



**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  
(224) 204-5405

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

---

**Enzalutamide Data to Be Presented  
at ASCO GU Symposium**

SAN FRANCISCO, CA AND TOKYO – January 30, 2013 – Medivation Inc. (NASDAQ: MDVN) and Astellas Pharma Inc. (Tokyo: 4503) today announced that six abstracts related to enzalutamide research will be presented on Thursday, February 14 at the American Society of Clinical Oncology (ASCO) 2013 Genitourinary (GU) Cancers Symposium in Orlando, Florida.

Oral Abstract Session A from 2:03-2:15pm ET:

- (Abstract #6) Impact of on-study corticosteroid use on efficacy and safety in the Phase 3 AFFIRM study of enzalutamide, an androgen receptor inhibitor. *Presenter: Howard I. Scher - Sidney Kimmel Center for Prostate and Urologic Cancers, Memorial Sloan-Kettering Cancer Center*

General Poster Session A from 11:45am-1:15pm ET and again from 5:05-6:35pm ET:

- (Abstract #18) Enzalutamide monotherapy: Phase 2 study results in hormone-naïve prostate cancer patients. *Presenter: Bertrand Tombal - Université Catholique de Louvain, Cliniques Universitaires Saint-Luc*
- (Abstract #63): Enzalutamide in combination with docetaxel in men with prostate cancer (PC): Preliminary results from a phase 1 study. *Presenter: Mark T. Fleming - Virginia Oncology Associates*
- (Abstract #16) Improved outcomes in elderly patients with metastatic castration-resistant prostate cancer (mCRPC) treated with the androgen receptor inhibitor enzalutamide: Results from the Phase 3 AFFIRM trial. *Presenter: Cora N. Sternberg - San Camillo and Forlanini Hospital*

- (Abstract #17) Effect of enzalutamide on health-related quality of life (HRQoL) in men with metastatic castration-resistant prostate cancer (mCRPC) following docetaxel-based therapy: Results from the AFFIRM study. *Presenter: Kurt Miller - Charité-Universitätsmedizin Berlin*
- (Abstract #20) Long-term responders to enzalutamide during the phase 3 AFFIRM trial: Baseline characteristics and efficacy outcomes. *Presenter: Mark T. Fleming - Virginia Oncology Associates*

### **About XTANDI®**

XTANDI® (enzalutamide) capsules is an oral, once-daily androgen receptor inhibitor. XTANDI was approved by the FDA on August 31, 2012 for the treatment of metastatic castration-resistant prostate cancer for patients who have previously received docetaxel (chemotherapy). A Marketing Authorization Application for XTANDI is currently under review by the European Medicines Agency (EMA).

The efficacy and safety of XTANDI were assessed in the randomized, placebo-controlled, global phase 3 AFFIRM clinical trial. A total of 1,199 patients with mCRPC who had previously received docetaxel were randomized 2:1 to receive either XTANDI orally at a dose of 160 mg once daily (N = 800) or placebo (N = 399). 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. The primary endpoint of the trial was OS.

XTANDI-treated patients had a statistically-significant improvement in median OS compared to the placebo group: 18.4 months in the XTANDI group versus 13.6 months in the placebo group ( $P < 0.0001$ ). XTANDI provided a 37% reduction in risk of death compared to placebo (hazard ratio = 0.631). Seizure occurred in 0.9% of patients on XTANDI and 0% of the placebo-treated patients. The most common adverse reactions ( $\geq 5\%$ ) are 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 3 and higher adverse reactions were reported among 47% of XTANDI-treated patients and 53% of placebo-treated patients.

The recommended dose of XTANDI is 160 mg (four 40 mg capsules) administered orally once daily. XTANDI can be taken with or without food and does not require concomitant steroid (e.g., prednisone) use. In the phase 3 clinical trial, 48% of XTANDI patients and 46% of patients in the placebo arm were treated with glucocorticoids.

## **XTANDI Mechanism of Action**

XTANDI (enzalutamide) is an androgen receptor inhibitor that acts on different steps in the androgen receptor signaling pathway. XTANDI has been shown to competitively inhibit androgen binding to androgen receptors, inhibit androgen receptor nuclear translocation and interaction with DNA. A major metabolite, N-desmethyl enzalutamide, exhibited similar in vitro activity to XTANDI. XTANDI decreased proliferation and induced cell death of prostate cancer cells in vitro, and decreased tumor volume in a mouse prostate cancer xenograft model.

## **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.

***Warning and Precautions*** - In the randomized phase 3 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.

***Drug Interactions*** - XTANDI is a strong CYP3A4 inducer and a moderate CYP2C9 and CYP2C19 inducer in humans. 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. 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](http://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 [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 XTANDI. For more information on Astellas Pharma Inc., please visit our website at [www.astellas.com/en](http://www.astellas.com/en).