolved.

Patients with a history of seizure, taking medications known to decrease the seizure threshold, or with other risk factors for seizure were excluded from the clinical trial. Because of the risk of seizure associated with XTANDI use, patients should be advised of the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others.

Adverse Reactions- The most common adverse drug reactions (\geq 5%) reported in patients receiving XTANDI in the randomized clinical trial were asthenia/fatigue, back pain, diarrhea, arthralgia, hot flush, peripheral edema, musculoskeletal pain, headache, upper respiratory infection, muscular weakness, dizziness, insomnia, lower respiratory infection, spinal cord compression and cauda equina syndrome, hematuria, paresthesia, anxiety, and hypertension. Grade 1-4 neutropenia occurred in 15% of XTANDI patients (1% Grade 3-4) and in 6% on placebo (no Grade 3-4). Grade 1-4 elevations in bilirubin occurred in 3% of XTANDI patients and 2% on placebo. One percent of XTANDI patients compared to 0.3% on placebo died from infections or sepsis. Falls or injuries related to falls occurred in 4.6% of XTANDI patients vs 1.3% on 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. Grade 1 or 2 hallucinations occurred in 1.6% of XTANDI patients and 0.3% on placebo, with the majority on opioid-containing medications at the time of the event.

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 can 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, please visit www.XtandiHCP.com.

About Medivation

Medivation, Inc. is a biopharmaceutical company focused on the rapid development of novel 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 <u>www.medivation.com</u>.

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 becoming a global category leader in Oncology, and has several oncology compounds in development in addition to enzalutamide. For more information on Astellas Pharma Inc., please visit our website at <u>www.astellas.com/en</u>.

Note Regarding Forward-Looking Statement - Medivation

This press release contains forward-looking statements, including statements regarding the continued clinical development of enzalutamide and potential future progress related thereto, the therapeutic potential of enzalutamide in breast cancer, our strategy, and the continued effectiveness of, and continuing collaborative activities and benefits under, Medivation's collaboration agreement with Astellas, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. 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 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 some or all of Medivation's product development activities, the risk that positive results seen in our clinical trials may not be predictive of the results of our ongoing or planned clinical trials, difficulties or delays in enrolling and retaining patients in Medivation's clinical trials, Medivation's dependence on the efforts of and funding by Astellas for the development of enzalutamide, the achievement of development, regulatory and commercial milestones under Medivation's collaboration agreement with Astellas, the manufacturing of Medivation's product candidates, the industry and competitive market, the adequacy of Medivation's financial resources, unanticipated expenditures or liabilities, Medivation's outstanding convertible senior notes, intellectual property matters, and other risks detailed in Medivation's filings with the Securities and Exchange Commission, including its guarterly report on Form 10-Q for the guarter ended March 31, 2013, filed with the SEC on May 10, 2013. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. Medivation disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release.

Note Regarding Forward Looking Statement – Astellas

This press release includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties. Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future, statements regarding the expected timing of filings and approvals relating to the transaction, the expected timing of the transaction, the ability to complete the transaction or to satisfy the various closing conditions, future revenues and profitability from or growth or any assumptions

underlying any of the foregoing. Statements made in the future tense, and words such as "anticipate," "expect," "project," "continue," "believe," "plan," "estimate," "pro forma," "intend," "potential," "target," "forecast," "guidance," "outlook," "seek," "assume," "will," "may," "should," and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements. Actual financial results may differ materially depending on a number of factors including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launch, pricing and product initiatives of competitors, the inability of the company to market existing and new products effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation. This press release contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these pharmaceuticals nor provide medical advice of any kind.