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Medivation and Astellas Announce Submission of New Drug Application for Enzalutamide for the Treatment of Castration-Resistant Prostate Cancer in Patients Previously Treated With Chemotherapy

SAN FRANCISCO, CA and TOKYO -- (Marketwire) -- 05/21/12 -- Medivation, Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. (TSE: 4503) announced that Medivation has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for enzalutamide (formerly MDV3100). The compound has been studied in patients with castration-resistant prostate cancer who have received docetaxel therapy.

Pursuant to the Prescription Drug User Fee Act (PDUFA), the FDA is expected to determine within 60 days whether to accept the filing for review. Medivation has requested Priority Review, a designation given to drugs that offer a significant improvement in treatment or provide treatment where no satisfactory alternative therapy exists. If a Priority Review is granted, the FDA goal for completing a review is six months.

About Enzalutamide (formerly MDV3100)
Enzalutamide is an oral, once-daily investigational agent that is an androgen receptor signaling inhibitor. Enzalutamide inhibits androgen receptor signaling in three distinct ways: it inhibits 1) testosterone binding to androgen receptors; 2) nuclear translocation of androgen receptors; and 3) DNA binding and activation by androgen receptors.

In the Phase 3 AFFIRM trial, enzalutamide was well tolerated. Common side effects observed more frequently in enzalutamide as compared with placebo-treated patients included fatigue, diarrhea and hot flush. Seizure was reported in < 1% of enzalutamide-treated patients. Serious adverse events, adverse events causing patients to stop treatment, and adverse events causing death all were lower in the enzalutamide group than in the placebo group.

About Medivation
Medivation, Inc. is a biopharmaceutical company focused on the rapid development of novel small molecule drugs 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 caregivers. Together with its corporate partner Astellas, Medivation currently has the investigational drug enzalutamide in Phase 3 development to treat advanced prostate cancer and in Phase 1 development to treat breast cancer. For more information, please visit us at 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 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 www.astellas.com/en.

This press release contains forward-looking statements, including statements regarding the therapeutic and commercial potential of enzalutamide, the timing of the FDA's potential acceptance for review of the NDA, the potential grant of priority review by the FDA, potential future regulatory approval and commercialization of enzalutamide and the timing thereof, 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 potential regulatory approval and commercialization of enzalutamide, the progress, 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 and the risk that life-prolonging treatments could prevent ongoing or planned enzalutamide trials from succeeding or could reduce any potential survival benefit that may be shown in these trials even if they do succeed, difficulties or delays in enrolling and retaining patients in Medivation's clinical trials, including as a result of the availability of competing treatments or clinical trials of competing drugs for the same indication, 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 quarterly report on Form 10-Q for the quarter ended March 31,

2012, filed with the SEC on May 9, 2012. 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.

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