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Medivation and Astellas Announce PDUFA Action Date for Enzalutamide NDA

SAN FRANCISCO, CA and TOKYO -- (Marketwire) -- 08/03/12 -- Medivation, Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. (TSE: 4503) today announced that the U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) action date of November 22, 2012 for the review of the investigational agent enzalutamide (formerly MDV3100) New Drug Application (NDA) for the potential treatment of men with castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy. The companies announced on July 24, 2012 that the FDA accepted the enzalutamide NDA filing for review and granted Priority Review Designation.

About Enzalutamide

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 common side effects observed more frequently in enzalutamide as compared with placebo-treated patients included fatigue, diarrhea and hot flush. Seizure was reported in less than 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 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 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.

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