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## **New England Journal of Medicine Publishes Results From Phase 3 AFFIRM Trial of Enzalutamide**

### **Study Appears in August 15 Online Edition**

SAN FRANCISCO, CA and TOKYO -- (Marketwire) -- 08/15/12 -- Medivation, Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. (TSE: 4503) today announced the publication in the New England Journal of Medicine of the results from the Phase 3 AFFIRM trial, an international, randomized, double-blind, placebo-controlled clinical study of enzalutamide (formerly MDV3100) in men with metastatic castration-resistant prostate cancer who have been previously treated with docetaxel-based chemotherapy. The paper, "Increased Survival with Enzalutamide in Prostate Cancer After Chemotherapy," appears in the August 15 online issue of the Journal.<sup>(1)</sup>

"The AFFIRM data represent an important body of clinical evidence on enzalutamide, a novel oral androgen receptor signaling inhibitor, as a potential new treatment that can prolong the lives of men with advanced prostate cancer. The achievement underlines the importance of integrating clinical observations and basic research to significantly improve patient outcomes and bring therapies to patients faster. It is extremely gratifying to share these results with the medical community," said Howard I. Scher, M.D., chief, Genitourinary Oncology Service at Memorial-Sloan Kettering Cancer Center, the co-principal investigator and lead author of the AFFIRM study paper.

In the AFFIRM trial, the data showed that enzalutamide exhibited a statistically significant benefit in overall survival compared to placebo. Men treated with enzalutamide had a median overall survival of 18.4 months (95% confidence interval, 17.3 to not yet reached) compared to 13.6 months (95% confidence interval 11.3 -15.8) for men treated with placebo (hazard ratio 0.63;  $p < 0.0001$ ), representing a 37 percent reduction in the risk of death.

In the Phase 3 AFFIRM trial three most 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 were lower in the enzalutamide group than in the placebo group.

#### *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. Medivation and Astellas announced on July 24, 2012 that the U.S. Food and Drug Administration accepted the enzalutamide New Drug Application filing for review and granted Priority Review Designation.

#### *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](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 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](http://www.astellas.com/en).

(1)Scher, HI, et al. Increased Survival with Enzalutamide in Prostate Cancer After Chemotherapy. New Engl J Med. 2012; 367.

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